Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

The use of GMDN codes for IVD medical devices in Australia

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TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

The use of GMDN codes for IVD medical devices in Australia

This section

Global Medical Device Nomenclature (GMDN)

The GMDN is an international nomenclature system used by regional or national regulatory bodies to consistently describe medical devices[1]. GMDN codes are used to assist in the:

- consistent assessment of devices before they are approved for supply
- ongoing monitoring of devices once they are available for supply.

[1] The use of the term 'medical device' is taken to include 'IVD medical devices'—the latter term will be used to denote references that are specific to IVD medical devices.

The GMDN database is made up of a large number of generic device descriptors called preferred terms (PTs), each consisting of a term name, a definition and a unique 5 digit code that is used to identify a particular medical device. The preferred terms are arranged within the GMDN database so that they are grouped together based on similar characteristics, using a system of collective terms (CTs). The GMDN database is maintained by a not for profit agency based in the United Kingdom, with assistance from various technical experts around the world.

International regulatory authorities, including the TGA, liaise with the GMDN Agency to request amendments to existing codes and to create new codes. Other GMDN users may also make requests for new codes to the GMDN Agency. For more information please see the GMDN Agency website at <www.gmdnagency.org>.

The structure of the terms for IVDs in the GMDN database is discussed in detail later in this chapter.

GMDN terminology

The international standard *ISO 15225:2010 Medical devices - Quality management - Medical device nomenclature data structure* provides definitions for the terminology used by the GMDN Agency for referring to various terms used within the database. Descriptions of the different terms (ie preferred term, collective term) that are used in relation to IVDs are also included throughout this guidance document to assist users with understanding the nomenclature structure and its relevance.

Use of GMDN codes for IVDs in Australia

IVDs must be included in the Australian Register of Therapeutic Goods (ARTG) as a "kind of medical device". This concept means that depending on the classification of the IVDs concerned, an entry in the ARTG may cover a range of products that are "of the same kind", or it may cover a unique device type.

As described in section 41BE of the *Therapeutic Goods, 1989* (the Act), IVDs are taken to be "of the same kind" as another IVD if they:

- have the same sponsor; and
- have the same manufacturer; and
- have the same device nomenclature system code (i.e. GMDN code); and
- have the same medical device classification; and
- are the same in relation to any other characteristics described in the Regulations.

Regulation 1.6 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) states that for the purposes of section 41BE (1) (e) of the Act, a characteristic for Class 4 IVDs, other than Class 4 immunohaematology reagents (Class 4 IHRs), is the unique product identifier (UPI) given to the device by its manufacturer to identify the individual device type and any variants. Thus, from a practical perspective, only applications for Class 1, Class 2, Class 3 or Class 4 IHR IVDs can have multiple products included under a single ARTG application.

For more information about kinds of IVD medical devices, including the details as prescribed in the legislation, please see ***Section – Including IVD medical devices in the ARTG.***

The Regulations also describe specific device nomenclature codes that are to be applied to certain medical devices, based on their risk classification.

From the Therapeutic Goods (Medical Devices) Regulations 2002 –
1.7 Device nomenclature system codes (Act s41BE (3))

(1) In accordance with the Global Medical Device Nomenclature System Code, as set out in ISO 15225:2000 (E), the device nomenclature code specified for a medical device is:

(a) for a Class 4 IVD medical device — the relevant preferred term; and

(b) for a Class 4 IVD medical device that is an immunohaematology reagent IVD medical device — the relevant Level 2 collective term; and

(c) for a Class 3 IVD medical device — the relevant Level 3 collective term, or if no Level 3 term exists, the relevant Level 2 collective term; and

(d) for a Class 2 IVD medical device — the relevant Level 2 collective term; and

(e) for a Class 1 IVD medical device or an export only IVD medical device — the relevant Level 1 collective.

The manufacturer is responsible for applying the appropriate GMDN code to an IVD or a group of IVDs, as manufacturers have declared the intended purpose and are best placed to determine the correct GMDN code. For Class 4 IVDs, the manufacturer must specify the relevant GMDN preferred term code, which is the unique 5-digit code used to identify the types of medical devices that perform similar or equivalent functions, or have characteristics in common. The preferred term code acts as the definitive reference for the preferred term name and definition, which for IVDs is generally based on the primary analyte or substance being tested for. Preferred terms are used to describe the generic nature of IVDs or their intended purpose, but do not reflect specific characteristics assigned by the manufacturer to a device type such as brand or trade name.

For Class 1, Class 2, Class 3 and Class 4 IHR IVDs, the legislation states that the relevant Level 1, Level 2 or Level 3 collective term must be specified. Collective terms are a set of hierarchical terms that collectively group together a number of preferred terms based on similar specified characteristics, and can be used to identify groups, families or types of medical devices covered by a manufacturer's quality management system. Collective terms may also be used to illustrate the scope of

certificates issued by Conformity Assessment Bodies (CAB), identify a range of skills and general technological abilities for which a CAB has been approved and is so appointed by the relevant regulatory authority, or for the exchange of regulatory information between regulatory authorities. GMDN collective term codes are identified by 'CT', followed by 3 or 4 digits (for example, CT123 or CT4567). Information provided for each of the various levels of CTs ranges from broadly descriptive information for Level 1 CTs, to more detailed analyte-specific information for Level 3 CTs. The use of collective terms in Australia allows for multiple products "of the same kind" to be included in a single entry in the ARTG.

Preferred terms are applied to medical devices for the purposes of identification. By utilising the one-to-many relationship of collective terms linked to multiple preferred terms in the GMDN database, specific collective terms have been selected from the GMDN database for use in an Australian-only context to identify IVDs "of the same kind" for the purposes of ARTG entry.

For Class 4 IVDs, manufacturers must always specify in their Australian Declaration of Conformity the preferred term code that identifies each product. For Class 1, Class 2 or Class 3 IVDs or for Class 4 IHRs, the manufacturer must provide the collective term code that describes all products "of the same kind". In line with the use of GMDN codes internationally, manufacturers may also choose to include in their Declaration of Conformity the preferred term codes that are applied to each product if they wish to identify them separately.

Sponsors are urged to seek the advice of the manufacturer and to obtain the manufacturer's Declaration of Conformity before submitting an application to the TGA. This will enable the sponsor to verify that the GMDN codes have been correctly applied by the manufacturer and that for each of the collective terms specified, only IVDs whose target analytes are detailed in Appendix 2 for the relevant risk classification will be included in the impending application for inclusion.

GMDN preferred term codes and collective term codes for identifying medical devices are available to registered TGA sponsors and manufacturers by logging on to the TGA eBusiness Services (eBS) at <http://www.ebs.tga.gov.au/>, and going to the GMDN look up tables. The hierarchical collective term structure, including the names, codes, descriptors and a list of the target analytes or the name of all IVDs captured by each Level 1, Level 2 and Level 3 CT are appended to this guidance document.

Please note:	*For Class 4 IVDs, where there appears to be no relevant GMDN preferred term in the GMDN database or code tables for a particular IVD, the Manufacturer is required to obtain a GMDN code suitable for describing their product. Please contact the TGA IVD team for advice on how to obtain new GMDN IVD codes.*

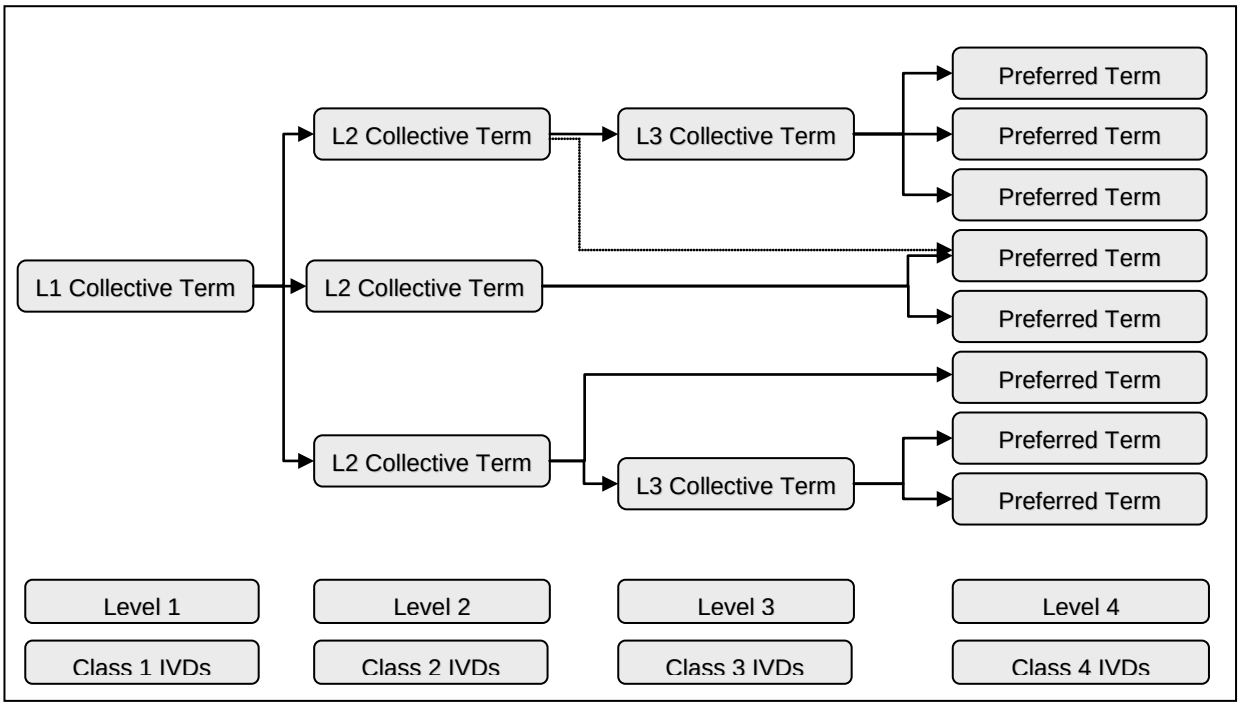
Structure of GMDN terms for IVDs

The GMDN database includes terms and descriptors for more than 25,000 medical devices. Terms are primarily linked to one of 16 device categories, one of which is *Category 06 – In vitro diagnostic medical devices (IVDs)*. All current terms within Category 06 that are intended for use in Australia include the letters "IVD" as part of their preferred term name. "IVD" is a useful search tool both within the GMDN database and in the TGA eBS look-up tables, to narrow the field of terms down from those describing all medical devices to those relevant only to IVDs.

Within the Category 06 terms for IVDs, a hierarchical collective term structure has been formed by arranging the collective terms into tiers. Each of the main tiers is referred to by its level, with Level 1 CTs describing IVDs at the broadest level of detail. Increasing detail is incorporated at each tier to progressively expand the structure using Level 2 CTs, and where necessary to organise large numbers of preferred terms, Level 3 CTs. All preferred terms are linked to at least one collective term thread that originates with a Level 1 CT, and grouping at each level is based on the degree of shared characteristics with other preferred terms, as described by each collective term. Level 4 of the hierarchical structure is set at the preferred term level and each of the four levels of collective terms is aligned with the four risk classifications for IVDs.

Diagram of collective term structure

The diagram below shows the three expanding levels of collective terms and their structural linkage to the Level 4 preferred terms. Preferred terms are the most specific GMDN terms available in the database for the identification of medical devices .



Within the GMDN database, a number of additional collective terms have been included in the overall structure of the database to complement the hierarchical structure and assist with navigation through the large number of terms and levels. A subset of the collective terms in the GMDN database have been selected for use in Australia for the purpose of including Class 1, 2 or 3 IVDs, or Class 4 IHRs of "the same kind" in the ARTG. The specific collective terms that are available for use in Australia at each level are detailed in the tables as follows.

Level 1 collective terms

Level 1 CTs represent the broadest level of detail, and grouping of preferred terms at level 1 is based on their common areas of usage, or the mainstream disciplines within a pathology laboratory. The appropriate Level 1 CT is used to identify Class 1 IVDs "of the same kind" in an application for inclusion in the ARTG. There are thirteen Level 1 CTs available for selection, and these will typically be used to identify Class 1 IVDs such as instruments and analysers, microbiological culture media, specimen receptacles, general laboratory reagents or any export-only IVDs. Level 1 CTs also allow users to start with the appropriate collective term thread when locating suitable collective terms to describe IVDs of higher classes.

The following table shows the GMDN collective term names and codes for Level 1 CTs, and an *abbreviated* description of the products in each. At the start of each new collective term thread, the relevant CT level is referenced in brackets e.g. L1CT, L2CT etc. For the full and detailed term definition which describes the IVDs identified by each collective term, please refer to Appendix 2.

Table 1 – Level 1 collective terms

CT287 Clinical Chemistry IVDs *(L1CT)* chemical, biological or immunological components including electrolytes, enzymes, substrates, specific proteins, hormones, vitamins, products of metabolism, cancer/tumour markers, trace elements, autoimmune markers, therapeutic drugs and/or toxicological substances.
CT870 Coagulation IVDs *(L1CT)* haemostasis and coagulation factors and other markers, platelet function, indicators of fibrinolysis, thrombophilia or inhibitors of blood coagulation.
CT945 General laboratoryware IVDs *(L1CT)* general reagents, laboratory products, consumables, biological stains, antimicrobial identification tests and antimicrobial susceptibility tests
CT292 Haematology IVDs *(L1CT)* cellular and functional components of whole blood, including white cells, red cells, platelets, haemoglobin, cellular metabolic enzymes and red cell membrane integrity.
CT901 Histology & Cytology IVDs *(L1CT)* tissue, cell markers and other cellular structures, their localisation and distribution in clinical tissue sections or cytological smears.
CT902 Human genetics IVDs *(L1CT)* inborn or inherited genetic disorders, mitochondrial disorders, constitutional chromosomal disorders and/or acquired genetic alterations.

CT885 Immunohaematology (blood banking) IVDs *(L1CT)*
blood groups, red cell antigens, red cell antibodies, compatibility of blood or blood components for transfusion.

CT701 Infectious disease IVDs *(L1CT)*
infection with or exposure to infectious agents capable of causing disease, including viruses, bacteria, fungi, parasites and/or prions.

CT943 Instrument/analyser IVDs *(L1CT)*
manual, semi-automated or automated equipment or apparatus for processing, examining and/or providing information about a clinical specimen.

CT922 Microbiological culture media IVDs *(L1CT)*
culture media for the selection, growth, isolation and/or differentiation of tissue cells or microorganisms including bacteria, yeast, fungi and/or viruses.

CT944 Software IVDs *(L1CT)*
software for the collection, input, storage, retrieval, interpretation or reporting of digital data or other information.

CT936 Specimen receptacle IVDs *(L1CT)*
vessels for the collection, containment, preservation and/or transport of all clinical specimens for analysis or investigation.

CT891 Tissue typing IVDs *(L1CT)*
tissue typing for human leukocyte antigens (HLA), HLA antibodies, platelet antigens and antibodies, and compatibility of white cells, platelets or tissue for transfusion or transplantation.

Level 2 collective terms

Level 2 CTs describe IVDs using an increased amount of detail at the specialty or sub-discipline level. All IVDs that are classified as Class 2 IVDs will be required to use a Level 2 CT for identifying IVDs "of the same kind" in the ARTG. Appropriate Level 2 CTs will be available for selection through eBS at the time of lodging an application. The full list of Level 2 CT codes, names and descriptions, and examples of analytes under each Level 2 CT is included in Appendix 2. The following table is an abbreviated list of Level 2 CT codes and names, separated by their relevant Level 1 CT. CT943 Instrument/analyser IVDs and CT922 Microbiological culture media IVDs are not linked to any Level 2 CTs as these products are always regarded as Class 1 IVDs, and therefore identification of any applications for these products will default to using the Level 1 CT.

Table 2 – Level 2 collective terms

CT287 Clinical Chemistry IVDs *(L1CT)*
- CT869 Clinical chemistry autoimmune IVDs *(L2CT)*
- CT1236 Clinical chemistry biological screening IVDs
- CT836 Clinical chemistry electrolyte IVDs
- CT827 Clinical chemistry enzyme IVDs
- CT850 Clinical chemistry hormone IVDs
- CT974 Clinical chemistry-specific protein IVDs
- CT833 Clinical chemistry substrate IVDs
- CT860 Clinical chemistry therapeutic drug monitoring IVDs
- CT184 Clinical chemistry toxicology/drug detection IVDs
- CT1237 Clinical chemistry trace element IVDs
- CT845 Clinical chemistry tumour marker IVDs
- CT847 Clinical chemistry vitamin and mineral IVDs
- CT806 Haemoximetry and blood gas IVDs

CT889 Multiple clinical chemistry constituent IVDs

CT870 Coagulation IVDs *(L1CT)*
- CT872 Coagulation calibrator/control IVDs *(L2CT)*
- CT877 Coagulation factor IVDs
- CT1248 Coagulation-related IVDs
- CT875 Fibrinolysis IVDs
- CT871 General coagulation IVDs
- CT874 Platelet factor IVDs
- CT873 Special coagulation IVDs
- CT876 Thrombophilia and coagulation inhibitor IVDs

CT945 General laboratoryware IVDs *(L1CT)*
- CT1260 Antimicrobial susceptibility testing IVDs *(L2CT)*
- CT215 Biological stain IVDs
- CT946 General laboratory reagent and consumables IVDs
- CT1261 Microbial-isolate identification and testing IVDs

CT292 Haematology IVDs *(L1CT)*
- CT879 Haematology calibrator/control IVDs *(L2CT)*
- CT878 Haematology full blood count IVDs
- CT1249 Haematology-related IVDs
- CT880 Haemoglobin IVDs
- CT881 Red and white cell metabolic enzyme and haemolysis IVDs

CT901 Histology & Cytology IVDs *(L1CT)*
- CT907 Histology and Cytology ancillary IVDs*(L2CT)*
- CT1056 Immunohistology cell marker IVDs

CT902 Human genetics IVDs *(L1CT)*
- CT929 Acquired genetic alteration IVDs *(L2CT)*
- CT826 Constitutional chromosomal disorder IVDs
- CT906 Human genetics-related IVDs
- CT903 Inborn/inherited genetic disorder IVDs
- CT905 Mitochondrial genetic disorder IVDs
- CT918 Pharmacogenetic IVDs

CT885 Immunohaematology (blood banking) IVDs *(L1CT)*
- CT887 Immunohaematology blood grouping antisera IVDs *(L2CT)*
- CT890 Immunohaematology calibrator/control IVDs
- CT1270 Immunohaematology-related IVDs
- CT888 Immunohaematology sensitised cell-typing IVDs
- CT753 Multiple blood grouping and typing IVDs
- CT886 Reagent red blood cell IVDs

CT701 Infectious disease IVDs *(L1CT)*
- CT353 Bacterial infectious disease IVDs *(L2CT)*
- CT354 Fungal infectious disease IVDs
- CT923 Multiple infectious organism IVDs
- CT356 Parasitic infectious diseases IVDs
- CT825 Prion infectious diseases IVDs
- CT355 Viral infectious disease IVDs

CT944 Software IVDs *(L1CT)*
- CT1250 Analyser software IVDs *(L2CT)*
- CT910 Interpretive software IVDs
- CT1251 Laboratory information system IVDs

CT936 Specimen receptacle IVDs *(L1CT)*

CT933 Blood specimen collection IVDs *(L2CT)*
CT1259 Non-blood specimen receptacle IVDs

CT891 Tissue typing IVDs *(L1CT)*
CT289 Human leukocyte antigen (HLA) typing IVDs *(L2CT)*
CT898 Human leukocyte antigen (HLA) antibody screening and identification IVDs
CT1041 Human neutrophil antigen (HNA) typing IVDs
CT1042 Human neutrophil antigen (HNA) antibody screening and identification IVDs
CT1039 Human platelet antigen (HPA) typing IVDs
CT1040 Human platelet antigen (HPA) antibody screening and identification IVDs
CT899 Tissue typing-related IVDs

Level 3 collective terms

Level 3 CTs are used to create an additional tier of grouping whenever there is a large number of preferred terms linked to a particular analyte group, as frequently seen in disciplines such as Infectious diseases or Clinical Chemistry. Level 3 CTs are not included in every collective term thread because for some disciplines there are not enough preferred terms present to require an additional tier of grouping. Therefore, for disciplines such as Coagulation, Human genetics or Immunohaematology (blood banking) no Level 3 CTs are available in the Australian code tables for selection. Where a user anticipates using a Level 3 CT to describe a group of Class 3 IVDs "of the same kind" but no relevant collective terms are available, the relevant Level 2 CT is used.

It is important to note that for Class 3 IVDs that are described using the Level 2 CT, they will not be considered to be the "same kind of device" as a Class 2 IVD that uses the same GMDN collective term code.

The following tables show the hierarchical relationship between Level 2 CTs and Level 3 CTs where they exist. A full set of all levels of collective terms and their descriptions, with examples of analytes included under each collective term is in Appendix 2 of this document.

Table 3 – Level 3 collective terms

CT287 Clinical Chemistry IVDs *(L1CT)*
CT1236 Clinical chemistry biological screening IVDs *(L2CT)*
CT1247 Faecal screening IVDs *(L3CT)*
CT1246 Urine screening IVDs
CT827 Clinical chemistry enzyme IVDs
CT1238 Acid phosphatase IVDs
CT828 Alkaline phosphatase IVDs
CT829 Amylase IVDs
CT830 Cholinesterase IVDs
CT831 Creatine kinase IVDs
CT1054 Glutathione S-transferase IVDs
CT832 Lactate dehydrogenase IVDs
CT842 Trypsin IVDs
CT850 Clinical chemistry hormone IVDs
CT1243 Catecholamine IVDs
CT851 Cortisol IVDs
CT852 Estrogen (Oestrogen) IVDs
CT856 Human chorionic gonadotropin (HCG) IVDs
CT857 Insulin-like growth factor IVDs
CT1244 Parathyroid hormone IVDs
CT1008 Thyroid IVDs

CT974 Clinical chemistry-specific protein IVDs
- CT884 Collagen IVDs
- CT844 Complement IVDs
- CT843 Immunoglobulin IVDs
- CT1241 Interleukin IVDs
- CT1242 Troponin IVDs

CT833 Clinical chemistry substrate IVDs
- CT834 Bilirubin IVDs
- CT835 Lipid and lipoprotein IVDs
- CT1239 Porphyria-related IVDs

CT860 Clinical chemistry therapeutic drug monitoring IVDs
- CT864 Anti-asthma therapeutic drug monitoring IVDs
- CT863 Antimicrobial therapeutic drug monitoring IVDs
- CT865 Anti-neoplastic therapeutic drug monitoring IVDs
- CT861 Cardiovascular therapeutic drug monitoring IVDs
- CT862 Central nervous system therapeutic drug monitoring IVDs
- CT866 Immunosuppressant therapeutic drug monitoring IVDs

CT845 Clinical chemistry tumour marker IVDs
- CT846 Prostate specific marker IVDs

CT847 Clinical chemistry vitamin and mineral IVDs
- CT848 Vitamin B IVDs
- CT849 Vitamin D IVDs

CT945 General laboratoryware IVDs *(L1CT)*

CT1260 Antimicrobial susceptibility testing IVDs *(L2CT)*
- CT750 Antimicrobial minimum inhibitory concentration IVDs *(L3CT)*
- CT942 Susceptibility testing disc IVDs

CT1261 Microbial-isolate identification and testing IVDs
- CT839 Organism identification and antimicrobial susceptibility testing IVDs

CT292 Haematology IVDs *(L1CT)*

CT881 Red and white cell metabolic *(L2CT)*
- CT882 Red cell membrane and haemolysis IVDs *(L3CT)*
- CT285 Red cell metabolic enzyme IVDs
- CT883 White cell metabolic enzyme IVDs

CT901 Histology & Cytology IVDs *(L1CT)*

CT1056 Immunohistology cell marker IVDs *(L2CT)*
- CT1238 Acid phosphatase IVDs *(L3CT)*
- CT828 Alkaline phosphatase IVDs
- CT915 CD cell marker (cluster of differentiation) IVDs
- CT884 Collagen IVDs
- CT844 Complement IVDs
- CT909 Cytokeratin profile IVDs
- CT852 Estrogen (Oestrogen) IVDs
- CT1054 Glutathione S-transferase IVDs
- CT856 Human chorionic gonadotropin (HCG) IVDs
- CT843 Immunoglobulin IVDs
- CT892 Multiple human leukocyte antigens (HLA) typing IVDs
- CT846 Prostate specific marker IVDs
- CT1008 Thyroid IVDs

CT701 Infectious disease IVDs *(L1CT)*

CT353 Bacterial infectious disease IVDs *(L2CT)*
- CT776 Bacillus IVDs *(L3CT)*
- CT777 Bartonella IVDs
- CT778 Bordetella IVDs
- CT779 Borrelia (Lyme disease) IVDs
- CT780 Brucella IVDs

CT928 Burkholderia IVDs
CT939 Calymmatobacterium (Klebsiella) granulomatis (Donovanosis) IVDs
CT781 Campylobacter IVDs
CT782 Chlamydia IVDs
CT783 Clostridium IVDs
CT913 Corynebacterium IVDs
CT921 Enterococcus IVDs
CT941 Erysipelothrix IVDs
CT784 Escherichia coli (E. coli) IVDs
CT858 Francisella IVDs
CT914 Gardnerella IVDs
CT785 Haemophilus IVDs
CT786 Helicobacter IVDs
CT787 Legionella IVDs
CT788 Leptospira IVDs
CT789 Listeria IVDs
CT774 Multiple-bacteria IVDs
CT791 Mycobacteria IVDs
CT792 Mycoplasma IVDs
CT793 Neisseria IVDs
CT794 Pseudomonas IVDs
CT868 Rickettsial disease IVDs
CT795 Salmonella IVDs
CT796 Shigella IVDs
CT797 Staphylococcus IVDs
CT798 Streptococcus IVDs
CT799 Treponema (syphilis) IVDs
CT1442 Tropheryma IVDs
CT859 Ureaplasma IVDs
CT800 Vibrio IVDs
CT801 Yersinia IVDs

CT354 Fungal infectious disease IVDs

CT937 Aspergillus IVDs
CT919 Blastomyces IVDs
CT802 Candida IVDs
CT904 Coccidioides IVDs
CT803 Cryptococcus IVDs
CT925 Histoplasma IVDs
CT938 Multiple-fungi IVDs
CT804 Pneumocystis IVDs
CT805 Saccharomyces IVDs
CT1262 Sporothrix IVDs

CT356 Parasitic infectious diseases IVDs

CT713 Anisakis IVDs
CT741 Ascaris IVDs
CT808 Babesia IVDs
CT809 Cryptosporidium IVDs
CT810 Echinococcus (hydatid) IVDs
CT811 Entameoba (ameobiasis) IVDs
CT812 Fasciola IVDs
CT1264 Free living amoebae IVDs
CT813 Giardia IVDs
CT814 Leishmania IVDs
CT807 Multiple-parasite IVDs
CT815 Paragonimus IVDs
CT816 Plasmodium (malaria) IVDs
CT817 Schistosoma IVDs
CT818 Strongyloides IVDs
CT735 Taenia (cysticercosis) IVDs
CT819 Toxocara IVDs

CT820 Toxoplasma IVDs
CT821 Trichinella IVDs
CT822 Trichomonas IVDs
CT823 Trypanosoma IVDs
CT824 Wuchereria/Brugia (filariasis) IVDs

CT355 Viral infectious disease IVDs

CT759 Adenovirus IVDs
CT718 Barmah Forest virus IVDs
CT758 BK virus IVDs
CT760 Borna disease virus IVDs
CT714 Coxsackie virus IVDs
CT940 Crimean-Congo haemorrhagic fever virus IVDs
CT748 Cytomegalovirus (Human herpesvirus 5) IVDs
CT725 Dengue virus IVDs
CT719 Eastern equine encephalomyelitis virus IVDs
CT761 Ebola virus IVDs
CT715 Echoviruses IVDs
CT716 Enterovirus 68-71 IVDs
CT747 Epstein-Barr virus (Human herpesvirus 4) IVDs
CT932 Hantavirus IVDs
CT736 Hendra virus IVDs
CT703 Hepatitis A virus IVDs
CT704 Hepatitis B virus IVDs
CT705 Hepatitis C virus IVDs
CT706 Hepatitis D virus IVDs
CT707 Hepatitis E virus IVDs
CT708 Hepatitis G virus IVDs
CT749 Herpes simplex virus (HSV) (Human herpesvirus 1 & 2) IVDs
CT762 Human astrovirus IVDs
CT754 Human herpes virus 6 IVDs
CT930 Human herpes virus 7 IVDs
CT755 Human herpes virus 8 IVDs
CT284 Human immunodeficiency virus (HIV) IVDs
CT737 Human metapneumovirus IVDs
CT947 Human papilloma virus IVDs
CT934 Human parechovirus IVDs
CT711 Human T-cell lymphotrophic virus (HTLV) IVDs
CT732 Influenza virus IVDs
CT726 Japanese encephalitis virus IVDs
CT757 JC virus IVDs
CT790 Junin virus IVDs
CT927 Lassa virus IVDs
CT763 Lymphocytic choriomeningitis virus IVDs
CT926 Machupo virus IVDs
CT764 Marburg virus IVDs
CT738 Measles (rubeola) virus IVDs
CT702 Multiple-viruses IVDs
CT739 Mumps virus IVDs
CT727 Murray Valley encephalitis virus IVDs
CT740 Nipah virus IVDs
CT765 Norovirus IVDs
CT766 Parainfluenza virus IVDs
CT767 Parvovirus B19 IVDs
CT717 Poliovirus IVDs
CT768 Rabies virus IVDs
CT917 Reovirus IVDs
CT746 Respiratory syncitial virus (RSV) IVDs
CT931 Rhinovirus IVDs
CT769 Rift Valley Fever virus IVDs
CT720 Ross River virus IVDs

CT770 Rotavirus IVDs
CT771 Rubella virus IVDs
CT911 Sandfly fever virus IVDs
CT721 Semliki Forest virus IVDs
CT772 Severe acute respiratory sydrome-associated coronavirus (SARS-CoV) IVDs
CT722 Sindbis virus IVDs
CT728 St. Louis encephalitis virus IVDs
CT729 Tick-borne encephalitis virus IVDs
CT756 Varicella zoster virus (Human herpesvirus 3) IVDs
CT723 Venzuelan equine encephalitis virus IVDs
CT773 Vesicular stomatitis virus IVDs
CT724 Western equine encephalitis virus IVDs
CT730 West Nile virus (WNV) IVDs
CT731 Yellow fever virus IVDs
CT924 Zika virus IVDs

CT891 Tissue typing IVDs *(L1CT)*

CT289 Human leukocyte antigen (HLA) typing IVDs *(L2CT)*
CT893 Human leukocyte antigen A (HLA-A) typing sera IVDs *(L3CT)*
CT894 Human leukocyte antigen B (HLA-B) typing sera IVDs
CT895 Human leukocyte antigen C (HLA-C) typing sera IVDs
CT900 Human leukocyte antigen DP (HLA-DP) typing sera IVDs
CT897 Human leukocyte antigen DQ (HLA-DQ) typing sera IVDs
CT896 Human leukocyte antigen DR (HLA-DR) typing sera IVDs
CT892 Multiple human leukocyte antigens (HLA) typing IVDs
CT898 Human leukocyte antigen (HLA) antibody screening and identification IVDs
CT1038 Multiple human leukocyte antigen (HLA) antibodies IVDs

Level 4 preferred terms

Preferred terms are generic device descriptors applied to medical devices for the purpose of product identification. The preferred term description provides enough detail to make the analyte being measured and the technology clear, and the preferred term code along with the Unique Product Identifier (UPI) is required for lodging applications to include Class 4 IVDs that are not IHRs in the ARTG.

Preferred terms for IVDs are developed using the primary analyte detected or measured by the IVD as the base concept, followed by a number of additional qualifiers. Qualifiers are used to provide information about the form in which the IVD is presented (for example kit, calibrator, control, reagent, antibody, primer etc) and if the IVD is presented as a kit, the technology used to perform the test.

A set of standardised technologies has been developed which describe the general methodology used by various different types of assays. The methodology is described to a level of detail that is represented by the following examples: enzyme colorimetry, gas chromatography, nucleic acid technique (NAT), enzyme immunoassay (EIA), direct fluorescent test (DFT), complement fixation test (CFT), agglutination, etc. Full definitions for each standard technology are included in Appendix 1 of this document and are also available in the GMDN database glossary.

Preferred terms for IVDs are arranged using the hierarchical collective term structure to group them together based on similar characteristics, and for IVDs this is principally analyte based. Each preferred term is linked to at least one collective term thread consisting of a Level 1 CT, a Level 2 CT, and where necessary a Level 3 CT.

Some analyte-based IVDs such as calibrators and controls can be utilised in more than one discipline. When this occurs, the relevant preferred terms are linked to more than one collective term thread originating with a Level 1 CT, as considered necessary.

Class 4 immunohaematology reagents (Class 4 IHRs)

Class 4 immunohaematology reagents (Class 4 IHRs) "of the same kind" are entered in the ARTG using one of the six Level 2 CTs specific to Immunohaematology (blood banking) IVDs. Individual product information identifying each separate reagent included in the Class 4 IHR application (i.e. the UPI) is collected using the variant field of the eBS application form at the time of lodging. Class 3 IHRs "of the same kind" require a separate application but utilise the same Level 2 CTs as for the Class 4 IHRs. However individual product information for Class 3 IHRs is not required to be provided.

Applying the correct GMDN Collective Term to your product

The process for applying the most appropriate collective term to a group of Class 1, Class 2, Class 3 IVDs, or Class 4 IHRs "of the same kind" relies upon the user recognising the specific characteristics described in the collective term definitions at each level for the products being grouped. It is recommended that the user start by identifying the broadest Level 1 CT and progressively working their way towards the appropriate level of collective term as predetermined by the risk classification.

Alternatively, by identifying within the GMDN database <http://www.gmdnagency.org> the most appropriate preferred term to describe the IVD, the user can view all linked collective terms and select the relevant collective term identified for use in Australia at the level corresponding to the risk classification. A detailed set of all available preferred terms and their linkages to each collective term thread in the GMDN database is not freely accessible to the public at the current time, although it is anticipated that this information will be widely available in the future. Until such time as this occurs, users who hold any of the different membership subscriptions available for the GMDN database can gain viewing access to all collective terms and each individual preferred term name and definition, however access to the 5-digit preferred term code in the GMDN database is on a pay-per-code basis.

Australian sponsors and manufacturers who have registered for access to the eBS website can obtain the preferred term codes required to be used to identify Class 4 IVDs however the linkage between the preferred terms used to describe the lower classes of IVDs and each level of the collective term thread is not viewable in the eBS code tables. A detailed list of examples of preferred terms linked to each collective term is included in Appendix 2 of this document to assist users, however in the event of any dispute about the presumed grouping of particular preferred terms under any nominated collective term, the GMDN database remains the definitive reference for preferred term-collective term links.

Frequently asked questions

What if the GMDN preferred term code advised by the manufacturer is not available in eBS for selection, even though that code has been used to describe the IVD for several years?

GMDN user guidance states that once a GMDN code has been applied to a product, the code can continue to be used throughout the life of that unchanged product. A number of existing IVD-related terms have been made obsolete to comply with new GMDN naming conventions for IVDs. As a result of the new naming conventions, all current terms within Category 06 for in vitro diagnostic medical devices now include in their name "IVD" and only current terms have been made available for selection in the Australian code tables in eBS. Any existing terms in the old format that may have been used to identify products previously can continue to be used for the life of the product, however where they have been made obsolete they are identified within the GMDN database using a direct link to a number of relevant new terms available for use. If a sponsor or manufacturer is unable to access the GMDN database directly to determine the equivalent term, please contact the TGA IVD team for assistance.

I can find a preferred term code that describes the analyte detected, however my test uses a different sort of methodology from that described by the term. Can I use another code that is almost correct?

For Class 4 IVDs, the preferred term code must accurately describe the analyte detected, the form the IVD takes (eg. kit, calibrator, control… etc) and also the standard technology used to perform the test. If a preferred term is present that describes the base analyte correctly, but it does not also include an appropriate standard technology qualifier, a new term must be created using the required methodology. A list of standard technologies is included in Appendix 1. Please contact the TGA IVD team for advice about how to obtain a preferred term suitable for describing a Class 4 IVD.

For Class 1, 2 or 3 IVDs which are required to use the collective term code linked to several preferred terms, if the base analyte is described for a preferred term, but the standard technology qualifiers listed do not cover the methodology used to perform the assay, it is not necessary to request a new preferred term to be created under the same collective term. Generally, the base analyte will be linked to the appropriate collective term thread and the addition of a different standard technology qualifier will not alter the collective term, provided the basic analyte which is the target of the assay remains unchanged. Please contact the IVD section of the TGA for advice, if this is not believed to be the case.

Appendix 1 – Standard technologies and definitions

The following methods represent the standard technology which is applied as a qualifier to the kit forms of preferred terms used to identify IVDs. Each standard technology includes a basic description of the methodology used.

Non-immune based methods

Atomic spectroscopy	A method for measuring the emission, absorption or fluorescence of electromagnetic radiation by atomic particles following atomisation, most commonly by flame.
Cell count	A method for the haematological enumeration of a cell population using manual, semi-automated or automated techniques which may include lysis, electrical impedance, conductivity, light scatter, volume measurement and/or calculation of cell parameters.
Chromogenic	A method for the qualitative and/or quantitative detection of specific analytes using chromogenic test reagents that undergo cleavage to induce a photometrically detectable colour change.
Clotting method	A method for qualitative and/or quantitative detection of specific coagulation proteins by inducing the coagulation cascade and determining the endpoint using optical light scatter, mechanical or electrochemical means.
Colorimetric dipstick	A method for the qualitative and/or semi-quantitative detection of specific analytes using a dipstick for colour comparison with standard values.
Electrophoresis	The migration of proteins, deoxyribonucleic acid, ribonucleic acid or nucleic acid segments through an electrically charged field to achieve component separation based on the size, shape and charge of the molecule, with visualisation by fluorescence, radioactivity, enzyme or chromogenic dye.
Electrometry	A method for measuring the difference in electrical potential across two electrodes to determine the concentration of an analyte.
Enzyme chemiluminescence	A method for measuring the kinetics or the resulting product of an enzyme-based reaction using a chemiluminescent detection system.
Enzyme colorimetry	A method for measuring the kinetics or the resulting product of an enzyme-based reaction by detecting the colorimetric change in absorbance either spectrophotometrically or visually.
Enzyme fluorescence	A method for measuring the kinetics or the resulting product of an enzyme-based reaction using a fluorescent detection system.

Enzyme radiometry	A method for measuring the kinetics or the resulting product of an enzyme-based reaction using radioactively labelled substrates.
Free radical assay	A method for the qualitative and/or quantitative detection of a specific analyte using the activity of oxidative free radicals upon aromatic molecules to produce a measurable compound.
Freezing point	A method for determining the osmotic concentration of a fluid by comparing the freezing point depression curve with that of a standard solution.
Gas chromatography	A method for the separation of volatile components in a gaseous mixture with subsequent identification and/or quantitation based on structure.
Haemoximetry	A method using multiple wavelength spectrophotometry to determine percentage of haemoglobin oxygenation and/or other haemoglobin fractions/complexes.
Ion-exchange chromatography	a method for the separation of ions and polarised molecules in a mixture based on charge properties of the molecules.
Ion selective electrode (ISE)	A method for determining the concentration of an ion in an aqueous solution by converting ionic activity into electrical potential.
Liquid chromatography	A method for the separation of components in a liquid mixture utilising chemical interactions as the solution passes through a stationary phase.
Mass spectrometry	A method for determining the molecular mass of a sample using ionisation to achieve particle separation and a detection system.
Microarray	A method for the qualitative and/or quantitative detection of multiple target analytes using oligonucleotide capture molecules arranged in a consistent pattern on a slide, chip or membrane.
Nephelometry/turbidimetry	A method which measures the amount or rate of particle aggregation or dispersion, typically by antigen-antibody complexes, particles or cells by detecting changes in light scatter and/or electrical impedence.
Nucleic acid sequencing technique	A method for determining the nucleotide sequence of a DNA fragment using chain termination, hybridisation, sequencing-by-synthesis and/or other sequencing technologies.
Nucleic acid technique (NAT)	A method for the detection and/or quantitation of nucleic acids by either amplification of a target sequence, by amplification of a signal or by hybridisation.
Protein binding assay	A method for the qualitative and/or quantitative detection of specific analytes by utilising the selective binding of proteins with target molecules.

Rapid test	A qualitative or semi-quantitative in vitro diagnostic medical device, intended to be used singly or in a small series, which involves non-automated procedures and has been designed to give a fast result.
Reduction/Oxidation	A method for the qualitative and/or quantitative detection of a change to the oxidative state using a visual or spectrophotometric detection system.
Spectrophotometry	A method which measures absorbance or transmission of light by a sample at one or multiple wavelengths to determine the composition or concentration of a target substance.
Stain	A method for the demonstration of tissue, cellular structures, cellular products or other substances using chemical agents and/or dyes.
Thin layer chromatography	A method for the separation of components in a mixture using interactions with a flat adsorbent stationary phase and comparison with standard compounds to aid identification of unknown substances.

Immune based methods

Agglutination	An immunological method where particles such as red blood cells or latex particles that have a specific antigenic determinant or antibody coating are clumped or aggregate together using a corresponding antigen or antibody in solution. Detection of agglutination may be manual, automated or using column agglutination technology.
Chemiluminescent immunoassay	A method for the qualitative and/or quantitative detection of antigens or antibodies in a specimen through the formation of immune complexes, using a chemiluminescent detection system.
Complement dependent cytotoxicity (CDC)	A method for the qualitative and/or quantitative detection of antigen or antibody in a specimen using complement mediated cell lysis or lymphocytotoxicity as an indicator.
Complement fixation test (CFT)	An immunological method for the qualitative and/or semi-quantitative detection of specific antigens or antibodies using the activation of complement proteins in a test system.
Direct fluorescent test (DFT)	An immunological method that uses an antibody labelled with a fluorescent dye to detect the presence of antigens in a specimen for visualisation.
Enzyme immunoassay (EIA)	A method for the qualitative and/or quantitative detection of antigens or antibodies in a specimen through the formation of immune complexes, using an enzyme-labelled detection system.

Enzyme immunohistochemistry	A method for the qualitative detection of antigens or specific cell markers in a histological specimen through the formation of immune complexes, using an enzyme-labelled detection system.
Immunoblot	A method to detect the presence of specific protein or nucleic acid sequences in a specimen using electrophoretic separation and detection by hybridisation or an immunological probe.
Immunochromatographic test (ICT)	A lateral flow or strip test method for the qualitative or semi-quantitative detection of a target analyte using a specific antibody bound to a visually detectable mobile phase (such as dyed microspheres), which forms a sandwich complex with the target analyte and pre-coated stationary phase capture points.
Fluorescent activated cell sorting/flow cytometry (FACS/Flow)	A technique for the qualitative and/or quantitative detection or separation of specific cell markers or cell types using fluorescent-labelled antibodies.
Fluorescent immunoassay	A method for the qualitative and/or quantitative detection of antigens or antibodies in a specimen through the formation of immune complexes, using a fluorescent-labelled detection system.
Multiplex	An immunological technique for the qualitative and/or quantitative detection of multiple analytes from a single specimen using antibody coated microparticles and a laser detection system.
Precipitation/ immunodiffusion	A method to detect the random spreading movement of antigen or antibody (or both) through a support medium by the formation of immune complexes.
Radioimmunoassay	A method for the qualitative and/or quantitative detection of antigens or antibodies in a specimen through the formation of immune complexes, using a radioactive-labelled detection system.

Appendix 2 – Collective term definitions and analytes

The following tables provide examples of the collective terms and definitions that are available for use in Australia for including IVDs "of the same kind" under a single entry on the ARTG. A number of analytes are provided for each collective term to indicate the base concepts used to form the range of preferred terms grouped by that collective term, and the risk classification it will be acceptable to be used for.

Clinical chemistry IVDs

L1CT (Class 1 IVDs)	**CT287 Clinical chemistry IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of chemical, biological or immunological components including electrolytes, enzymes, substrates, specific proteins, hormones, vitamins, products of metabolism, cancer/tumour markers, trace elements, autoimmune markers, therapeutic drugs and/or toxicological substances. All analytes as represented in Level 2 and Level 3 clinical chemistry collective terms.
L2CT (Class 2 & 3 IVDs)	**CT869 Clinical chemistry autoimmune IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of autoimmune markers in a clinical specimen. Antibodies to: acetylcholine receptor, adrenal, anticardiolipin, anticardiolipin-B2-glycoprotein I complex, asuaki-GM1, beta-2 glycoprotein I, cancer-associated retinopathy (CAR), centromere, centromere protein, circulating immune complex (CIC), cyclic citrulline peptide (CCP2), dsDNA, endomysium (EMA), F-actin, Gal (beta-1-3), ganglioside GD1b/GM1/GQ1/total antibody, gliadin, glomerular basement membrane, glutamic acid decarboxylase, glycoprotein 210, growth hormone, histone, hu, IgA, insulin, intrinsic factor, islet cell 512, islet cell, Jo-1, Ku, lamin-B receptor, LDL, liver cytosol, liver-kidney microsome 1, mitochondrial M2, anti-neutrophil cytoplasmic antibody (ANCA), anti-nuclear antibody (ANA), celiac disease-associated antibody, diabetes mellitus-associated antibody, extractable nuclear antigen (ENA), liver disease-associated antibody, myositis-associated antibody, pernicious anaemia-associated antibody, rhematoid arthritis-associated antibody, systemic lupus erythematosus-associated (SLE) antibody, myelin-associated glycoprotein (MAG), vasculitis associated antibody, myeloperoxidase anti-neutrophil cytoplasmic antibody (MPO-ANCA), myocardial, N-acetyl galactosamine, native DNA, nuclear pore glycoprotein 210, nucleosomal, parietal cell, phosphatidylserine, phospholipid, polymyositis-scleroderma, proliferating cell nuclear antigen (PCNA), proteinase 3, prothrombin, RA33, rhematoid factor, Ri, ribonucleoprotein, ribosomal phosphoprotein, Ro52, scleroderma-70, ssDNA, skeletal muscle, skin, sm/RNP, Smith antibody, smooth muscle, soluble liver antigen (SLA), sp-100 protein, sperm, SSA/Ro, SSB/La, striated muscle, sulfatide, teichoic acid, thyroglobulin, thryoglobulin/thyroid peroxidase/microsomal antibody thyrosin phosphatase, thyroxine, tissue transglutaminase, U1-RNP, Yo.
L2CT (Class 2 & 3 IVDs)	**CT1236 Clinical chemistry biological screening IVDs** IVDs that are intended to be used for the qualitative and/or quantitative screening of urine, faeces and other biological specimens for chemical, cellular or other components using a dipstick or other broadly indicative method. Biological fluid occult blood, vaginal pH, faecal screening tests for faecal (meconuim) albumin, faecal fat, faecal occult blood, faecal reducing substance, and urine screening tests for bilirubin, blood, creatinine, glucose, ketone, leukocyte, nitrite, pH, protein, sediment, specific gravity, urobilinogen.
L3CT (Class 3 IVDs)	**CT1247 Faecal screening IVDs** IVDs that are intended to be used for the qualitative and/or quantitative screening of faeces specimens for chemical, cellular or other biological components. Screening for faecal (meconuim) albumin, faecal fat, faecal occult blood, faecal reducing substance.
L3CT (Class 3 IVDs)	**CT1246 Urine screening IVDs** IVDs that are intended to be used for the qualitative and/or quantitative screening of urine specimens for chemical, cellular or other biological components. Screening for multiple urine analytes, including bilirubin, blood, creatinine, glucose, ketone, leukocyte, nitrite, pH, protein, sediment, specific gravity, urobilinogen.
L2CT (Class 2 & 3	**CT836 Clinical chemistry electrolyte IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of electrolytes and other ions in a clinical specimen.

IVDs)	Bicarbonate, calcium, chloride, inorganic phosphate, magnesium, multiple blood gas/electrolyte analytes, osmolality, potassium, potassium, sodium.
L2CT (Class 2 & 3 IVDs)	**CT827 Clinical chemistry enzyme IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of clinical chemistry enzymes in a clinical specimen. 2-5A synthetase, 5-aminolaevulinate dehydratase, 5-nucleotidase, acetylcholinesterase, acid phosphatases including isoezymes, adenosine deaminase, alanine aminotransferase (ALT), aldolase, alkaline phosphatases including isoenzymes, alpha-galactosidase, alpha-glutathione S-transferase, alpha-hydroxybutyrate dehydrogenase, amylase isoenzyme, angiotensin converting enzyme (ACE), arylamine N-acetyltransferase, aspartate aminotransferase (AST), beta-galactosidase, beta-glucuronidase, beta-hexosaminidase A, beta-hydroxybutyrate dehydrogenase, biotinidase, bone alkaline phosphatase, cholinesterase dibucaine number (% inhibition), chymotrypsin, creatine kinase (CK) including isoenzymes, multiple cardiac markers, galactokinase, galactose transferase, galactose-1-phosphate uridyl transferase, gamma-glutamyltrasferase (GGT), glutamate dehydrogenase, glycerol kinase, glycogen phophorylase BB, granulocyte elastosidase, guanase, human placental alkaline phosphatase (hPLAP), isocitric dehydrogenase, lactase, lactate dehydrogenase (LDH) incl isoenzymes, leukocyte esterase, leukocyte alkaline phosphatase, leukocyte myeloperoxidase, lipase, lipoprotein lipase, lysozyme (muraminidase), malate dehydrogenase, multiple clinical chemistry enzymes, multiple clinical chemistry analytes, multiple stroke (CVA) markers, myeloperoxidase, N-acetyl-beta-D-glucosaminidase (NAG), neonatal trypsin, oxytocinase, pancreatic elastase (PE), pepsin, phosphohexose isomerase, phospholipase A2, pi-glutathione S-transferase, prolyl hydroxylase, prostatic acid phosphatase (PAP), pseudocholinesterase, pyruvate kinase, sorbitol dehydrogenase, tartrate resistant acid phosphatase (TRAP), thymidine kinase, total acid phosphatase (TAP), total alkaline phosphatase (ALP), total amylase, total aspartate aminotransferase (AST), total creatine kinase (CK), total lactate dehydrogenase (LDH), total/prostatic acid phosphatase (TcP), trypsin, trypsin-alpha-1-antitrypsin complex (elastase), tryptase, UDP-galactose 4-epimerase (GALE), uropepsin.

L3CT (Class 3 IVDs)	**CT1238 Acid phosphatase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of acid phosphatase enzyme and its various forms in a clinical specimen. Acid phosphatase isoenzyme, prostatic acid phosphatase, tartrate-resistant acid phosphatase (TRAP), total acid phosphatase (TAT), total/tartrate-resistant acid phosphatase (TcP).
L3CT (Class 3 IVDs)	**CT828 Alkaline phosphatase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of alkaline phosphatase enzyme and its various forms in a clinical specimen. Alkaline phosphatase isoenzyme, bone alkaline phosphatase (BALP), human placental alkaline phosphatase (hPLAP), leukocyte alkaline phosphatase, total alkaline phosphatase (ALP).
L3CT (Class 3 IVDs)	**CT829 Amylase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of amylase enzyme and its various forms in a clinical specimen. Amylase isoenzyme, total amylase
L3CT (Class 3 IVDs)	**CT830 Cholinesterase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of cholinesterase enzyme and its various forms in a clinical specimen. Acetylcholinesterase, cholinesterase dibucaine number (percentage inhibition), chymotrypsin, pseudocholinesterase,
L3CT (Class 3 IVDs)	**CT831 Creatine kinase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of creatine kinase enzyme and its various forms in a clinical specimen. Creatine kinase multiple isoenzymes, creatine kinase brain isoenzyme (CKBB), creatine kinase myocardial isoenzyme (CKMB), creatine kinase skeletal isoenzyme (CKMM), total creatine kinase (CK), multiple cardiac markers.
L3CT (Class 3 IVDs)	**CT1054 Glutathione S-transferase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of glutathione S-transferase enzyme and its various forms in a clinical specimen. Alpha-glutathione S-transferase, pi-glutathione S-transferase.
L3CT	**CT832 Lactate dehydrogenase IVDs**

	(Class 3 IVDs)	IVDs that are intended to be used for the qualitative and/or quantitative determination of lactate dehydrogenase enzyme and its various forms in a clinical specimen. Lactate dehydrogenase multiple isoenzymes, lactate dehydrogenase bone isoenzyme, lactate dehydrogenase intestinal isoenzyme, lactate dehydrogenase kidney isoenzyme, lactate dehydrogenase liver isoenzyme, lactate dehydrogenase placenta isoenzyme, total lactate dehydrogenase (LDH).
	L3CT (Class 3 IVDs)	**CT842 Trypsin IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of the enzyme trypsin and its various forms, in a clinical specimen. Neonatal typsin, trypsin, trypsin-alpha-1-antitrypsin complex (elastase).
L2CT (Class 2 & 3 IVDs)	**CT850 Clinical chemistry hormone IVDs**	IVDs that are intended to be used for the qualitative and/or quantitative determination of clinical chemistry hormones in a clinical specimen. 11-Deoxycortisol, 17-hydroxycorticoid, 17-hydroxyketosterone (17OH), 17-hydroxypregnenolone, 17-hydroxyprogesterone, 17-ketogenic steroid (17KGS), 17-ketosteroid (17KS), 18-hydroxycorticosterone, 3-methoxy-4-hydroxyphenylglycol (MHPG), 5-hydroxyindoleacetic acid (5HIAA), adrenaline (epinephrine), adrenocorticotropic hormone (ACTH), aldosterone, alpha-2-pregnancy associated glycoprotein, alpha-fetoprotein, alpha-fetoprotein L3 fraction (AFP-L3), alpha-melanocyte stimulating hormone (MSH), androstanediol glucuronide (3a-diol G), androstenedione, androsterone, angiotensin, antidiuretic hormone (ADH), arginine vasopressin, beta-endorphin, calcitonin, corticoid-binding globulin, corticosterone, C-peptide, dehydroepiandrosterone (DHEA), dehydroepiandrosterone sulphate (DHEAS), deoxycorticosterone, dihydrotestosterone, direct renin, dopamine, erythropoietin (EPO), estradiol (oestradiol) (E2), estriol-16-alpha-glucuronide, estrogen receptor, estrone, estrone-3-glucuronide, follicle stimulating hormone (FSH), free cortisol, free estriol (oestriol), free testosterone, free thyroxine (FT4), free triiodothyronine (FT3), gastrin, glucagon, gonadotropin releasing hormone (GnRH), growth hormone releasing hormone (GHRH), homovanillic acid, human chorionic gonadotropin beta-subunit (beta-HCG/β-HCG), human chorionic gonadotropin beta-subunit/follicle stimulating hormone, human growth hormone (HGH), human placental lactogen, hydroxyproline, immunoreactive renin, inhibin A, inhibin B, insulin, insulin-like growth factor binding protein 1 (IGFBP-1), insulin-like growth factor binding protein 3 (IGFBP-3), insulin-like growth factor I (IGF1), insulin-like growth factor II (IGFII), intact parathyroid hormone, leptin, luteinising hormone (LH), melatonin, metanephrine, motilin, multiple clinical chemistry analytes, multiple gastrointestinal disease markers, multiple human hormones, neonatal TSH, neopterin, neurotensin, noradrenaline (norepinephrine), osteocalcin, oxytocin, parathyroid hormone terminal fragment, parathyroid hormone related peptide (PTHrP), pepsinogen 1, pepsinogen II, placental growth factor (PLGF), pregnancy-associated plasma protein A (PAPP-A), pregnancy-specific beta1-glycoprotein, pregnanetriol, pregnenolone, procalcitonin, progesterone, progesterone receptor, proinsulin, prolactin, prostaglandin, pyridinoline, reverse triiodothyronine (reverse T3), secretin, serotonin, sex hormone binding globulin, somatostatin, substance P, thyroglobulin, thyroid releasing factor, thyroid stimulating hormone (TSH), TSH receptor immunoglobulin (TSI), thyroid uptake, thyroxine binding capacity, thyroxine binding globulin (TBG), total cortisol, total estriol (oestriol), total human chorionic gonadotropin (HCG), trisomy 21-risk hormone, vanillylmandelic acid (VMA),vasointestinal peptide (VIP), vasopressin.
	L3CT (Class 3 IVDs)	**CT1243 Catecholamine IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of catecholamine hormones and their derivatives, in a clinical specimen. 3-Methoxy-4-hydroxyphenylglycol (MHPG), adrenaline (epinephrine), dopamine, homovanillic acid (HVA), metanephrine, noradrenaline (norepinephrine), vanillylmandelic acid (VMA).
	L3CT (Class 3 IVDs)	**CT851 Cortisol IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of cortisol hormones and its various forms in a clinical specimen. Free cortisol, total cortisol.
	L3CT (Class 3 IVDs)	**CT852 Estrogen (Oestrogen) IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of estrogen (oestrogen) hormones in a clinical specimen. Estradiol (oestradiol) (E2), estriol-16-alpha-glucuronide, estrogen receptor, estrone, estrone-3-glucuronide, free estriol, total estriol.
	L3CT (Class 3	**CT856 Human chorionic gonadotropin (HCG) IVDs** IVDs that are intended to be used for the qualitative and/or quantitative

	IVDs)	determination of Human chorionic gonadotropin (HCG) hormone and its various forms in a clinical specimen. Human chorionic gonadotropin beta-subunit (beta-HCG/β-HCG), total human chorionic gonadotropin (HCG).
	L3CT (Class 3 IVDs)	**CT857 Insulin-like growth factor IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of insulin-like growth factor hormone and its various forms in a clinical specimen. Insulin-like growth factor binding protein 1 (IGFBP-1), insulin-like growth factor binding protein 3 (IGFBP-3), Insulin-like growth factor I (IGF1) (somatomedin C), Insulin-like growth factor II (IGFII).
	L3CT (Class 3 IVDs)	**CT1244 Parathyroid hormone IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of parathyroid hormone and its various forms in a clinical specimen. Intact parathyroid hormone, parathyroid hormone terminal fragment, parathyroid hormone related peptide (PTHrP).
	L3CT (Class 3 IVDs)	**CT1008 Thyroid IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of hormones relating to thyroid function, thyroid stimulation and thyroid uptake, in a clinical specimen. Free thyroxine (FT4), free triiodothyronine (FT3), neonatal thyroid stimulating hormone (neonatal TSH), reverse triiodothyronine, thyroglobulin, thyroid releasing factor, thyroid stimulating hormone (TSH), TSH receptor immunoglobulin (TSI), thyroid uptake, thyroxine binding capacity, thyroxine binding globulin (TBG).
L2CT (Class 2 & 3 IVDs)		**CT889 Multiple clinical chemistry constituent IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of multiple analytes (chemical, biological, and/or immunological) from more than one clinical chemistry specialty, in a clinical specimen. Glucose/haemoglobin, glucose/ketones/lipid profile, multiple blood gas/haemoximetry/electrolyte analytes, multiple clinical chemistry analytes, multiple gastrointestinal disease markers.
L2CT (Class 2 & 3 IVDs)		**CT974 Clinical chemistry-specific protein IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of proteins specific to clinical chemistry, in a clinical specimen. Agalactosyl immunoglobulin G, albumin, albumin-globulin ratio, allergen-specific immunoglobulin E (IgE) antibody, alpha-1-acid glycoprotein (orosomucoid), alpha-1-antitrypsin (protease inhibitor), alpha-1-B glycoprotein, alpha-1-macroglobulin, alpha-1-microglobulin, alpha-1-T glycoprotein, alpha-2-AP-glycoprotein, alpha-2-glycoprotein, alpha-2-HS-glycoprotein, alpha-2-macroglobulin, alpha-globulin, beta-2-glycoprotein, beta-2-microglobulin, beta-globulin, B-type natriuretic protein/N-terminal pro b-type natriuretic peptide, C1 esterase inhibitor, calprotectin, carbohydrate deficient transferrin, ceruloplasmin, collagen deoxypyridonoline, collagen type I cross-linked C-telopeptide, collagen type I cross-linked N-telopeptide, collagen type IV, complement cascade component B, complement cascade component C1q, complement cascade component C2, complement cascade component C3b, complement cascade component C3/C3c, complement complex C5-C9, complement component C1 inactivator, complement component C5a, complement component C4/C4c, C-reactive protein (CRP), cryoglobulin, cystatin C, eosinophil basic protein, ferritin, fibronectin, galectin-3, globulin (total), haemopexin, haptoglobin, histamine, histamine release, homocysteine, immunoglobulin A subclass (IgA subclass), immunoglobulin D subclass (IgD subclass), immunoglobulin G subclass (IgG subclass), Immunoglobulin M subclass (IgM subclass), immunoreactive trypsinogen, interferon, interleukin-1 (IL-1), interleukin-10 (IL-10), interleukin-11 (IL-11), interleukin-12 (IL-12), interleukin-13 (IL-13), interleukin-1a (IL-1a), interleukin-1b (IL-1b), interleukin-2 (IL-2), interleukin-3 (IL-3), interleukin-4 (IL-4), interleukin-5 (IL-5), interleukin-6 (IL-6), interleukin-6 receptor (IL-6r), interleukin-7 (IL-7), interleukin-8 (IL-8), interleukin-9 (IL-9), kappa/lambda light chain immunoglobulin, lactoferrin, laminin, lecithin/Sphingomyelin ratio (amniotic fluid), mammaglobulin, melanin, methemalbumin, mucin, multiple allergen-specific immunoglobulin E (IgE) antibodies, multiple clinical chemistry proteins, multiple complement components, multiple interleukins/interleukin receptors, myelin basic protein, myoglobin, myosin light chain, neutrophil gelatinase-associated lipocalin (NGAL), plasma protein, prealbumin (transthyretin), procollagen type I C-terminal propeptide, procollagen type III C-terminal propeptide, properdin factor B, protein 14-3-3, protein electrophoresis, retinol binding protein, S100 protein, secretory immunoglobulin A (secretory IgA), soluble transferrin receptor, tau protein (beta-2 transferrin), total complement activity (CH50), total immunoglobulin (gamma globulin), total immunoglobulin A (IgA total), total

		immunoglobulin D (IgD total), total immunoglobulin E (IgE total), total immunoglobulin G (IgG total), total immunoglobulin M (IgM total), total iron binding capacity, total protein, transcobalamin (S), transferrin, troponin I, troponin T, troponin I/troponin T, vasoactive intestinal peptide.
	L3CT (Class 3 IVDs)	**CT884 Collagen IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of collagen protein and its various forms in a clinical specimen. Collagen deoxypyridonoline, collagen pyridonoline, collagen type I cross-linked C-telopeptide, collagen type I cross-linked N-telopeptide, collagen type IV, procollagen type I C-terminal propeptide, procollagen type III C-terminal propeptide.
	L3CT (Class 3 IVDs)	**CT844 Complement IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of complement proteins in a clinical specimen. C1 esterase inhibitor, complement cascade component B, complement cascade component C1q, complement cascade component C2, complement cascade component C3b, complement cascade component C3/C3c, complement complex C5-C9, complement component C1 inactivator, complement component C5a, complement component C4/C4c, properdin factor B, total complement activity (CH50).
	L3CT (Class 3 IVDs)	**CT843 Immunoglobulin IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of immunoglobulins in a clinical specimen Agalactosyl immunoglobulin G (IgG), allergen-specific immunoglobulin E (IgE) antibody, immunoglobulin A subclass (IgA subclass), immunoglobulin D subclass (IgD subclass), immunoglobulin G subclass (IgG subclass), Immunoglobulin M subclass (IgM subclass), kappa/lambda light chain immunoglobulin, multiple allergen-specific immunoglobulin E (IgE) antibodies, secretory immunoglobulin A (secretory IgA), total immunoglobulin (gamma globulin), total immunoglobulin A (IgA total), total immunoglobulin D (IgD total), total immunoglobulin E (IgE total), total immunoglobulin G (IgG total), total immunoglobulin M (IgM total).
	L3CT (Class 3 IVDs)	**CT1241 Interleukin IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of interleukins in a clinical specimen. Interleukin-1 (IL-1), interleukin-10 (IL-10), interleukin-11 (IL-11), interleukin-12 (IL-12), interleukin-13 (IL-13), interleukin-1a (IL-1a), interleukin-1b (IL-1b), interleukin-2 (IL-2), interleukin-3 (IL-3), interleukin-4 (IL-4), interleukin-5 (IL-5), interleukin-6 (IL-6), interleukin-6 receptor (IL-6r), interleukin-7 (IL-7), interleukin-8 (IL-8), interleukin-9 (IL-9), multiple interleukins/interleukin receptors.
	L3CT (Class 3 IVDs)	**CT1242 Troponin IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of troponin and its various forms in a clinical specimen. Troponin I, troponin T, troponin I/troponin T
L2CT (Class 2 & 3 IVDs)		**CT833 Clinical chemistry substrate IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of clinical chemistry substrates in a clinical specimen. 1,3-Beta-D-glucan, 1,5-anhydroglucitol, 3-methylglutaconic acid, 5-aminolaevulinate dehydratase, acylglycine, alpha-1-antichymotrypsin, amino-nitrogen, ammonia, apolipoprotein A-I (Apo A1), apolipoprotein A-II (Apo A2), apolipoprotein B (Apo B), apolipoprotein C-II (Apo C2), apolipoprotein C-III (Apo C3), apolipoprotein E (Apo E), beta-hydroxybutyrate, beta-thromboglobulin (β-thromboglobulin), blood urea nitrogen (BUN), bromide, carnitine, cholyglycine bile acid, conjugated (direct) bilirubin, conjugated sulfalithocholic (SLCG) bile acid, creatine, creatinine, cyclic adenosine monophosphate (cAMP), cyclic guanosine monophosphate (cGMP), cysteinyl leukotriene (cys-LT), cystine, delta-aminolaevulinic acid (delta-ALA), dense low density lipoprotein (DLDL) cholesterol, D-xylose, essential fatty acid profile, fatty acid binding protein (FABP), fructosamine, fructose, galactose, galactose-1-phosphate, glucose, glucose monitoring system, glucose/haemoglobin (Hb), glucose/ketone/lipid profile, glycated albumin, glycated haemoglobin (HbA1c), glycocholic acid, guanidinoacetate, heart fatty acid binding protein, high density lipoprotein (HDL) cholesterol, histidine, hyaluronic acid (HA), inter-alpha trypsin inhibitor, iron, ketone (acetoacetate), lactate, lecithin, L-fucose, lipoprotein A, lipoprotein X, low density lipoprotein (LDL) cholesterol, methionine, methylmalonic acid (MMA), microalbumin, microprotein, monoethylglycinexylidide (MEGX), mucopolysaccharide fraction, multiple amino acids, multiple cardiac markers, multiple clinical chemistry analytes, multiple lipid analytes, multiple stroke (cerebral vascular

		accident) marker, N-acetyl aspartic acid (NAA), N-acetyl galactosamine, N-acetyl procainamide (NAPA), non-esterified fatty acid, organic acid profile, oxalate, pancreatic secretory trypsin inhibitor, phenylalanine, phosphatidyl glycerol (PG), phospholipid, porphobilinogen deaminase, porphobilinogen, prostacyclin, protoporphyrin IX, pyruvate, remnant lipoprotein, serum amyloid A, sialic acid (free), sorbitol, succinyl acetone, sulfatide, thiocyanate, thromboxane, total apolipoprotein, total bilirubin, total cholesterol lipid, total fatty acid, total lipoprotein, total porphyrin (coproporphyrin/uroporphyrin), triglyceride, tyrosine, uric acid, uroporphyrin, very long chain fatty acid, very low density lipoprotein (VLDL) cholesterol.
	L3CT (Class 3 IVDs)	**CT834 Bilirubin IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of bilirubin in a clinical specimen. Conjugated (direct) bilirubin, total bilirubin.
	L3CT (Class 3 IVDs)	**CT835 Lipid and lipoprotein IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of cholesterol, fatty acid, lipids, lipoproteins and/or triglycerides in a clinical specimen Apolipoprotein A-I (Apo A1), apolipoprotein A-II (Apo A2), apolipoprotein B (Apo B), apolipoprotein C-II (Apo C2), apolipoprotein C-III (Apo C3), apolipoprotein E (Apo E), dense low density lipoprotein (DLDL) cholesterol, essential fatty acid profile, fatty acid binding protein (FABP), free fatty acid profile, heart fatty acid binding protein, high density lipoprotein (HDL) cholesterol, lipoprotein A, lipoprotein X, low density lipoprotein (LDL) cholesterol, multiple lipid analytes, non-esterified fatty acid, remnant lipoprotein, serum amyloid A, total apolipoprotein, total cholesterol lipid, total fatty acid, total lipoprotein, triglyceride, very long chain fatty acid, very low density lipoprotein (VLDL).
	L3CT (Class 3 IVDs)	**CT1239 Porphyria-related IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of porphyrins, and the various precursors and intermediates involved in the heme biosynthetic pathway, in a clinical specimen. 5-Aminolaevulinate dehydratase, delta-aminolaevulinic acid (delta-ALA), porphobilinogen deaminase, porphobilinogen, protoporphyrin IX, Total porphyrin (coproporphyrin/uroporphyrin), uroporphyrin.
L2CT (Class 2 & 3 IVDs)		**CT860 Clinical chemistry therapeutic drug monitoring IVDs** IVDs that are intended to be used in monitoring of therapeutic drug levels in a clinical specimen. 5-Fluorocytosine, amikacin, aminophylline, amoxapine, caffeine, choramphenicol, carbamazepine, chlorpromazine, clomipramine/norclomipramine, cocaine/cocaine, cyclosporin A/cyclosporine, desipramine, dibekacin, digitoxin, digoxin, disopyramide, escitalopram, ethambutol, ethosuxamide, flecainide, fluconazole, gentamicin, haloperidol (haldol), hydroxyzine chloride (atarax), imipramine, isepamicin, itraconazole, kanamycin, ketoconazole, lidocaine, lithium, methotrexate, methsuximide, mexiletine, multiple therapeutic drug monitoring, mycophenolate (Cellcept), N-acetylprocainamide, netilmycin, phenobarbital, phenothiazine, phenytoin (dilantin), primidone, procainamide, propanolol, quinidine, rapamycin (sirolimus), sisomycin, streptomycin. tacrolimus, teicoplanin, theophylline, tobramycin, tricyclic antidepressant, valproic acid, vancomycin, voriconazole, zonisamide.
	L3CT (Class 3 IVDs)	**CT864 Anti-asthma therapeutic drug monitoring IVDs** IVDs that are intended to be used in therapeutic monitoring of asthma medication in a clinical specimen. Aminophylline, caffeine, theophylline.
	L3CT (Class 3 IVDs)	**CT863 Antimicrobial therapeutic drug monitoring IVDs** IVDs that are intended to be used in therapeutic drug monitoring of antimicrobial medication in a clinical specimen. 5-Fluorocytosine, amikacin, chloramphenicol, dibekacin, ethambutol, fluconazole, gentamicin, itraconazole, isepamicin, kanamycin, ketoconazole, netilmycin, sisomycin, streptomycin, teicoplanin, tobramycin, vancomycin, voriconazole.
	L3CT (Class 3 IVDs)	**CT865 Anti-neoplastic therapeutic drug monitoring IVDs** IVDs that are intended to be used in therapeutic monitoring of anti-neoplastic drugs in a clinical specimen. Methotrexate.
	L3CT (Class 3 IVDs)	**CT861 Cardiovascular therapeutic drug monitoring IVDs** IVDs that are intended to be used in therapeutic monitoring of cardiovascular drugs in a clinical specimen. Digitoxin, digoxin, disopyramide, flecainide, lidocaine, mexiletine, N-

		acetylprocainamide, procainamide, propanolol, quinidine.
	L3CT (Class 3 IVDs)	**CT862 Central nervous system therapeutic monitoring IVDs** IVDs that are intended to be used in therapeutic monitoring of drugs targeting the central nervous system in a clinical specimen. Amoxapine, carbamazepine, chlorpromazine, clomipramine/norclomipramine, desipramine, escitalopram, ethosuximide, haloperidol (haldol), hydroxyzine chloride (atarax), imipramine, lithium, methsuximide, phenobarbital, phenothiazine, phenytoin (dilantin), primidone, valproic acid, zonisamide.
	L3CT (Class 3 IVDs)	**CT866 Immunosuppressant therapeutic drug monitoring IVDs** IVDs that are intended to be used in therapeutic monitoring of drugs targeting the immune system in a clinical specimen. Cyclosporin A/cyclosporine, mycophenolate (Cellsept), rapamycin (sirolimus), tacrolimus.
L2CT (Class 2 & 3 IVDs)		**CT184 Clinical chemistry toxicology/drug detection IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of toxic substances, pharmaceutical drugs and/or drugs of abuse in a clinical specimen 6-Acetyl morphine, acetaminophen, acetazolamide, acetone, amanitin, amiodarone, amitriptyline, amphetamine/methamphetamine group, amphetamine-specific group, atenololo, bacterial toxin, barbiturate, benzodiazepine group, brompheniramine, caffeine, chlorpheniramine, cannabinoid, chlorpheniramine, clonazepam, clonidine, clorazepate (nordiazepam), clozapine, cocaine/cocaine metabolite, codeine, cotinine (nicotine metabolite), cyanide, dapsone (sulphonamide), desethylamiodarone, desipramine, diazepam (valium), diphenhydramine, doxepin/doxepin metabolite, doxylamine, drug/toxicology adulteration kit, ethanol alcohol (ETOH), ethchlorvynol, ethotoin, ethylene glycol, felbamate (felbatol), fentanyl, fluoxetine (prozac), fluphenazine, flurazepam, gamma-hydroxybutyrate (GHB), hippuric acid, ibuprofen, imipramine, isoniazid, isopropanol alcohol, leflunomide, levetiracetam (keppra), lysergic acid diethylamide (LSD)/LSD metabolite, methadone haemagglutination inhibition, methadone, methamphetamine-specific, methanol alcohol, methapyrilene, methaqualone, morphine/morphine metabolite haemagglutination inhibition, morphine/morphine metabolite, multiple antihistamines, multiple drugs of abuse, multiple therapeutic drugs/drugs of abuse, Neurontin (gabapentin), nortryptiline, norverapamil, opiate haemagglutination inhibition, opiate, organophosphate pesticide, orphenadrine, oxocarbazepine, oxycodone, perphenazine, phencyclidine (PCP), phenobarbital, phenol, polychlorinated bipheny (PCB), promethazine, propoxyphene, psilocin/bufotenine, quetiapine, quinine, rifabutin, salicylate, snake venom, trichloroacetic acid, trichloroethylene, tricyclic antidepressant, verapamil.
L2CT (Class 2 & 3 IVDs)		**CT1237 Clinical chemistry trace element IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of clinical chemistry trace elements in a clinical specimen. Aluminium, antimony, arsenic, beryllium, bismuth, bromide, cadmium, chromium, cobalt, copper, fluoride, gold, iodine, iron, lead, manganese, mercury, molybdenum, multiple heavy metals, nickel, selenium, silver, thallium, tin, zinc.
L2CT (Class 2 & 3 IVDs)		**CT845 Clinical chemistry tumour marker IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of specific tumour markers in a clinical specimen. Bladder tumour associated antigen, bombesin, cancer antigen 11-19 (CA11-19), cancer antigen 125 (CA125), cancer antigen 130 (CA130), Cancer antigen 15-3 (CA15-3), cancer antigen 195 (CA195), cancer antigen 19-9 (CA19-9), cancer antigen 242 (CA242), cancer antigen 27.29 (CA27.29), Cancer antigen 50 (CA50), cancer antigen 54-61 (CA54-61), cancer antigen 549 (CA549), cancer antigen 6402 (CA602), cancer antigen 72-4 (CA72-4), cancer associated serum antigen (CASA), carcinoembryonic antigen (CEA), chromogranin A, complexed prostate specific antigen (PSA), cytokeratin fragment 19 (CK19), DUPAN-2 antigen, free (unbound) prostate specific antigen (PSA), human ovarian tumour antigen NB/70K, KMO1 tumour associated carbohydrate antigen, lipid-associated sialic acid (LASA), lung cancer-associated protein, mucin-like carcinoma-associated antigen (MCA), multiple tissue-associated protein, NCC-ST-439 tumour-associated carbohydrate antigen, neuron-specific enolase, nuclear mitotic apparatus protein (NuMA), oncogene protein p21(ras), p53 tumour protein antibody, progastrin-releasing peptide (ProGRP), sialyl Lex antigen, sialyl Lex-I antigen, sialyl Lex-i antigen, sialyl Tn antigen, SPan-1 antigen, squamous cell carcinoma antigen, terminal deoxynucleotidyl transferase (TdT), tissue polypeptide antigen, total prostate specific antigen (PSA), tumour necrosis factor-alpha/tumour necrosis factor-beta (TNF-alpha/TNF-beta), vascular endothelial growth factor (VEGF).
	L3CT (Class 3 IVDs)	**CT846 Prostate specific marker IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of prostate specific markers in a clinical specimen.

	Complexed prostate specific antigen, free (unbound) prostate specific antigen, total prostate specific antigen (PSA).
L2CT (Class 2 & 3 IVDs)	**CT847 Clinical chemistry vitamin and mineral IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of vitamins and minerals in a clinical specimen. 1,25-Dihydroxy vitamin D3, 25-hydroxy vitamin, folate (vitamin B9), multiple form 25-hydroxy vitamin D, multiple vitamin, renal/physiological stone analysis, vitamin A (carotene), vitamin B1 (thiamine), vitamin B12, vitamin B2 (riboflavin), vitamin B3 (niacin), vitamin B6 (pyridoxine), vitamin C (ascorbic acid), vitamin D2 ergocalciferol, vitamin D3 cholecalciferol, vitamin E, vitamin K IVD.
L3CT (Class 3 IVDs)	**CT848 Vitamin B IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of vitamins from Group B complex in a clinical specimen. Folate (vitamin B9), vitamin B1 (thiamine), vitamin B12, vitamin B2 (riboflavin), vitamin B3 (niacin), vitamin B6 (pyridoxine).
L3CT (Class 3 IVDs)	**CT849 Vitamin D IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of vitamins from Group D complex in a clinical specimen 1,25-Dihydroxy vitamin D3, 25-hydroxy vitamin D2, multiple form 25-hydroxy vitamin D, vitamin D2 ergocalciferol, vitamin D3 cholecalciferol,
L2CT (Class 2 & 3 IVDs)	**CT806 Haemoximetry and blood gas IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of blood gas analytes, calculated blood gas parameters and haemoglobin complexes using gas permeable membranes and co-oximetery, in a clinical specimen. Blood gas pCO2, blood gas pO2, blood gas pH, ionized calcium (iCa), multiple blood gas analyte, multiple blood gas/haemoximetry/electrolyte analyte, multiple haemoximetry analyte, percentage carboxyhaemoglobin (COHb%), percentage methaemoglobin (MetHb%), percentage oxyhaemoglobin (O2Hb%), percentage sulphaemoglobin (SulphHb%), reduced haemoglobin (RHb), total haemoglobin (Hb) IVD.

Coagulation IVDs

L1CT (Class 1 IVDs)	**CT870 Coagulation IVDs** IVDs that are intended to be used in testing to provide information about haemostasis, the coagulation cascade, platelet function, fibrinolysis, thrombophilia and any of the individual factors, components or inhibitors involved in the coagulation of blood. All analytes as represented in Level 2 Coagulation collective terms.
L2CT (Class 2 & 3 IVDs)	**CT872 Coagulation calibrator/control IVDs** IVDs that are intended to be used in testing to establish known points of reference and/or verify the performance of coagulation assays. Multiple coagulation factors.
L2CT (Class 2 & 3 IVDs)	**CT877 Coagulation factor IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of individual clotting factors within the coagulation cascade. Coagulation factor II (prothrombin), coagulation factor IIa (thrombin), coagulation factor IX, coagulation factor prekallikrein/kallikrein, coagulation factor V, coagulation factor VII, coagulation factor VIIa, coagulation factor VIII, coagulation factor VIII: ristocetin cofactor complex activity (FVIII:RCO), coagulation factor VIII-associated antigen, coagulation factor X, coagulation factor XI, coagulation factor XII, coagulation factor XIIa, coagulation factor XIIIa pro-enzyme subunit, coagulation factor XIIIa/factor XIIIs, coagulation factor XIIIs carrier protein sub-unit, fibrinogen assay (factor I), high molecular weight kininogen (HMWK), multiple coagulation factor, von Willebrand factor: collagen binding activity (vWF:CBA), von Willebrand factor: ristocetin cofactor complex activity (vWF:RCO).
L2CT (Class 2 & 3 IVDs)	**CT1248 Coagulation-related IVDs** IVDs that are intended to be used alone or in combination with other IVDs to perform various coagulation-related tests and procedures Calcium chloride.
L2CT (Class 2 & 3 IVDs)	**CT875 Fibrinolysis IVDs** IVDs that are intended to be used in testing to provide information about fibrinolysis, fibrin degradation products and components involved in the process of clot breakdown. Alpha-2-antiplasmin, aprotinin, D-dimer, fibrinogen degradation product (FDP), plasmin, plasmin-alpha-2-antiplasmin complex (PAP), plasminogen activator inhibitor, plasminogen, soluble fibrin monomer complex, thrombin activating fibrinolysis inhibitor, tissue plasminogen activator, total degradation product (TDP), urokinase plasminogen activator.
L2CT (Class 2 & 3 IVDs)	**CT871 General coagulation IVDs** IVDs that are intended to be used in testing to provide information about the general coagulation of blood and the time taken for a clinical blood specimen to clot following initiation of the intrinsic and/or extrinsic coagulation pathways. Activated clotting time (ACT), activated partial thromboplastin time (APTT), fibrinogen assay (factor I), prothrombin time (PT), reptilase time, thrombin time (TT).
L2CT (Class 2 & 3 IVDs)	**CT874 Platelet factor IVDs** IVDs that are intended to be used in testing to provide information about platelet factor components or platelet functionality. Platelet aggregation study, platelet factor 4, platelet membrane glycoprotein IIb-IIIa, Platelet-mediated adenosine triphosphate (ATP) release.
L2CT (Class 2 & 3 IVDs)	**CT873 Special coagulation IVDs** IVDs that are intended to be used in testing to provide information about substances that are associated with the coagulation cascade or complexes formed within the coagulation cascade. Fibrin monomer, fibrinopeptide A,
L2CT (Class 2 & 3 IVDs)	**CT876 Thrombophilia and coagulation inhibitor IVDs** IVDs that are intended to be used in testing to provide information about thrombosis or the abnormal development of clots, and inhibitors of the coagulation process. Activated protein C resistance ratio (APCR), activated protein C resistant factor V (factor V Leiden), antithrombin III (ATIII), coagulation factor II inhibitor, coagulation factor IX inhibitor, coagulation factor VII inhibitor, coagulation factor VIII inhibitor, coagulation factor X inhibitor, coagulation factor Xa inhibitor, coagulation factor XI inhibitor, coagulation factor XII inhibitor, coagulation inhibitory substance neutralization, endogenous thrombin potential (ETP), heparin anti-Xa, heparin cofactor II, hirudin, lupus anticoagulant marker, multiple thrombophilia marker, protein C, protein C, protein Z, prothrombin fragment 1 + 2, thrombin-antithrombin III complex (TAT)

General laboratoryware IVDs

L1CT (Class 1 IVDs)	**CT945 General laboratoryware IVDs** Laboratoryware such as general reagents, laboratory products, consumables, biological stains, antimicrobial identification tests and antimicrobial susceptibility tests that are intended to be used specifically as an IVD in the testing of clinical specimens within any discipline of a pathology laboratory. All analytes as represented in Level 2 and Level 3 general laboratoryware collective terms.
L2CT (Class 2 IVDs)	**CT1260 Antimicrobial susceptibility testing IVDs** IVDs that are intended to be used in testing to determine the antimicrobial susceptibility profile of microorganisms such as bacteria, yeast or fungi against a range of individual antimicrobial agents. All analytes as represented in Level 3 Antimicrobial minimum inhibitory concentration and susceptibility testing disc collective terms.
L3CT (Class 3 IVDs)	**CT750 Antimicrobial minimum inhibitory concentration IVDs** IVDs that are graduated test strips or similar, containing specified concentrations of an antimicrobial agent and that are intended to be used to determine the minimum inhibitory concentration of the antimicrobial for a particular microorganism. Multiple antifungal MIC; Multiple antimicrobial MIC; Multiple antimycobacterial MIC; The following individual minimum inhibitory concentration antimicrobials: Amikacin, Amoxycillin, Amoxycillin/clavulanic acid, Amphotericin B, Ampicillin, Ampicillin/sulbactam, Anidulafungin, Azithromycin, Aztreonam, Bacitracin, Benzylpenicillin, Caspofungin, Cefaclor, Cefepime, Cefepime/cefepime + clavulanic acid, Cefixime, Cefoperazone, Cefoperazone/sulbactam, Cefotaxime, Cefotaxime/cefotaxime + clavulinic acid, Cefotetan, Cefotetan/cefotetan + cloxacillin, Cefoxitin, Cefpirome, Cefpodoxime, Ceftazidime, Ceftazidime/ceftazidime + clavulanic acid, Ceftizoxime, Ceftriaxone, Cefuroxime, Cephalothin, Chloramphenicol, Ciprofloxacin, Clarithromycin, Clindamycin, Colistin, Daptomycin, Doripenem, Doxycycline, Enrofloxacin, Ertapenem, Erythromycin, Ethambutol, Ethionamide, Fluconazole, Flucytosine, Fosfomycin, Fusidic acid, Gatifloxacin, Gemifloxacin, Gentamicin, Imipenem, Imipenem/imipenem + EDTA, Isonazid, Itraconazole, Kanamycin, Ketoconazole, Levofloxacin, Linezolid, Mecillinam, Meropenem, Metronidazole, Minocycline, Mupirocin, Nalidixic acid, Netilmicin, Nitrofurantoin, Norfloxacin, Ofloxacin, Oxacillin, Penicillin G, Piperacillin, Piperacillin/tazobactam, Polymixin B, Posaconazole, Quinupristin/dalfopristin, Rifampicin, Streptomycin, Spectinomycin, Sulbactam, Sulphamethoxazole, Teicoplanin, Temocillin, Tetracycline, Ticarcillin/clavulanic acid, Tigecycline, Tobramycin, Trimethoprim, Trimethoprim/sulphamethoxazole, Vancomycin, Vancomycin/Teicoplanin, Voriconazole.
L3CT (Class 3 IVDs)	**CT942 Susceptibility testing disc IVDs** IVDs that are discs, filter paper or similar, which are impregnated with a defined amount of an antimicrobial agent and that are intended to be used as an indicator of antimicrobial susceptibility by a particular microorganism. Multiple antifungal susceptibility testing discs; Multiple antimicrobials susceptibility testing discs; Multiple antimycobacterial susceptibility testing discs; The following individual antimicrobials susceptibility testing discs: Amikacin, Amoxycillin, Amoxycillin/clavulanic acid, Ampicillin, Ampicillin/sulbactam, Apramycin, Arbekacin, AZD2563, Azithromycin, Azlocillin, Aztreonam, Bacitracin, Carbenicillin, Carumonam, Cefaclor, Cefazolin, Cefadroxil, Cefamandole, Cefbuperazone, Cefdinir, Cefditoren, Cefepime, Cefetamet, Cefixime, Cefmenoxime, Cefodizime, Cefonicid, Cefminox, Cefoperazone, Cefoperazone/sulbactam, Cefotaxime, Cefotaxime/clavulanic acid, Cefotetan, Cefotiam, Cefoxitin, Cefpirome, Cefpiramide, Cefpodoxime, Cefprozil, Cefsulodin, Ceftazidime, Ceftazidime/clavulanic acid, Cefteram, Ceftibutem, Ceftiofur, Ceftizoxime, Ceftriaxone, Cefuroxime sodium, Cephalexin, Cephalothin, Cephazolin, Cephradine, Chloramphenicol, Cinoxacin, Ciprofloxacin, Clarithromycin, Clindamycin, Cloxacillin, Colimycin, Colistin sulphate, Compound sulphonamides, Danofloxacin, Daptomycin, Dibekacin, Doxycycline, Enrofloxacin, Ertapenem, Erythromycin, Ethambutol, Ethionamide, Faropenem sodium, Fleroxacin, Flomoxef, Florfenicol, Flucloxacillin, Fluconazole, Flumequine, Fosfomycin, Fosfomycin/trometamol, Framycetin, Furazolidone, Fusidic acid, Gatifloxacin, Gentamicin, Grepafloxacin hydrochloride, Imipenem, Isepamycin sulfate, Isoniazid, Josamycin, Kanamycin, Latamoxef, Levofloxacin, Lincomycin, Lincomycin/neomycin, Lincomycin/spectinomycin, Linezolid, Lomefloxacin, Loracarbef, Mecillinam, Meropenem, Methicillin, Metronidazole, Mezlocillin, Minocycline, Moxalactam, Moxifloxacin, Mupirocin, Nafcillin, Nalidixic acid, Neomycin sulfate, Netilmicin, Nitrofurantoin, Nitrofurantoin/sulfadiazine, Nitroxolin,

	Norfloxacin, Novobiocin, Nystatin, Ofloxacin, Oleandomycin, Oxacillin, Oxolinic acid, Oxytetracycline, Panipenem, Perfloxacin, Penicillin G, Penicillin/novobiocin, Pipemidic acid, Piperacillin, Piperacillin/tazobactam, Pirlimycin, Polymixin B, Premafloxacin, Pristinamycin, Quinupristin/dalfopristin, Rifampicin, Rokitamycin, Roxithromycin, Salicylic acid, Sanfetrinem, Sarafloxacin, Sisomicin, Sparfloxacin, Spiramycin, Spectinomycin, Streptomycin, Sulbactam/ampicillin, Sulbactam/mezlocillin, Sulbactam/piperocillin, Sulphafurazole, Sulphamethoxazole, Sulphamethoxazole/trimethoprim, Sulphonamides compound, Teicoplanin, Telithromycin, Temocillin, Tetracycline, Ticarcillin, Ticarcillin/clavulanic acid, Tigecycline, Tobramycin, Tosulfloxacin, Trimethoprim, Trimethoprim/sulphamethoxazole, Tilmicosin, Vancomycin, Voriconazole.
L2CT (Class 2 & 3 IVDs)	**CT215 Biological stain IVDs** Dyes, chemicals, stains or solutions that are intended to be used specifically as an IVD, either alone or in combination with others, for the visualisation of structures and/or other intra/extracellular elements in biological tissues. Aceto-carmine solution, Aceto-orcein solution, Acetyl cholinesterase, Acid Fast Bacteria (AFB) stain, Acridine Orange solution, Albert's stain, Albert's solution, Alcian blue - Periodic Acid Shiff's (PAS) (PAB) stain, Alcian blue stain, Alcian yellow stain, Alcian blue solution, Aldehyde Fuchsin solution, Alizarin Red S solution, Amylase (diastase) solution, Ammoniacal Silver solution, Aniline blue solution, Armand stain solution, Auramine-Rhodamine stain, Auramine-Rhodamine solution, Azan solution, Azocarmine solution, Azure B solution, Biebrich Scarlet solution, Biebrich Scarlet-Acid Fuchsin solution, Bismarck Brown Y solution, Bluing solution, Boric Acid - borate buffer solution, Borax solution, Brilliant Cresyl Blue solution, Brilliant green solution, Bromcresol purple solution, Bromthymol blue solution, Calcofluor white stain, Carbol Fuchsin solution, Colloidal iron solution, Combined Eosinophil/Mast Cell Stain (CEM) stain, Congo red stain, Congo red solution, Cresyl Violet Acetate solution, Crystal Violet solution, Decolourising solution, Differentiation solution, Elastic stain, Eosin Y solution, Eosin Y-Phloxine B solution, Fast Green solution, Ferric Ammonium sulfate solution, Ferric chloride solution, Feulgen stain, Field's Stain solution, Fuchsin (acid) solution, Fuchsin (basic) solution, Gentian violet solution, Giemsa stain solution, Gold chloride solution, Gram stain, Gridley's (amoeba) stain, Gridley's (fungi) stain, Grocott's Methenamine Silver (GMS) stain, Hematoxylin & Eosin (H&E) stain, Hematoxylin & Eosin (H&E) (one-step) solution, Hematoxylin solution, Hematoxylin substitute solution, Indian ink solution, Iodine solution, Iron stain, Jenner stain solution, Jones' Basement Membrane stain, Kleihauer stain, Lactate dehydrogenase, Lactophenol cotton blue stain solution, Leishman's stain solution, Light green solution, Light green SF Yellowish solution, Lipid stain, Luxol fast blue stain, Luxol fast blue solution, Malachite green solution, Masson-Fontana stain, Martius Scarlet Blue (MSB) stain, May-Grünwald stain solution, Metanil yellow solution, Methenamine solution, Methyl blue solution, Methyl green solution, Methyl green-Pyronin Y solution, Methyl orange solution, Methylene blue solution, Mucicarmine stain, New methylene blue solution, Mucicarmine solution, Nuclear fast red solution, Neutral red solution, Nigrosin solution, Nile Blue A solution, Oil Red O solution, Orange G solution, Orcein solution, Papanicolaou (Pap) stain, Papanicolaou Eosin Azure 36 (EA-36) solution, Papanicolaou Eosin Azure 50 (EA-50) solution, Papanicolaou Eosin Azure 65 (EA-65) solution, Papanicolaou Orange G 6 (OG-6) solution, Periodic Acid Schiff's PAS stain, Periodic Acid solution, Phenol red solution, Phosphate Buffer (Sorenson's buffer) solution, Phosphotungstic Acid Hematoxylin (PTAH) stain, Phosphotungstic Acid Hematoxylin (PTAH) solution, Picric Acid Acetone solution, Picro-Sirius Red solution, Potassium ferrocyanide solution, Potassium permanganate solution, Quinacrine stain, Reticulin stain, Romanowsky stain, Ryu's Flagella stain solution, Saffron solution, Safranin O solution, Schiff's solution, Schmorl stain, Shorr's stain solution, Silver sulphate solution, Silver nitrate solution, Sodium Bisulfate solution, Sodium Thiosulfite solution, Spirochete stain, Succinic dehydrogenase, Sudan III solution, Sudan IV solution, Sudan black solution, Tartrate resistant acid phosphatase (TRAP) stain, Tartrazine solution, Toluidine blue O solution, Trichrome (Gomori) stain, Trichrome (Gomori's blue) solution, Trichrome (Gomori's green) solution, Trichrome (Masson) stain, Trichrome (Wheatley's Modified) stain, Trichrome (Wheatley's Modified) solution, Trichrome Blue/Ryan Blue stain, Trichrome Blue/Ryan Blue solution, Triphenol tetrazolium chloride (TTC) solution, Tyrosinase, Van Gieson stain, Van Gieson's solution, Von Kossa stain, Wright-Giemsa stain solution, Wright's stain solution.
L2CT (Class 2 & 3 IVDs)	**CT946 General laboratory reagent and consumables IVDs** IVDs that are general laboratory reagents, products or consumables, that are intended to be used specifically as an IVD in the testing of specimens within a clinical laboratory. Acetone solution, Acid-alcohol solution, Atmospheric generation kit, Atmospheric carbon dioxide (CO2) generation, Atmospheric anaerobic (AnO2) generation, Antimicrobial sensitivity disc dispenser, ph adjusted buffer, Wash solution buffer, Diluent buffer, Cell culture line, Citrate reagent, Complement protein reagent, Dithiothriotol (DTT) reagent, Human

	Immunoglobulin G (IgG) conjugate antibody (Caprine) reagent, Human Immunoglobulin M (IgM) conjugate antibody (Caprine) reagent, Human Immunoglobulin A (IgA) conjugate antibody (Caprine) reagent, Human Immunoglobulin G (IgG), Immunoglobulin M (IgM) and Immunoglobulin A (IgA) conjugate antibody (Caprine) reagent, Human Immunoglobulin G (IgG) conjugate antibody (Murine) reagent, Human Immunoglobulin M (IgM) conjugate antibody (Murine) reagent, Human Immunoglobulin A (IgA) conjugate antibody (Murine) reagent, Human Immunoglobulin G (IgG), Immunoglobulin M (IgM) and Immunoglobulin A (IgA) conjugate antibody (Murine) reagent, Immunoglobulin removal (adsorbent/absorbent) reagent, Inoculating loop, Isotonic saline reagent, Microscope counting chamber, Microscope slide, Microscopy mounting fluid, Mycobacteria specimen digestion/decontamination reagent, Nucleic acid extraction/isolation, Specimen preparation enzyme, Phosphoric acid (stop solution) reagent, Tetramethylbenzidine/hydrogen peroxide (TMB) substrate reagent, Toluene reagent, Xylene reagent, Xylene substitute reagent.
L2CT (Class 2 & 3 IVDs)	**CT1261 Microbial-isolate identification and testing IVDs** IVDs that are intended to be used in testing to provide information about the specific in vitro characteristics and/or identification of microorganisms including bacteria, yeast, fungi, viruses and parasites that have been isolated from a clinical specimen. Adonitol carbohydrate utilisation; Anaerobic microorganism DD (diagnostic disc); Anaerobic microorganism identification; Arabinose carbohydrate utilisation; Bacitracin DD; Beta-haemolytic (BH) Streptococcus serological (Lancefield) grouping kit; BH Streptococcus group A agglutination reagent, BH Streptococcus group B agglutination reagent, BH Streptococcus group C agglutination reagent, BH Streptococcus group D agglutination reagent, BH Streptococcus group F agglutination reagent, BH Streptococcus group G agglutination reagent, Beta-lactamase production, Bile esculin DD, Bile solubility, Catalase production, Cefinase DD, Cefoxitin DD, Coagulase production, Dextrose carbohydrate utilisation, DNase production, DMACA spot indole, Dulcitol carbohydrate utilisation, Galactose carbohydrate utilisation, Hippurate reagent, Indole (Kovac's) reagent, Indole DD, Indole broth (peptone water), Inositol carbohydrate utilisation, Lactose carbohydrate utilisation, Maltose carbohydrate utilisation, Mannitol carbohydrate utilisation, Metronidazole DD, Nitrate reduction, Novobiocin DD, ONPG (ortho-Nitrophenyl-β-galactoside) DD, Optochin (ethylhydrocupreine) DD, Oxidase production, PYR (L-pyrrolidonyl-ß-naphthylamide) reagent, Raffinose carbohydrate utilisation, Rhamnose carbohydrate utilisation, Sorbitol carbohydrate utilisation, Spectinomycin DD, SPS DD, Sucrose carbohydrate utilisation, Sulphonamide DD, TDA, Trehalose carbohydrate utilisation, Tributyrin hydolysis, Urea DD, Vibrio 0129 DD, Voges-Proskauer, X-factor DD, V-factor DD, X+V-factor DD.
L3CT (Class 3 IVDs)	**CT839 Organism identification and antimicrobial susceptibility testing IVDs** IVDs that are intended to be used in testing to provide information about the identification of a microorganism culture isolate and its antimicrobial susceptibility profile. Gram negative bacteria species culture isolate identification and antimicrobial susceptibility, Gram positive bacteria species culture isolate identification and antimicrobial susceptibility, Haemophilus or Neisseria bacteria species culture isolate identification and antimicrobial susceptibility, Staphylococcus aureus culture isolate identification and methicillin susceptibility, Streptococcus bacteria species culture isolate identification and antimicrobial susceptibility, Yeast species culture isolate identification and antimicrobial susceptibility.

Haematology IVDs

L1CT (Class 1 IVDs)	**CT292 Haematology IVDs** IVDs that are intended to be used in testing to provide haematological information about characteristics of the cellular components of whole blood, including qualitative and/or quantitative information about white cells, red cells, platelets, haemoglobin, cellular metabolic enzymes and red cell membrane integrity. Chloroacetate esterase (CAE), copper sulphate solution, Donath-Landsteiner antibody IVD, erythrocyte sedimentation rate (ESR), foeto-maternal haemorrhage/Kleihauer test, full blood count, glucose/haemoglobin (Hb), glycated haemoglobin (HbA1c), haemoglobin A2 (HbA2), haemoglobin B2 (HbB2), haemoglobin C (HbC), haemoglobin D (HbD), haemoglobin E (HbE), haemoglobin F (HbF), haemoglobin H (HbH), haemoglobin S (HbS), Ham's acid red cell test, leukocyte alkaline phosphatase, leukocyte myeloperoxidase (MPO), methaemalbumin, multiple blood gas/haemoximetry/electrolyte analyte, multiple haemoglobin subtype, non-blood cell primer/calibrator/control material, non-specific esterase (NSE), platelet count, red blood cell count, red cell 2,3-diphosphoglycerate (2,3DPG), red cell adenylate kinase (AK), red cell glucose phosphate isomerase (GPI), red cell glucose-6-phosphate dehydrogenase (G6PD), red cell hexokinase, red cell plasmalogen, red cell pyruvate kinase (PK), red cell triose phosphate isomerase (TPI), reticulocyte count, reticulocyte haemoglobin content (CHr), sucrose red cell lysis, total haemoglobin (totHb), white blood cell count.
L2CT (Class 2 & 3 IVDs)	**CT879 Haematology calibrator/control IVDs** IVDs that are intended to be used in testing to establish known points of reference and/or verify the performance of haematological assays. Full blood count calibrator and control, glucose/haemoglobin (Hb) calibrator and control, haemoglobin A2 (HbA2) calibrator and control, haemoglobin B2 (HbB2) calibrator and control, haemoglobin C (HbC) calibrator and control, haemoglobin D (HbD) calibrator and control, haemoglobin E (HbE) calibrator and control, haemoglobin F (HbF) calibrator and control, haemoglobin H (HbH) calibrator and control, haemoglobin S (HbS) calibrator and control, multiple blood gas/haemoximetry/electrolyte analyte calibrator and control, multiple haemoglobin subtype calibrator and control, non-blood cell primer/calibrator/control material, platelet count calibrator and control, red blood cell count calibrator and control, reticulocyte calibrator and control, total haemoglobin (totHb) calibrator, control and reagent, white blood cell count calibrator and control.
L2CT (Class 2 & 3 IVDs)	**CT878 Haematology full blood count IVDs** IVDs that are intended to be used for the qualitative and/or quantitative haematological determination of measured and/or calculated whole blood cell parameters. Full blood count, platelet, red blood cell count, reticulocyte count, white blood cell count.
L2CT (Class 2 & 3 IVDs)	**CT1249 Haematology-related IVDs** IVDs that are intended to be used alone or in combination with other IVDs to perform various haematology-related tests and procedures [e.g. erythrocyte sedimentation rate (ESR), plasma viscosity tests, feto-maternal haemorrhage detection tests (Kleihauer tests)]. Copper sulphate solution, Donath-Landsteiner antibody, erythrocyte sedimentation rate (ESR), foeto-maternal haemorrhage/Kleihauer test
L2CT (Class 2 & 3 IVDs)	**CT880 Haemoglobin IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of haemoglobin and the various subtypes of haemoglobin in a clinical specimen. Glucose/haemoglobin (Hb), haemoglobin A2 (HbA2), haemoglobin B2 (HbB2), haemoglobin C (HbC), haemoglobin D (HbD), haemoglobin E (HbE), haemoglobin F (HbF), haemoglobin H (HbH), haemoglobin S (HbS), multiple blood gas/haemoximetry/electrolyte analyte, multiple haemoglobin subtype, reticulocyte haemoglobin content (CHr), total haemoglobin (totHb).
L2CT (Class 2 IVDs)	**CT881 Red and white cell metabolic enzyme and haemolysis IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of white and red cell metabolic enzymes and cellular membrane integrity in a clinical specimen. Chloroacetate esterase (CAE), Ham's acid red cell test, leukocyte alkaline phosphatase, leukocyte myeloperoxidase (MPO), methaemalbumin, non-specific esterase (NSE), red cell 2,3-diphosphoglycerate (2,3DPG), red cell adenylate kinase (AK), red cell glucose phosphate isomerase (GPI), red cell glucose-6-phosphate dehydrogenase (G6PD), red cell hexokinase, red cell plasmalogen, red cell pyruvate kinase (PK), red cell triose phosphate isomerase (TPI), sucrose red cell lysis.
L3CT (Class 3 IVDs)	**CT882 Red cell membrane and haemolysis IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of red blood cell membrane integrity and osmotic resistance of red blood cells. Ham's acid red cell test, methaemalbumin, red cell plasmalogen, sucrose red cell lysis.
L3CT (Class	**CT285 Red cell metabolic enzyme IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination

3 IVDs)	of enzymes associated with red cell metabolic processes. Red cell 2,3-diphosphoglycerate (2,3DPG), red cell adenylate kinase (AK), red cell glucose phosphate isomerase (GPI), red cell glucose-6-phosphate dehydrogenase (G6PD), red cell hexokinase, red cell pyruvate kinase (PK), red cell triose phosphate isomerase (TPI).
L3CT (Class 3 IVDs)	**CT883 White cell metabolic enzyme IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of enzymes associated with white cell metabolic processes. Chloroacetate esterase (CAE), leukocyte alkaline phosphatase, leukocyte myeloperoxidase (MPO), non-specific esterase (NSE).

Histology and cytology IVDs

L1CT (Class 1 IVDs)	**CT901 Histology & Cytology IVDs** IVDs that are intended to be used in histology and cytology to provide information about tissue, cell markers and other cellular structures, and their localisation and distribution in clinical tissue sections or cytological smears. All analytes as represented in Level 2 and Level 3 Histology and Cytology collective terms.
L2CT (Class 2 & 3 IVDs)	**CT907 Histology and Cytology ancillary IVDs** IVDs that are intended to be used alone or in combination with other IVDs to perform various histology and cytology-related tests and procedures (e.g. tissue processing solutions, resins, enhancing reagents). Acrylic resin embedding medium, acrylic resin embedding kit, B-5 solution, B-5 substitute solution, Bouin's solution, Bouin's substitute solution, Carnoy's solution, modified Carnoy's solution, celloidin embedding medium, cytology fixative spray, ethyl alcohol blended solution, 95% ethyl alcohol blended solution, 80% ethyl alcohol blended solution, 70% ethyl alcohol blended solution, epoxy resin embedding medium, epoxy resin embedding kit, 37% formaldehyde solution, 16% formaldehyde solution, 10% formaldehyde solution, formalin substitute solution, frozen tissue fixative, glutaraldehyde solution, glycol methacrylate (GMA) resin embedding medium, glycol methacrylate (GMA) resin embedding kit, Hartmann's solution, Hollande's solution, hydroxypropyl methacrylate (HPMA) resin embedding medium, hydroxypropyl methacrylate (HPMA) resin embedding kit, immunohistochemistry antibody detection kit, immunohistochemistry antibody diluent, immunohistochemistry chromogenic substrate, immunohistochemistry endogenous avidin-biotin dual blocking, immunohistochemistry endogenous enzyme blocking, immunohistochemistry endogenous biotin blocking, Immunohistochemistry endogenous protein blocking, immunohistochemistry negative control (animal immunoglobulin), immunohistochemistry negative control (normal animal serum), immunohistochemistry protease, immunohistochemistry secondary (conjugated) antibody, immunohistochemistry secondary (unconjugated) antibody, immunohistochemistry signal amplification, immunohistochemistry streptavidin-enzyme conjugate, immunohistochemistry wash buffer, immunohistochemistry decalcifying solution, isopropyl alcohol (isopropanol) solution, McDowell Trumps solution, methyl alcohol (methanol) solution, Michel's solution, 10% non-buffered formalin, 10% neutral buffered formalin, 10% neutral buffered formalin with wintergreen scent, 10% neutral buffered formalin, 10% neutral buffered formalin (zinc) with 0.03% eosin, 10% non-buffered formalin (zinc), 10% neutral buffered formalin (alcoholic), 20% neutral buffered formalin, 20% neutral buffered formalin (alcoholic), 10% neutral buffered formalin (alcoholic zinc), paraffin-based embedding medium, paraformaldehyde solution, 100% reagent grade alcohol solution, 95% reagent grade alcohol solution, 80% reagent grade alcohol solution, 70% reagent grade alcohol solution, 50% reagent grade alcohol solution, Russel's modified Zenker's solution, saccamanno solution, tissue freezing/embedding medium, Trump's solution, Zenker's solution.
L2CT (Class 2 & 3 IVDs)	**CT1056 Immunohistology cell marker IVDs** IVDs that are intended to be used in histology and cytology to provide information about the presence and localisation of specific proteins and antigens present in histological tissue sections, cytological smears and fluids A/B transferase enzyme, prostatic acid phosphatase (PAP), tartrate resistant acid phosphatase (TRAP), human placental alkaline phosphatase (hPLAP), acetyl cholinesterase, adrenocorticotrophin hormone (ACTH), albumin, alpha-1-antichymotrypsin, alpha-foetoprotein (AFP), alpha-naphthyl acetate esterase (ANAE), amyloid A component, amyloid B component, amyloid P component, anaplastic lymphoma kinase, androgen receptor, basal cell cocktail, Bax protein, B-cell specific activator protein (BSAP), B lymphocyte, Bcl-2 oncoprotein, Bcl-6 protein, Bcl-10 protein, Bcl-X protein, beta-2-microglobulin, BRCA1 protein, breast carcinoma antigen 225 (BCA-225), bromodeoxyuridine (BrdU) nucleoside, E-cadherin epithelial marker, N-cadherin neuronal cell marker, calcitonin, caldesmon protein, calponin protein, calretinin protein, cancer antigen 15-3 (CA15-3), cancer antigen 19-9 (CA19-9), cancer antigen 125 (CA125), cancer antigen 130 (CA130), carcinoembryonic antigen (CEA), caspase-3, cathepsin-D protease, alpha-catenin, beta-catenin, multiple CD cell marker, CD1a cell marker, CD2 T cell marker, CD3 cell marker, CD4 cell marker, CD5 cell marker, CD6 cell marker, CD7 cell marker, CD8 cell marker, CD10 cell marker, CD11b cell marker, CD11c cell marker, CD13 cell marker, CD14 cell marker, CD15 cell marker, CD16 cell marker, CD19 cell marker, CD20 cell marker, CD21 cell marker, CD22 cell marker, CD23 cell marker, CD25 cell marker, CD27 cell marker, CD28 cell marker, CD30 cell marker, CD31 endothelial cell marker, CD33 cell marker, CD34 cell marker, CD35 follicular dendritic reticulum cell marker, CD38 cell marker, CD41 cell marker, CD42b cell marker, CD43 cell marker, CD44 cell marker, CD45 leukocyte common antigen cell marker, CD45RA cell marker, CD45RO cell marker, CD54 Intercellular adhesion molecule-1 (ICAM-1), CD55 red cell antigen, CD56 neural cell adhesion molecule-1

	(NCAM-1), CD57 natural killer cell marker, CD59 red cell antigen, CD61 platelet glycoprotein IIIa marker, CD64 cell marker, CD66 cell marker, CD68 cell marker, CD69 cell marker, CD71 cell marker, CD74 cell marker, CD79a cell marker, CD79b cell marker, CD86 cell marker, CD90 cell marker, CD95 cell marker, CD99 cell marker, CD103 cell marker, CD105 endoglin marker, CD117 (c-kit) cell marker, CD138 cell marker, CD141 cell marker, CD235a glycophorin A red blood cell marker, CD236R glycophorin C red blood cell marker, CDw74 LN2 cell marker, CDw75 LN1 cell marker, C-erbB2/Her2/neu oncoprotein, chromogranin A, coagulation factor VIII-associated antigen, collagen type IV, complement cascade component C1q, complement cascade components C3/C3c, complement cascade components C4/C4c, Cox-2, cyclin D1, cystatin C, pan cytokeratin antibody cocktail, multiple high molecular weight (HMW) cytokeratin filaments, multiple low molecular weight (LMW) cytokeratin filaments, cytokeratin subtypes CK5/CK6, cytokeratin subtypes CK5/CK6/CK18, Cytokeratin subtypes CK8/CK18, cytokeratin subtypes CK10/CK13, cytokeratin subtype CK5, cytokeratin subtype CK6, cytokeratin subtype CK7, cytokeratin subtype CK8, cytokeratin subtype CK10, cytokeratin subtype CK14, cytokeratin subtype CK15, cytokeratin subtype CK16, cytokeratin subtype CK17, cytokeratin subtype CK18, cytokeratin subtype CK19, cytokeratin subtype CK20, D2-40 mesothelial marker, desmin protein, elastin, epidermal growth factor receptor (EGFR), epithelial antigen, epithelial membrane antigen (EMA), epithelial specific antigen (ESA), estrogen (oestrogen)/progesterone receptor, fascin, fibrinogen (Factor I) assay, fibronectin, follicle stimulating hormone (FSH), follicular dentritic cell, galectin-3, gastric mucin, gastrin, glial fibrillary acidic protein (GFAP), glucagon, alpha-glutathione S-transferase (alphaGST), pi-glutathione S-transferase (piGST), granulocyte, granzyme B, gross cystic disease fluid protein-15 (BRST-2), hairy cell leukaemia (HCL) cell marker, HAM56 (macrophage marker), haemoglobin detection, hepatocyte specific antigen, Her2-pY 1248 phosphorylation site, Her3 protein, HLA class I antigen tissue typing, HLA class II antigen tissue typing, HLA-DR (LN3) antigen tissue typing, total human chorionic gonadotropin (HCG), human chorionic gonadotropin beta-subunit (β-HCG), human growth hormone (HGH), human placental lactogen (HPL), human immunoglobulin antibody, total IgA, total IgD, total IgE, total IgG, total IgM, kappa/lambda light chain messenger RNA, kappa/lambda light chain immunoglobulin, inhibin A, inhibin B, insulin, Intestine specific transcription factor Cdx2, Ki67 antigen, L523S protein, lactate dehydrogenase, lactoferrin, laminin, L-fucose-binding Ulex Europaeus lectin, linker for activation of T cells (LAT) protein, luteinising hormone (LH), lysozyme (muramidase), macrophage detection, MAGE-C1 (melanoma antigen family C,1)MAGE-Melan-A/MART-1 peptideC1 (melanoma antigen family C,1), mammaglobin, mast cell tryptase, matrix metalloproteinase 9 (MMP-9), MCM3 protein, melanoma specific protein, melanosome, mesothelial cell, metallothionein, microphthalmia-associated transcription factor (MITF), MLH1 antigen, MSH2 antigen, MSH6 antigen, mucin, MUM1 transcription factor, muscle specific alpha/gamma actin, myelin basic protein, myeloid/histiocyte antigen, leukocyte myeloperoxidase (MPO), myogenin, myo-D1 protein rhabdomyosarcoma marker, myoglobin, nerve growth factor receptor p75, neuroblastoma antigen, neurofilament protein, neuron specific enolase, neutrophil elastase, oncogene protein p21(ras), p16 antigen, p27 antigen, p501s, p504s, p53 tumour protein, placental growth factor (PLGF), plasma cell, PMS-2 protein, prealbumin (transthyretin), progesterone receptor, prolactin, proliferating cell nuclear antigen (PCNA), multiple prostatic intraepithelial neoplasia markers, membrane bound prostate specific antigen (PSA), protein gene product 9.5 (PGP9.5), PTEN protein, renal cell carcinoma antigen, S100-beta (S100-β) protein, secretin, serotonin, smooth muscle actin, skeletal muscle myosin, smooth muscle myosin, somatostatin, spectrin, succinic dehydrogenase, surfactant apoprotein A, surfactant apoprotein B, surfactant protein D, survivin protein, synaptophysin, T-lymphocyte, T-cell intracytoplasmic antigen (TIA-1), tau protein, terminal deoxynucleotidyl transferase (TdT), thrombomodulin, thymidilate synthase, thyroglobulin, thyroid peroxidase (TPO), thyroid stimulating hormone (TSH), thyroid transcription factor-1 (TTF1), topoisomerase IIa, transferrin, tryptase, tumour associated glycoprotein-72 (TAG72), tyrosinase, ubiquitin, urokinase plasminogen activator receptor (uPAR), vascular endothelial growth factor (VEGF), villin, vimentin, Wilms' tumor (WT1) protein, zeta chain associated protein kinase 70 (ZAP-70).
L3CT (Class 3 IVDs)	**CT1238 Acid phosphatase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of acid phosphatase enzyme and its various forms in a clinical specimen. Prostatic acid phosphatase (PAP), tartrate resistant acid phosphatase (TRAP). Collective term CT1238 Acid phospatase IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT828 Alkaline phosphatase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of alkaline phosphatase enzyme and its various forms in a clinical specimen. Human placental alkaline phosphatase (hPLAP).

	Collective term CT828 Alkaline phospatase IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT915 CD cell marker (cluster of differentiation) IVDs** IVDs that are intended to be used in histology and cytology to provide information about the presence and localisation of cell markers, collectively referred to as CD markers (cluster of differentiation) present on the surface of leukocytes. Multiple CD cell marker, CD1a cell marker, CD2 T cell marker, CD3 cell marker, CD4 cell marker, CD5 cell marker, CD6 cell marker, CD7 cell marker, CD8 cell marker, CD10 cell marker, CD11b cell marker, CD11c cell marker, CD13 cell marker, CD14 cell marker, CD15 cell marker, CD16 cell marker, CD19 cell marker, CD20 cell marker, CD21 cell marker, CD22 cell marker, CD23 cell marker, CD25 cell marker, CD27 cell marker, CD28 cell marker, CD30 cell marker, CD31 endothelial cell marker, CD33 cell marker, CD34 cell marker, CD35 follicular dendritic reticulum cell marker, CD38 cell marker, CD41 cell marker, CD42b cell marker, CD43 cell marker, CD44 cell marker, CD45 leukocyte common antigen cell marker, CD45RA cell marker, CD45RO cell marker, CD54 Intercellular adhesion molecule-1 (ICAM-1), CD55 red cell antigen, CD56 neural cell adhesion molecule-1 (NCAM-1), CD57 natural killer cell marker, CD59 red cell antigen, CD61 platelet glycoprotein IIIa marker, CD64 cell marker, CD66 cell marker, CD68 cell marker, CD69 cell marker, CD71 cell marker, CD74 cell marker, CD79a cell marker, CD79b cell marker, CD86 cell marker, CD90 cell marker, CD95 cell marker, CD99 cell marker, CD103 cell marker, CD105 endoglin marker, CD117 (c-kit) cell marker, CD138 cell marker, CD141 cell marker, CD235a glycophorin A red blood cell marker, CD236R glycophorin C red blood cell marker, CDw74 LN2 cell marker, CDw75 LN1 cell marker.
L3CT (Class 3 IVDs)	**CT884 Collagen IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of collagen protein and its various forms in a clinical specimen. Collagen type IV. Collective term CT884 Collagen IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT844 Complement IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of complement proteins in a clinical specimen. Complement cascade component C1q, complement cascade components C3/C3c, complement cascade components C4/C4c. Collective term CT844 Complement IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT909 Cytokeratin profile IVDs** IVDs that are intended to be used in histology and cytology to provide information about cytokeratin filament proteins and the various subtypes expressed by cells in histological tissue sections or cytological smears. Pan cytokeratin antibody cocktail, multiple high molecular weight (HMW) cytokeratin filaments, multiple low molecular weight (LMW) cytokeratin filaments, cytokeratin subtypes CK5/CK6, cytokeratin subtypes CK5/CK6/CK18, Cytokeratin subtypes CK8/CK18, cytokeratin subtypes CK10/CK13, cytokeratin subtype CK5, cytokeratin subtype CK6, cytokeratin subtype CK7, cytokeratin subtype CK8, cytokeratin subtype CK10, cytokeratin subtype CK14, cytokeratin subtype CK15, cytokeratin subtype CK16, cytokeratin subtype CK17, cytokeratin subtype CK18, cytokeratin subtype CK19, cytokeratin subtype CK20.
L3CT (Class 3 IVDs)	**CT852 Estrogen (Oestrogen) IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of estrogen (oestrogen) hormones in a clinical specimen. Estrogen (oestrogen)/progesterone receptor. Collective term CT852 Estrogen (oestrogen) IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT1054 Glutathione S-transferase IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of glutathione S-transferase enzyme and its various forms in a clinical specimen. Alpha-glutathione S-transferase (alphaGST), pi-glutathione S-transferase (piGST).
L3CT	**CT856 Human chorionic gonadotropin (HCG) IVDs**

(Class 3 IVDs)	IVDs that are intended to be used for the qualitative and/or quantitative determination of Human chorionic gonadotropin (HCG) hormone and its various forms in a clinical specimen. Total human chorionic gonadotropin (HCG), Human chorionic gonadotropin beta-subunit (β-HCG). Collective term CT856 Human chorionic gonadotropin (HCG) IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT843 Immunoglobulin IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of immunoglobulins in a clinical specimen Human immunoglobulin antibody, total IgA, total IgD, total IgE, total IgG, total IgM, kappa/lambda light chain messenger RNA, kappa/lambda light chain immunoglobulin. Collective term CT843 Immunoglobulin IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT892 Multiple human leukocyte antigens (HLA) typing IVDs** IVDs that are supplied together and intended to be used in combination to provide tissue typing information about multiple human leukocyte antigens (HLA) from one or multiple loci. HLA class I antigen tissue typing, HLA class II antigen tissue typing, HLA-DR (LN3) antigen tissue typing. Collective term CT892 Multiple human leukocyte antigens (HLA) typing IVDs also includes the additional analytes listed under the tissue typing thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT846 Prostate specific marker IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of prostate specific markers in a clinical specimen. Multiple prostatic intraepithelial neoplasia markers, membrane bound prostate specific antigen (PSA), p501s, p504s. Collective term CT846 Prostate specific marker IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.
L3CT (Class 3 IVDs)	**CT1008 Thyroid IVDs** IVDs that are intended to be used for the qualitative and/or quantitative determination of hormones relating to thyroid function, thyroid stimulation and thyroid uptake, in a clinical specimen. Thyroglobulin, thyroid peroxidase (TPO), thyroid transcription factor-1 (TTF1). Collective term CT1008 Thyroid IVDs also includes the additional analytes listed under the clinical chemistry thread, however only those relevant to Histology and Cytology are provided here.

Human Genetics IVDs

L1CT (Class 1 IVDs)	**CT902 Human genetics IVDs** IVDs that are intended to be used in genetic testing to provide information about inborn or inherited genetic disorders, mitochondrial disorders, constitutional chromosomal disorders and/or acquired genetic alterations.
L2CT (Class 2 & 3 IVDs)	**CT929 Acquired genetic alteration IVDs** IVDs that are intended to be used in genetic testing to provide information about acquired genetic alterations, which may include chromosomal alterations, mutations and/or alterations in gene expression, and which may be used to characterise haematological or solid tumour malignancies and/or provide prognostic information. Acute lymphoblastic leukaemia (ALL) chromosome translocations; acute myeloid leukaemia (AML) genetic mutations; B-cell lymphoma; BRAF V600E gene mutation; CD117 (c-kit) cell marker, C-erbB2/Her2/neu oncoprotein, cyclin D1 oncogene mRNA expression; desmoplastic small round cell tumor (DSRCT); epidermal growth factor receptor (EGFR) gene mutation/mRNA expression; Ewing's sarcoma; Her2/neu/erbB2 mRNA expression; ideopathic hypereosinophilic syndrome/chronic eosinophilic leukaemia; KIT D816V gene mutation; KRAS gene mutation; microsatellite instability; MYCN gene mRNA expression; NRAS gene mutation; oligodendroglioma LOH; Philadelphia chromosome/BCR-ABL transcript; polycythemia vera; T-cell lymphoma; topoisomerase type II alpha (TOP2alpha) gene mRNA expression; Wilm's tumor gene (WT1) mRNA expression.
L2CT (Class 2 & 3 IVDs)	**CT826 Constitutional chromosomal disorder IVDs** IVDs that are intended to be used in genetic testing for diagnosing, monitoring or predicting the presence of chromosomal abnormalities of a constitutional nature (ie. present in all cells of the body). Multiple aneuploidy (prenatal and postnatal screening panel); Angelman syndrome; Beckwith-Wiedemann syndrome; Cri-du-Chat syndrome; DiGeorge syndrome; Facioscapulohumeral muscular dystrophy (FSHD); Klinefelter's syndrome (47,XXY); Monosomy 1p36 syndrome; Miller-Dieker lissencephaly syndrome; Prader-Willi syndrome; Prader-Willi/Angelman syndrome; Sex chromosome; Sex determination (SRY gene); Silver-Russell syndrome; Smith-Magenis syndrome; Sotos syndrome; Trisomy 13 (Pätau syndrome); Trisomy 18 (Edward's syndrome); Trisomy 21 (Down syndrome); Turner syndrome (45,X); WAGR syndrome; William-Beuren syndrome; Wolf-Hirschhorn syndrome.
L2CT (Class 2 & 3 IVDs)	**CT906 Human genetics-related IVDs** IVDs that are intended to be used alone or in combination with other IVDs to perform various human genetics-related tests and procedures (e.g. foetal blood group genotypes, infertility status tests, donor cell engraftment studies). DNA in situ hybridisation detection; DNA-based tissue typing; Engraftment studies (post bone-marrow transplant); Foetal blood group genotyping; Infertility genotyping; Bone marrow karyotype suspension reagent; Amniotic fluid/Chorionic villus sample (CVS) karyotype suspension reagent.
L2CT (Class 2 & 3 IVDs)	**CT903 Inborn/inherited genetic disorder IVDs** IVDs that are intended to be used in genetic testing for diagnosing, monitoring or predicting the presence of monogenic or polygenic disorders that are either inborn or inherited and that are not associated with mitochondrial disease. Multiple Ashkenazi genetic conditions; Adenylosuccinase deficiency/adenylsuccinate lyase deficiency; Adrenoleukodystrophy/Adrenomyeloneuropathy (ALD/AMN); Alagille syndrome; Alpha-1-antitrypsin deficiency; Androgen insensitivity syndrome (AIS); Aniridia; Ankylosing spondylitis; Apert syndrome; Ataxia telangiectasia; Bannayan-Riley-Ruvalcaba syndrome; Barth syndrome; Bloom syndrome; Cardiovascular disease genetic risk; Canavan disease; Central core disease; Cerebral autosomal dominant arteriopathy (CADASIL); Charcot-Marie-Tooth (CMT) neuropathy (types 1, 2, 3, 4 or X-linked CMT); Choroideremia; Coeliac disease exclusion; Congenital adrenal hyperplasia; Congenital disorders of glycosylation; Congenital hypomyelinating neuropathy; Cowden syndrome; Craniosynostosis; Crouzon syndrome; Crouzonodermoskeletal syndrome; Cystic fibrosis; D-bifunctional protein deficiency; Dentatorubral-pallidoluysian atrophy (DRPLA); Denys-Drash syndrome (DDS); Diabetes insipidus; Duchenne/Becker muscular dystrophy; Emery Dreifuss muscular dystrophy; Episodic ataxia type 2 (EA2); Fabry disease; Familial Alzheimer's disease; Familial amyotrophic lateral sclerosis (FALS)/familial motor neurone disease; Familial adenomatous polyposis (FAP)/Attenuated FAP (AFAP); Familial breast/ovarian cancer; Familial combined pituitary hormone deficiency; Familial dysautonomia; Familial glucocorticoid deficiency (FGD); Familial hemiplegic migraine; Familial hyperaldosteronism type I; Familial hypercholesterolaemia; Familial lipoprotein lipase deficiency. Familial Mediterranean fever (FMF); Familial medullary thyroid carcinoma (FMTC); Familial melanoma; Familial

	paraganglioma; Familial Parkinson's disease; Fanconi anaemia; Fragile XA syndrome; Fragile XE non-specific x-linked mental retardation; Frasier syndrome; Friedreich's ataxia; Frontotemporal lobar degeneration with ubiquitin-positive inclusions (FTLD-U); Galactosaemia; Gaucher disease; Gilbert's syndrome; Hallervorden-Spatz disease; Hereditary amyloidosis; Hereditary cerebral haemorrhage with amyloidosis (Dutch type); Hereditary fructose intolerance; Hereditary haemochromatosis; Hereditary neuropathy with liability to pressure palsies (HNPP); Hereditary nonpolyposis colon cancer (HNPCC); Hereditary pancreatitis; Hereditary prion disease IVD, kit, nucleic acid; Hereditary renal cell carcinoma; Hereditary retinoblastoma; Hyperinsulinism-hyperammonemia syndrome; Hypochondroplasia/Achondroplasia; Huntington's disease; IGF2 overgrowth syndrome; Incontinentia pigmenti; Inherited dystonia; Inherited haemoglobinopathy/thalassaemia; Inherited primary open angle glaucoma; Inherited thrombophilia; Kallmann syndrome; Krabbe disease; Lesch-Nyhan syndrome; Li-Fraumeni syndrome; Loey's-Dietz syndrome; Long QT syndrome; Lowe syndrome/oculocerebrorenal syndrome; McArdle's syndrome (glycogen storage disease type V); Malignant hyperthermia; Marfan syndrome; Maturity-onset diabetes of the young (MODY); Melanesian ovalocytosis; Menkes disease; Metachromatic leukodystrophy; Methylenetetrahydrofolate reductase (MTHFR) deficiency; Mucopolysaccharidosis types I - IX; Multiple endocrine neoplasia type 1 (MEN1); Multiple endocrine neoplasia type 2 (MEN2); MYH-Associated Polyposis (MAP); Myotonia congenita; Myotonic dystrophy; Narcolepsy; Nemaline myopathy; Neurofibromatosis type 1; Neurofibromatosis type 2; Neuronal ceroid lipofuscinosis 1 (infantile onset); Neuronal ceroid lipofuscinosis 2 (late infantile onset); Neuronal ceroid lipofuscinosis 3/Batten disease (juvenile onset); Niemann-Pick Disease (SMPD1 associated); Niemann-Pick Disease (type C); Non-syndromic hearing loss and deafness (DFNB1); Norrie disease; Oculocutaneous albinism; Oculopharyngeal muscular dystrophy; Ornithine carbamoyltransferase deficiency; Periodic paralysis; Persistent hyperinsulinemic hypoglycemia of infancy (PPHI); Peutz-Jeghers syndrome; Pfeiffer sydrome; Phenylketonuria (PKU); Porphyria; Pulmonary surfactant protein B deficiency; Refsum disease (infantile form); Retinitis pigmentosa; Rett syndrome; Rheumatoid arthritis; Rhizomelic chondrodysplasia punctata type 1; Saethre-Chotzen syndrome; Sandhoff disease; SCN1A-related epilepsy; Skewed X inactivation; Spinal muscular atrophy (SMA); Spinocerebellar ataxia (SCA); Multiple tauopathies; Tay-Sachs disease; TNF-receptor associated periodic syndrome (TRAPS); von Hippel-Lindau syndrome; von Willebrand disease (type 2B); Wiskott-Aldrich syndrome; X-linked hydrocephalus; X-linked hyper-IgM sydrome; X-linked agammaglobulinemia (Bruton type); X-linked agammaglobulinemia (Bruton type); X-linked lymphoproliferative syndrome/Duncan's disease; X-linked myotubular myopathy; X-linked severe combined immunodeficiency (XSCID); X-linked spinal and bulbar muscular atrophy (Kennedy's disease); Zellweger syndrome.
L2CT (Class 2 & 3 IVDs)	**CT905 Mitochondrial genetic disorder IVDs** IVDs that are intended to be used in genetic testing for diagnosing, monitoring or predicting the presence of mitochondrial disorders, which are genetic diseases affecting the function of the mitochondria caused by mutations in mitochondrial DNA (mtDNA) or nuclear DNA that encodes for mitochondrial components. Carnitine palmitoyltransferase II deficiency; Kearns-Sayre syndrome; Leber's hereditary optic neuropathy (LHON); Leigh's sydrome; Long-chain 3-hydroxyacyl-coenzyme A dehydrogenase (LCHAD) deficiency; Medium-chain acyl-CoA dehydrogenase (MCAD) deficiency; Mitochondrial encephalomyopathy, lactic acidosis and stroke-like episodes (MELAS); Myoclonic epilepsy associated with ragged red fibers (MERRF); Neuropathy, ataxia and retinitis pigmentosa (NARP); Pearson's syndrome; POLG-associated mitochondrial disorder; Short-chain acyl-CoA dehydrogenase (SCAD) deficiency.
L2CT (Class 2 & 3 IVDs)	**CT918 Pharmacogenetic IVDs** IVDs that are intended to be used in genetic testing to assist in predicting an individuals response to exposure to xenobiotics/drugs based on their genetic makeup. Cytochrome P450 (CYP450) gene polymorphism; Suxamethonium sensitivity/scoline apnoea (butyrylcholinesterase); Thiopurine S-methyltransferase (TPMT) gene polymorphism; Uridine diphosphate-glucuronyltransferase 1A1 (UGT1A1) gene polymorphism; Vitamin K epoxide reductase complex subunit-1 (VKORC1) gene polymorphism.

Immunohaematology (blood banking) IVDs

L1CT (Class 1 IVDs)	**CT885 Immunohaematology (blood banking) IVDs** IVDs that are intended to be used in testing to provide information about blood groups, red cell antigens, red cell antibodies and to determine compatibility of blood or blood components for transfusion. All analytes as represented in Level 2 Immunohaematology (blood banking) collective terms.
L2CT (Class 2, 3 IVDs; Class 4 IHRs)	**CT887 Immunohaematology blood grouping antisera IVDs** Immunoglobulins capable of binding to specific red blood cell antigens and intended to be used in immunohaematological testing to provide information about red blood cell antigen phenotypes. Anti-A, anti-A1, anti-AB, anti-An^a, anti-AnWj (Anton), anti-At^a, anti-Au^a, anti-Au^b, anti-B, anti-Be^a, anti-Bg^a, anti-Bg^b, anti-Bg^c, anti-Bp^a, anti-By, anti-C, anti-c, anti-C^w, anti-C^x, anti CDE, anti-Ce, anti-cE, anti-Ch^a, anti-Co^a, anti-Cr^a, anti-Cs^a, anti-Dantu, anti-Di^a, anti-Di^b, anti-Do^a, anti-Do^b, anti-Dr^a, anti-E, anti-e, anti-ELO, anti-Emm, anti-En^a, anti-Er^a, anti-f, anti-Fy^a, anti-Fy^b, anti-Fy3, anti-G, anti-Ge2, anti-Ge3, anti-Go^a, anti-Gy^a, anti-H, anti-He, anti-Hg^a, anti-hr^B, anti-hr^S, anti-Hr-o, anti-Hut/anti-Mur red blood cell grouping, anti-Hy, anti-In^b, anti-Jk^a, anti-Jk^b, anti-Jk3, anti-JMH, anti-Jr^a, anti-Js^a, anti-Js^b, anti-K, anti-K11, anti-K14, anti-K17, anti-K22, anti-Kn^a, anti-Kn^a/McC^a, anti-Kn^b, anti-Kp^b, anti-Kp^c, anti-Ku, anti-Kx, anti-Lan, anti-Le^a, anti-Le^b, anti-Le^bH, anti-Ls^a, anti-Lu^a, anti-Lu^b, anti-Lub/Au^b, anti-Lu14, anti-Lu17, anti-Lu3, anti-Lu6, anti-Lu7, Anti-Lu8, anti-LW^a, anti-LW^ab, anti-M, anti-M lectin, anti-Mg, anti-MARS, anti-McC^a, anti-McC^b, anti-Mi^a, anti-Mit, anti-Mt^a, anti-N, anti-N lectin, anti-Ny^a, anti-Ok^a, anti-Ol^a, anti-Or, anti-Os^a, anti-P, anti-P1, anti-PEL, anti-PP1P^k, anti-Pt^a, anti-R^N, anti-Rb^a, anti-Rg^a, anti-Rh total, anti-Rh(D), anti-S, anti-s, anti-s^D, anti-SARA, anti-Sc1, anti-Sc2, anti-Sc3, anti-Sd^a, anti-Sl^a, anti-Sw^a, anti-Tar, anti-Tc^a, anti-Tr^a, anti-U, anti-V, anti-Vel, anti-Vg^a, anti-VS, anti-Vw, anti-WARR, anti-Wd^a, anti-Wr^a, anti-Wr^b, anti-Wu, Xg^a, anti-Yk^a, anti-Yt^a, anti-Yt^b, partial (variant) Rh(D) category VI.
L2CT (Class 2, 3 IVDs; Class 4 IHRs)	**CT890 Immunohaematology calibrator/control IVDs** IVDs that are intended to be used in testing to establish known points of reference and/or verify the performance of immunohaematological tests. Anti-C control & standard reference solution, anti-c control & standard reference solution, anti-E control & standard reference solution, anti-e control & standard reference solution, anti-Fy^a control & standard reference solution, anti-K control & standard reference solution, anti-Rh(D) control & standard reference solution, non-reactive antisera matrix, complement coated reagent red blood cells, enzyme immunohaematology reagent, group AB serum, immunoglobulin G (IgG) sensitized reagent red blood cell, multiple immunohaematology red cell and antisera test controls, weak anti-D.
L2CT (Class 2, 3 IVDs; Class 4 IHRs)	**CT1270 Immunohaematology-related IVDs** IVDs that are intended to be used alone or in combination with other IVDs to perform various immunohaematology-related tests and procedures (e.g. agglutination detection and enhancing reagents, red cell preservative/storage solutions). A/B transferase enzyme, Bovine serum albumin (BSA) immunohaematology reagent, bromelin immunohaematology reagent, column agglutination technology IVD, ficin immunohaematology reagent, low ionic strength saline (LISS) immunohaematology reagent, papain immunohaematology reagent, polyethylene glycol (PEG) immunohaematology reagent, protease immunohaematology reagent, red cell antibody eluting kit, red cell antibody eluting reagent, red cell freezing/cryoprotectant solution, Red cell preservative/storage solution, red cell thawing solution, trypsin immunohaematology reagent.
L2CT (Class 2, 3 IVDs; Class 4 IHRs)	**CT888 Immunohaematology sensitised cell-typing IVDs** Immunoglobulins capable of binding to substances on the surface of sensitised red blood cells that are intended to be used in immunohaematological testing to provide information about the nature of red blood cell sensitisation, including immunoglobulin heavy chain class or complement protein type. Monospecific anti-complement component C3 (anti-C3), monospecific anti-complement component C3b (anti-C3b), monospecific anti-complement component C3b/anti-C3d (anti-C3b/anti-C3d), monospecific anti-complement component C3c (anti-C3c), monospecific anti-complement component C3d (anti-C3d), monospecific anti-complement component C4 (anti-C4), monospecific immunoglobulin A antihuman globulin (IgA AHG), monospecific immunoglobulin G antihuman globulin (IgG AHG), monospecific immunoglobulin M antihuman globulin (IgM AHG), multiple monospecific antihuman globulin/anti-complement cell coat typing, polyspecific antihuman globulin, polyspecific antihuman globulin/complement.
L2CT (Class 2, 3 IVDs;	**CT753 Multiple blood grouping and typing IVDs** Immunoglobulins capable of binding to specific antigenic determinants that are supplied together and intended to be used in testing for a combination of blood group antigens within one or multiple blood group systems.

Class 4 IHRs)	ABO multiple blood grouping kit, ABO/Rh(D) multiple blood grouping kit, ABO/Rh(D)/Kell multiple blood grouping kit, Duffy (Fy^a & Fy^b) multiple blood grouping kit, Duffy (Fy^a & Fy^b)/Kidd (Jk^a & Jk^b) multiple blood grouping kit, Kidd (Jk^a & Jk^b) multiple blood grouping kit, multiple lectin panel, partial (variant) Rh(D) multiple blood grouping kit, Rh(D)/Kell multiple blood grouping kit, Rhesus (Rh) phenotype (CcDEe) multiple blood grouping, Rhesus (Rh) phenotype (CcDEe)/Kell multiple blood grouping kit.
L2CT (Class 2, 3 IVDs; Class 4 IHRs)	**CT886 Reagent red blood cell IVDs** Specifically characterised reagent red blood cells that are intended to be used in immunohaematological testing due to the known specificity of their red cell antigens. Antibody identification panel reagent red blood cells, antibody screening reagent red blood cells, group A reagent cord blood cell, group A1 Rh (D) negative reagent red blood cell, group A1 Rh (D) positive reagent red blood cell, group A2 Rh (D) negative reagent red blood cell, group A2 Rh (D) positive reagent red blood cell, group AB Rh (D) negative reagent red blood cell, group AB Rh (D) positive reagent red blood cell, group B reagent cord blood cell, group B Rh(D) negative reagent red blood cell, group B Rh(D) positive reagent red blood cell, group O r''r reagent red blood cell, group O R1^wR1 reagent red blood cell, group O R1r reagent red blood cell, group O R1R1 reagent red blood cell, group O R2r reagent red blood cell, group O R2R2 reagent red blood cell, group O reagent cord blood cell, group O Rh (D) negative reagent red blood cell, group O Rh (D) positive reagent red blood cell, group O r'r reagent red blood cell, Kell negative reagent red blood cell, Kell positive reagent red blood cell, partial (variant) Rh(D) reagent red blood cell, pooled antibody screening reagent red blood cell, reverse ABO grouping reagent red blood cell (A1/A2/B/AB/O), Rhesus phenotype-specific reagent red blood cell (C/c/D/E/e/C^w), weak Rh(D) reagent red blood cell.

Infectious disease IVDs

L1CT (Class 1 IVDs)	**CT701 Infectious disease IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to infectious agents capable of causing disease, including viruses, bacteria, fungi, parasites and/or prions. All analytes as represented in Level 2 and Level 3 Infectious diseases collective terms.
L2CT (Class 2 IVDs)	CT353 Bacterial infectious disease IVDs IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of bacterial diseases. All analytes as represented in Level 3 bacterial infectious disease collective terms.
L3CT (Class 3 IVDs)	**CT776 Bacillus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Bacillus bacteria. Bacillus anthracis antigen, IgG, nucleic acid; Bacillus cereus enterotoxin.
L3CT (Class 3 IVDs)	**CT777 Bartonella IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Bartonella bacteria. Bartonella bacilliformis IgG, IgM, nucleic acid; Bartonella henselae IgG, IgM, nucleic acid; Bartonella quintana IgG, IgM, nucleic acid; Multiple Bartonella species.
L3CT (Class 3 IVDs)	**CT778 Bordetella IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Bordetella bacteria. Bordetella pertussis IgA, IgG, IgM, nucleic acid, total antibody; Multiple Bordetella species antibody, multiple Bordetella species nucleic acid.
L3CT (Class 3 IVDs)	**CT779 Borrelia (Lyme disease) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Borrelia bacteria associated with Lyme disease. Borrelia afzelii IgG, IgM, nucleic acid, total antibody; Borrelia burgdorferi antigen, IgG, IgM, nucleic acid, total antibody; Borrelia garinii IgG, IgM, nucleic acid; Multiple Borrelia species IgA/IgG/IgM, total antibody.
L3CT (Class 3 IVDs)	**CT780 Brucella IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Brucella bacteria. Brucella abortus total antibody; Multiple Brucella species culture isolate antigen, nucleic acid; Multiple Brucella species IgA, IgG, IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT928 Burkholderia IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Burkholderia bacteria Burkholderia cepacia culture isolate antigen; Burkholderia mallei culture isolate antigen; Burkholderia mallei IgG, nucleic acid, total antibody; Burkholderia pseudomallei culture isolate antigen; Burkholderia pseudomallei IgG, IgM, nucleic acid.
L3CT (Class 3 IVDs)	**CT939 Calymmatobacterium (Klebsiella) granulomatis (Donovanosis) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Calymmatobacterium granulomatis bacteria associated with Donovanosis. Calymmatobacterium (Klebsiella) granulomatis nucleic acid.
L3CT (Class 3 IVDs)	**CT781 Campylobacter IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Campylobacter bacteria. Campylobacter coli antibody; Campylobacter fetus antibody; Campylobacter jejuni antibody, nucleic acid; Multiple Campylobacter species antibody, antigen, nucleic acid; Multiple Campylobacter species culture isolate antigen.
L3CT (Class 3 IVDs)	**CT782 Chlamydia IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Chlamydia bacteria. Chlamydia pneumoniae antigen, IgA, IgG, IgM, nucleic acid, total antibody; Chlamydia psittaci antigen, nucleic acid, total antibody; Chlamydia trachomatis antigen, IgA, IgG, IgM, nucleic acid, total antibody; Multiple Chlamydia species antigen, IgA, IgG, IgM, nucleic acid, total antibody.
L3CT (Class 3	**CT783 Clostridium IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Clostridium bacteria.

IVDs)	Clostridium botulinum antibody; Clostridium botulinum toxin A antibody; Clostridium botulinum toxin B antibody; Clostridium botulinum toxin E antibody; Clostridium botulinum toxin F antibody; Clostridium botulinum toxin nucleic acid; Clostridium difficile antigen; Clostridium difficile toxin A antibody, Clostridium difficile toxin A/B antibody, antigen, nucleic acid; Clostridium difficile toxin B antibody, antigen; Clostridium perfringens enterotoxin A/B antibody, antigen; Clostridium perfringens enterotoxin nucleic acid, Clostridium tetani IgG; Clostridium tetani toxin antigen, nucleic acid; Multiple Clostridium botulinum toxin antigens.
L3CT (Class 3 IVDs)	**CT913 Corynebacterium IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Corynebacterium bacteria. Corynebacterium diphtheriae IgG; Corynebacterium diphtheriae toxin antibody, antigen, nucleic acid.
L3CT (Class 3 IVDs)	**CT921 Enterococcus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Enterococcus bacteria. Multiple Enterococcus species antigen; Multiple Enterococcus species culture isolate identification; Vancomycin-resistant Enterococcus (VRE) culture isolate nucleic acid; Vancomycin-resistant Enterococcus (VRE) nucleic acid.
L3CT (Class 3 IVDs)	**CT941 Erysipelothrix IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Erysipelothrix bacteria. Erysipelothrix rhusiopathiae antigen; Erysipelothrix rhusiopathiae culture isolate identification.
L3CT (Class 3 IVDs)	**CT784 Escherichia coli (E. coli) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Escherichia coli (E. coli) bacteria. Enterohaemorrhagic Escherichia coli (EHEC) nucleic acid; Escherichia coli Alkalescens-Dispar antigen; Escherichia coli heat labile enterotoxin antibody, antigen; Escherichia coli heat stable enterotoxin antibody, antigen; Escherichia coli O157:H7 antigen; Escherichia coli verotoxin antibody, antigen.
L3CT (Class 3 IVDs)	**CT858 Francisella IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Francisella bacteria. Francisella tularensis antigen, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT914 Gardnerella IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Gardnerella bacteria. Gardnerella vaginalis antigen.
L3CT (Class 3 IVDs)	**CT785 Haemophilus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Haemophilus bacteria. Haemophilus ducreyi IgG, nucleic acid; Haemophilus influenzae culture isolate antigen, nucleic acid.
L3CT (Class 3 IVDs)	**CT786 Helicobacter IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Helicobacter bacteria. Helicobacter pylori antigen, IgA, IgA/IgG, IgG, IgM, nucleic acid, total antibody; Helicobacter pylori urease; Multiple gastrointestinal disease markers.
L3CT (Class 3 IVDs)	**CT787 Legionella IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Legionella bacteria. Legionella longbeachae IgA, IgG, IgM, IgA/IgG/IgM, nucleic acid; Legionella pneumophila antigen, IgA, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT788 Leptospira IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Leptospira bacteria. Multiple Leptospira species antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT789 Listeria IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Listeria bacteria. Listeria monocytogenes antigen, IgG, IgM, IgG/IgM, nucleic acid; Listeria monocytogenes culture isolate antigen.
L3CT	**CT774 Multiple-bacteria IVDs**

(Class 3 IVDs)	IVDs that are intended to be used in testing to provide information about infection with or exposure multiple specified bacterial organisms. Multiple aerobic gram positive bacteria species culture isolate identification, multiple anaerobic bacteria species culture isolate identification, multiple Enterobacteriaceae species culture isolate identification, multiple febrile infection-associated bacteria antigen, multiple gastrointestinal disease-associated bacteria nucleic acid, multiple gram negative bacteria species culture isolate identification, multiple Haemophilus/Neisseria bacteria species culture isolate identification, multiple meningitis-associated bacteria antigen, multiple non-Enterobacteriaceae species culture isolate identification, multiple non-glucose fermenting bacteria species culture isolate identification, multiple peridontal disease-associated bacteria nucleic acid, multiple sexually transmitted disease-associated bacteria nucleic acid, peridontal disease-associated multiple bacteria peptidase.
L3CT (Class 3 IVDs)	**CT791 Mycobacteria IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Mycobacteria. Multiple Mycobacterium species antigen; Multiple Mycobacterium species culture isolate identification; Multiple Mycobacterium species nucleic acid; Mycobacteriophage antimicrobial susceptibility testing; Mycobacteriophage nucleic acid; Mycobacterium leprae antigen, nucleic acid, total antibody; Mycobacterium tuberculosis antigen, IgA, IgG, IgM; Mycobacterium tuberculosis nucleic acid.
L3CT (Class 3 IVDs)	**CT792 Mycoplasma IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Mycoplasma bacteria. Multiple Mycoplasma species nucleic acid; Mycoplasma genitalium nucleic acid; Mycoplasma pneumoniae antigen, antigen/antibody, IgA, IgG, IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT793 Neisseria IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Neisseria bacteria. Multiple Neisseria species culture isolate identification, Neisseria gonorrhoea culture isolate antigen; Neisseria gonorrhoea culture isolate identification; Neisseria gonorrhoea antigen, nucleic acid, total antibody; Neisseria meningitidis antigen; Neisseria meningitidis culture isolate antigen; Neisseria meningitidis IgG, nucleic acid.
L3CT (Class 3 IVDs)	**CT794 Pseudomonas IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Pseudomonas bacteria. Multiple Pseudomonas species culture isolate identification; Pseudomonas aeruginosa antigen, IgG, nucleic acid.
L3CT (Class 3 IVDs)	**CT868 Rickettsial disease IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to bacteria associated with Rickettsial disease, which may include Anaplasma, Coxiella, Erlichia, Orientia and/or Rickettsia species. Anaplasma phagocytophilum IgG, IgM, nucleic acid; Coxiella burnetii IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody; Ehrlichia chaffeensis IgG, IgM, IgA/IgG/IgM, nucleic acid; Multiple Ehrlichia species IgG, IgM, IgA/IgG/IgM; Multiple Rickettsia species (spotted fever group) antigen, IgG, IgM, nucleic acid, total antibody; Multiple Rickettsia species (typhus group) antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody; Orientia tsutsugamushi antigen, IgG, IgA/IgG/IgM, nucleic acid; Rickettsia conorii antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody; Rickettsia prowazekii IgG, IgM, IgA/IgG/IgM, total antibody; Rickettsia rickettsii antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody; Rickettsia typhi IgG, IgM, IgA/IgG/IgM, total antibody.
L3CT (Class 3 IVDs)	**CT795 Salmonella IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Salmonella bacteria. Multiple Salmonella species culture isolate antigen; Multiple Salmonella species antigen, IgG, IgM, nucleic acid, total antibody; Salmonella paratyphi culture isolate antigen; Salmonella paratyphi antigen, nucleic acid, total antibody; Salmonella typhi culture isolate antigen; Salmonella typhi antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody; Salmonella typhimurium culture isolate antigen, nucleic acid.
L3CT (Class 3	**CT796 Shigella IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Shigella bacteria.

IVDs)	Escherichia coli Alkalescens-Dispar antigen; Multiple Shigella species culture isolate antigen; Multiple Shigella species verotoxin 1 & 2 antigen, nucleic acid; Shigella boydii culture isolate antigen; Shigella boydii total antibody; Shigella dysenteriae culture isolate antigen; Shigella dysenteriae total antibody; Shigella dysenteriae verotoxin antigen; Shigella flexneri culture isolate antigen; Shigella flexneri total antibody; Shigella flexneri verotoxin antigen; Shigella sonnei culture isolate antigen; Shigella sonnei total antibody; Shigella sonnei verotoxin antigen.
L3CT (Class 3 IVDs)	**CT797 Staphylococcus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Staphylococcus bacteria. MRSA culture isolate nucleic acid; MRSA nucleic acid detection; MRSE nucleic acid detection; Multiple Staphylococcus bacterial species culture isolate; Staphylococcus aureus culture isolate antigen; Staphylococcus aureus culture isolate identification and methicillin susceptibility testing; Staphylococcus aureus enterotoxin nucleic acid; Staphylococcus aureus multiple enterotoxin antigen, total antibody; Staphylococcus aureus staphylolysin total antibody; Staphylococcus aureus total antibody; Staphylococcus aureus TSST-1 toxin antigen, total antibody.
L3CT (Class 3 IVDs)	**CT798 Streptococcus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Streptococcus bacteria. Beta-haemolytic Group A Streptococcus antigen, nucleic acid, total antibody; Beta-haemolytic Group A Streptococcus DNAse B antibody, hyaluronidase antibody, streptokinase antibody, streptolysin O antibody; Multiple Beta-haemolytic Group A Streptococcus enzyme antibody; Beta-haemolytic Group B Streptococcus antigen, nucleic acid, total antibody; Beta-haemolytic Group C Streptococcus antigen; Beta-haemolytic Group D Streptococcus antigen; Beta-haemolytic Group F Streptococcus antigen; Beta-haemolytic Group G Streptococcus antigen; Multiple Beta-haemolytic Streptococcus species antigen; Multiple Streptococcus bacterial species culture isolate identification; Streptococcus mutans group antigen; Streptococcus pneumoniae culture isolate antigen; Streptococcus pneumoniae antigen, IgG, nucleic acid.
L3CT (Class 3 IVDs)	**CT799 Treponema (syphilis) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Treponema bacteria, the spirochete bacteria associated with syphilis Treponema pallidum antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody; Treponema pallidum reagin antibody.
L3CT (Class 3 IVDs)	**CT1442 Tropheryma IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Tropheryma species, the bacteria associated with Whipple's disease Tropheryma whippeli nucleic acid.
L3CT (Class 3 IVDs)	**CT859 Ureaplasma IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Ureaplasma bacteria. Ureaplasma urealyticum IgG, IgM, nucleic acid.
L3CT (Class 3 IVDs)	**CT800 Vibrio IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Vibrio bacteria. Multiple Vibrio cholera serotyping antigen; Multiple Vibrio parahaemolyticus serotyping antigen; Multiple Vibrio species culture isolate identification; Vibrio cholerae enterotoxin antigen, nucleic acid; Vibrio parahaemolyticus thermostable direct haemolysin (TDH) antigen, nucleic acid; Vibrio vulnificus antigen, Vibrio vulnificus enterotoxin antigen, nucleic acid.
L3CT (Class 3 IVDs)	**CT801 Yersinia IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Yersinia bacteria. Multiple Yersinia species culture isolate identification; Multiple Yersinia species IgA/IgG, total antibody; Yersinia enterocolitica antigen, IgA, IgG, IgM, IgA/IgG, nucleic acid, total antibody; Yersinia pestis antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody; Yersinia pseudotuberculosis antigen, IgG, IgM, nucleic acid, total antibody.
L2CT (Class 2 IVDs)	**CT354 Fungal infectious disease IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of yeast and/or fungal diseases. All analytes as represented in Level 3 fungal infectious disease collective terms.

	L3CT (Class 3 IVDs)	**CT937 Aspergillus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to species from the fungus Aspergillus. Aspergillus fumigatus IgA, IgG, IgM, nucleic acid, total antibody; Aspergillus species galactomannan antigen; Aspergillus species antigen; Multiple Aspergillus species antigen, total antibody.
	L3CT (Class 3 IVDs)	**CT919 Blastomyces IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to the fungus Blastomyces. Blastomyces dermatitidis exoantigen, total antibody.
	L3CT (Class 3 IVDs)	**CT802 Candida IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Candida yeast species. Candida albicans antigen, IgA, IgG, IgM, IgG/IgM, nucleic acid; Candida albicans/C. glabrata antigen; Candida albicans/C. tropicalis/C. parapsilosis antigen; Multiple Candida species arabinitol metabolite; Multiple Candida species IgG, IgM, IgA/IgG/IgM, nucleic acid; Multiple Candida species mannan antigen.
	L3CT (Class 3 IVDs)	**CT904 Coccidioides IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to species from the fungus Coccidioides Coccidioides immitis exoantigen; Coccidioides immitis total antibody.
	L3CT (Class 3 IVDs)	**CT803 Cryptococcus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Cryptococcus yeast species. Cryptococcus neoformans antigen.
	L3CT (Class 3 IVDs)	**CT925 Histoplasma IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to species from the fungus Histoplasma. Histoplasma capsulatum antigen, total antibody; Histoplasma capsulatum exoantigen.
	L3CT (Class 3 IVDs)	**CT938 Multiple-fungi IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to multiple specified yeast and/or fungal organisms. Multiple Candida/yeast species culture isolate identification; Multiple fungi exoantigen; Multiple fungi/yeast species nucleic acid; Pan-fungal nucleic acid.
	L3CT (Class 3 IVDs)	**CT804 Pneumocystis IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Pneumocystis yeast. Pneumocystis jiroveci antigen.
	L3CT (Class 3 IVDs)	**CT805 Saccharomyces IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Saccharomyces yeast species. Saccharomyces cerevisiae IgA, IgG, IgM, total antibody.
	L3CT (Class 3 IVDs)	**CT1262 Sporothrix IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to the fungus Sporothrix shenckii. Sporothrix schenckii total antibody.
L2CT (Class 2 & 3 IVDs)		**CT923 Multiple infectious organism IVDs** IVDs that are intended to be used in testing to provide information about mixed infection with or exposure to multiple specified infectious organisms from different microbial groups, which may include viruses, bacteria, fungi, parasites and/or prions Babesia microti/Borrelia burgdorferi IgG/IgM; HIV1/HIV2/Mycobacterium tuberculosis antibody; Multiple infectious organism/newborn TORCH screen; Multiple respiratory disease antigen; Multiple vaginitis-associated organism nucleic acid.
L2CT (Class 2 IVDs)		**CT356 Parasitic infectious diseases IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with one or a number of parasitic organisms including protozoa, amoebae, nematodes and/or other worms. All analytes as represented in Level 3 parasitic infectious disease collective terms.
	L3CT (Class 3 IVDs)	**CT713 Anisakis IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic nematode Anisakis. Anisakis species IgA, IgE, IgG, IgA/IgG.
	L3CT (Class	**CT741 Ascaris IVDs** IVDs that are intended to be used in testing to provide information about the presence

3 IVDs)	of, or infection with the parasitic nematode Ascaris. Ascaris lumbricoides IgG.
L3CT (Class 3 IVDs)	**CT808 Babesia IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic protozoan Babesia. Babesia microti IgG, IgM, IgG/IgM, nucleic acid; Babesia WA1 IgG, nucleic acid.
L3CT (Class 3 IVDs)	**CT809 Cryptosporidium IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic protozoan Cryptosporidium species. Cryptosporidium hominis nucleic acid; Cryptosporidium hominis/C. parvum nucleic acid; Cryptosporidium parvum antigen, IgA, IgG, IgM, IgA/IgG/IgM, nucleic acid; Cryptosporidium species antigen IgA, IgG, IgM, IgA/IgG/IgM, nucleic acid.
L3CT (Class 3 IVDs)	**CT810 Echinococcus (hydatid) IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with Echinococcus, the parasitic tapeworm associated with hydatids disease. Echinococcus granulosis IgG, total antibody.
L3CT (Class 3 IVDs)	**CT811 Entameoba (ameobiasis) IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with Entamoeba, the protozoan parasite associated with amoebiasis. Entameoba histolytica antigen, IgG, total antibody.
L3CT (Class 3 IVDs)	**CT812 Fasciola IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic flatworm Fasciola. Fasciola hepatica total antibody.
L3CT (Class 3 IVDs)	**CT1264 Free living amoebae IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with free living amoebae, which may include Acanthamoeba species and/or Naegleria fowleri. Acanthamoeba species antigen, nucleic acid; Naegleria fowleri nucleic acid.
L3CT (Class 3 IVDs)	**CT813 Giardia IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic protozoan Giardia lamblia. Giardia lamblia antigen, IGA, IgG, IgM, IgA/IgG/IgM.
L3CT (Class 3 IVDs)	**CT814 Leishmania IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic protozoan Leishmania. Leishmania donovani antigen, IgG, IgM, IgG/IgM, nucleic acid; Leishmania species antigen, IgG, IgM, IgG/IgM, total antibody, nucleic acid.
L3CT (Class 3 IVDs)	**CT807 Multiple-parasite IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with multiple specified parasites which may include protozoa, amoebae, nematodes and/or other worms. Multiple faecal parasite antigens.
L3CT (Class 3 IVDs)	**CT815 Paragonimus IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic flatworm Paragonimus. Paragonimus westermani IgG, IgM, total antibody.
L3CT (Class 3 IVDs)	**CT816 Plasmodium (malaria) IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with Plasmodium species, the parasite associated with malaria. Multiple Plasmodium species antigen, IgG, nucleic acid, total antibody; Plasmodium falciparum antigen, IgG, nucleic acid; Plasmodium falciparum/P. vivax total antibody; Plasmodium knowlesi nucleic acid; Plasmodium malariae antigen, nucleic acid; Plasmodium ovale antigen, nucleic acid; Plasmodium vivax antigen, nucleic acid.
L3CT (Class 3 IVDs)	**CT817 Schistosoma IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic flatworm Schistoma species. Schistosoma mansoni IgE, IgG, IgE/IgG, total antibody; Schistosoma mansoni/S. haematobium IgE, IgG, IgE/IgG; Schistosoma species IgE, IgG, IgE/IgG.
L3CT (Class 3 IVDs)	**CT818 Strongyloides IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic nematode Strongyloides. Strongyloides stercoralis IgG.

	L3CT (Class 3 IVDs)	**CT735 Taenia (cysticercosis) IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with Taenia, the parasitic tapeworm associated with cysticercosis. Taenia solium antigen, IgG.
	L3CT (Class 3 IVDs)	**CT819 Toxocara IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic nematode Toxocara. Toxocara canis IgG.
	L3CT (Class 3 IVDs)	**CT820 Toxoplasma IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic protozoan Toxoplasma. Toxoplasma gondii antigen, IgA, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody.
	L3CT (Class 3 IVDs)	**CT821 Trichinella IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic nematode Trichinella. Trichinella spiralis IgG, total antibody.
	L3CT (Class 3 IVDs)	**CT822 Trichomonas IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic protozoan Trichomonas. Trichomonas vaginalis antigen, nucleic acid.
	L3CT (Class 3 IVDs)	**CT823 Trypanosoma IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with the parasitic protozoan Trypanosoma. Trypanosoma cruzi IgG, IgM, IgG/IgM, total antibody.
	L3CT (Class 3 IVDs)	**CT824 Wuchereria/Brugia (filariasis) IVDs** IVDs that are intended to be used in testing to provide information about the presence of, or infection with Wuchereria bancrofti and/or Brugia malayi, the parasitic nematodes associated with filariasis. Wuchereria bancrofti antigen, IgG, IgG/IgM; Wuchereria bancrofti/Brugia malayi IgG.
L2CT (Class 2 & 3 IVDs)		**CT825 Prion infectious diseases IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of prion diseases. Disease-associated prion protein (PrPSc).
L2CT (Class 2 IVDs)		**CT355 Viral infectious disease IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of viral diseases. All analytes as represented in Level 3 viral infectious disease collective terms.
	L3CT (Class 3 IVDs)	**CT759 Adenovirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Adenovirus. Adenovirus antigen, IgA, IgG, IgM, IgG/IgM, nucleic acid, total antibody.
	L3CT (Class 3 IVDs)	**CT718 Barmah Forest virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Barmah Forest (BF) virus. Barmah Forest (BF) virus antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization; Barmah Forest (BF) virus haemagglutination inhibition
	L3CT (Class 3 IVDs)	**CT758 BK virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to BK virus. BK virus (BKV) antigen, nucleic acid.
	L3CT (Class 3 IVDs)	**CT760 Borna disease virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Borna disease virus. Borna disease virus antigen, IgG, nucleic acid, total antibody, total antibody neutralization.
	L3CT (Class 3 IVDs)	**CT714 Coxsackie virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Coxsackie viruses. Coxsackie A virus antigen (serotypes A1-A24), Coxsackie A virus nucleic acid (serotypes A1-A24); Coxsackie A virus IgA, IgG, total antibody, total antibody neutralization; Coxsackie A9 virus antibody; Coxsackie B virus antigen (serotypes B1-B6); Coxsackie B virus nucleic acid (serotypes B1-B6); Coxsackie B virus IgA, IgG, IgM, total antibody, total antibody neutralization; Coxsackie B1 virus antibody,

	Coxsackie B2 virus antibody; Coxsackie B3 virus antibody; Coxsackie B4 virus antibody, Coxsackie B5 virus antibody, Coxsackie B6 virus antibody; Coxsackie virus IgA, IgG, IgM, total antibody; Multiple Coxsackie virus antigen.
L3CT (Class 3 IVDs)	**CT940 Crimean-Congo haemorrhagic fever virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Crimean-Congo haemorrhagic fever virus. Crimean-Congo haemorrhagic fever (CCHF) virus antigen, IgG, IgM, nucleic acid.
L3CT (Class 3 IVDs)	**CT748 Cytomegalovirus (Human herpesvirus 5) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Cytomegalovirus (CMV), also referred to as Human herpesvirus 5. Cytomegalovirus (CMV) antigen, IgG, IgM, nucleic acid, total antibody; Cytomegalovirus (CMV) IgG antibody avidity index.
L3CT (Class 3 IVDs)	**CT725 Dengue virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Dengue virus. Dengue virus antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid; Dengue virus haemagglutination inhibition; Dengue virus NS1 antigen, Dengue virus serotyping (types 1-4).
L3CT (Class 3 IVDs)	**CT719 Eastern equine encephalomyelitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Eastern equine encephalomyelitis (EEE) virus. Eastern equine encephalitis (EEE) virus antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT761 Ebola virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Ebola virus. Ebola virus antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT715 Echovirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Echoviruses. Echovirus (serotypes EV1-EV33) antigen, nucleic acid, IgM, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT716 Enteroviruses 68-71 IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Enteroviruses from serotypes 68 to 71. Enterovirus (serotypes 68-71) antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT747 Epstein-Barr virus (Human herpesvirus 4) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Epstein-Barr virus (EBV), also referred to as Human herpesvirus 4. Epstein-Barr virus (EBV) early antigen (EA) IgG; Epstein-Barr virus (EBV) heterophile antibody, Epstein-Barr virus (EBV) LMP1 antigen, nucleic acid; Epstein-Barr virus (EBV) p18 IgG, Epstein-Barr virus (EBV) VCA IgG, IgG; Epstein-Barr virus nuclear antigen.
L3CT (Class 3 IVDs)	**CT932 Hantavirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Hantavirus. Hantavirus IgG, IgM, nucleic acid.
L3CT (Class 3 IVDs)	**CT736 Hendra virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Hendra virus. Hendra virus IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT703 Hepatitis A virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Hepatitis A virus. Hepatitis A virus antigen, IgG, IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT704 Hepatitis B virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Hepatitis B virus. Hepatitis B virus antigen/antibody marker; Hepatitis B virus core antigen, IgG, IgM, nucleic acid, total antibody; Hepatitis B virus e-antigen, IgG, IgM, nucleic acid, total antibody; Hepatitis B virus e-antigen/antibody; Hepatitis B virus surface antigen, IgG,

	IgM, total antibody; Hepatitis B virus surface antigen-albumin complex/albumin receptor.
L3CT (Class 3 IVDs)	**CT705 Hepatitis C virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Hepatitis C virus. Hepatitis C virus antibody/antigen; Hepatitis C virus antigen, IgG, IgM, nucleic acid, total antibody; Hepatitis C virus core antigen; Hepatitis C virus GOR protein antibody; Hepatitis C virus serotyping.
L3CT (Class 3 IVDs)	**CT706 Hepatitis D virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Hepatitis D virus. Hepatitis D virus antigen, IgG, IgM nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT707 Hepatitis E virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Hepatitis E virus. Hepatitis E virus antigen, IgG, IgM nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT708 Hepatitis G virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Hepatitis G virus. Hepatitis G virus antigen, IgG, IgM nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT749 Herpes simplex virus (HSV) (Human herpesvirus 1 & 2) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Herpes simplex virus 1 and/or Herpes simplex virus 2 (HSV1 and/or HSV2), also referred to as Human herpesvirus 1 & 2. Herpes simplex virus 1 & 2 (HSV1 & 2) antigen, IgG, IgM, IgG/IgM, nucleic acid; Herpes simplex virus 1 (HSV1) antigen, IgG, IgM, IgG/IgM, nucleic acid; Herpes simplex virus 2 (HSV2) antigen, IgG, IgM, IgG/IgM, nucleic acid.
L3CT (Class 3 IVDs)	**CT762 Human astrovirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Human astrovirus. Human astrovirus antigen, nucleic acid.
L3CT (Class 3 IVDs)	**CT754 Human herpes virus 6 IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Human herpesvirus 6 (HHV6). Human herpesvirus 6 (HHV6) antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT930 Human herpes virus 7 IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Human herpes virus 7 (HHV7). Human herpesvirus 7 (HHV7) antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT755 Human herpes virus 8 IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Human herpes virus 8 (HHV8). Human herpesvirus 8 (HHV8) antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT284 Human immunodeficiency virus (HIV) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Human immunodeficiency viruses (HIV). HIV1 antibody, antigen, nucleic acid, antigen/antibody; HIV1 antigen neutralization; HIV1 genotyping; HIV1 IgG avidity; HIV1/HIV2 antibody, antigen, nucleic acid, antigen/antibody; HIV1/HIV2 antigen neutralization; HIV2 antibody, antigen, nucleic acid, antigen/antibody; HIV2 antigen neutralization.
L3CT (Class 3 IVDs)	**CT737 Human metapneumovirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Human metapneumovirus. Human metapneumovirus (hMPV) antigen, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT947 Human papilloma virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Human papilloma viruses. Human papillomavirus (HPV) antigen, nucleic acid; Human papillomavirus (HPV) high risk strain nucleic acid.
L3CT	**CT934 Human parechovirus IVDs**

(Class 3 IVDs)	IVDs that are intended to be used in testing to provide information about infection with or exposure to Human parechovirus. Human parechovirus (HPeV) nucleic acid.
L3CT (Class 3 IVDs)	**CT711 Human T-cell lymphotrophic virus (HTLV) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Human T-cell lymphotrophic virus 1 and/or Human T-cell lymphotrophic virus 2 (HTLV-1 and/or HTLV-2). Human T-cell lymphotrophic virus 1 & 2 (HTLV1 & HTLV2) antibody, antigen, nucleic acid; Human T-cell lymphotrophic virus 1 (HTLV1) antibody, antigen, nucleic acid; Human T-cell lymphotrophic virus 2 (HTLV2) antibody, antigen, nucleic acid.
L3CT (Class 3 IVDs)	**CT732 Influenza virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Influenza viruses. Influenza A virus antigen, IgA, IgG, IgM, IgG/IgM, nucleic acid, total antibody; Influenza A virus H1N1 subtype (swine influenza) nucleic acid; Influenza A virus H5N1 subtype (avian influenza) antigen, nucleic acid; Influenza A/B virus antigen, IgG, IgM, nucleic acid, total antibody; Influenza A/B virus neuraminidase activity; Influenza B virus antigen, IgA, IgG, IgM, IgG/IgM, nucleic acid, total antibody; Influenza C virus nucleic acid.
L3CT (Class 3 IVDs)	**CT726 Japanese encephalitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Japanese encephalitis (JE) virus. Japanese encephalitis (JE) virus antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT757 JC virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to JC virus. JC virus (JCV) antigen, nucleic acid.
L3CT (Class 3 IVDs)	**CT790 Junin virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Junin virus. Junin virus antigen, IgG, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT927 Lassa virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Lassa virus. Lassa virus antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT763 Lymphocytic choriomeningitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Lymphocytic choriomeningitis virus (LCMV). Lymphocytic choriomeningitis virus (LCMV) IgG, IgM, IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT926 Machupo virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Machupo virus. Machupo virus antigen, IgG, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT764 Marburg virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Marburg virus. Marburg virus antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT738 Measles (rubeola) virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Measles virus, also referred to as rubeola. Measles virus antigen, IgA, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT702 Multiple-viruses IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to multiple specified viruses. HIV1/Hepatitis C virus nucleic acid; HIV1/Hepatitis C virus/Hepatitis B virus nucleic acid; Influenza A/B virus/parainfluenza virus antigen, total antibody; Influenza A/B virus/respiratory syncytial virus (RSV) antigen; Multiple arbovirus IgG, IgM, IgA/IgG/IgM; Multiple enterovirus IgA, IgG, IgM; Multiple filovirus antigen, nucleic acid; Multiple gastrointestinal virus antigen; Multiple haemorrhagic fever virus

	nucleic acid; Multiple mosquito-borne flavivirus antibody; Multiple respiratory virus antigen, nucleic acid.
L3CT (Class 3 IVDs)	**CT739 Mumps virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Mumps virus. Mumps virus antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT727 Murray Valley encephalitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Murray Valley encephalitis (MVE) virus. Murray Valley encephalitis (MVE) virus IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT740 Nipah virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Nipah virus. Nipah virus IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT765 Norovirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Norovirus. Norovirus antigen, IgA, IgG, nucleic acid.
L3CT (Class 3 IVDs)	**CT766 Parainfluenza virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Parainfluenza viruses. Human parainfluenza virus 1 antigen, IgA, IgG/IgM, nucleic acid, total antibody; Human parainfluenza virus 2 antigen, IgA, IgG/IgM, nucleic acid, total antibody; Human parainfluenza virus 3 antigen, IgA, IgG/IgM, nucleic acid, total antibody; Human parainfluenza virus 4A antigen, nucleic acid, total antibody; Human parainfluenza virus 4B antigen, nucleic acid, total antibody; Multiple human parainfluenza virus antigen, IgA, IgG, IgM, IgG/IgM; Parainfluenza 5 virus antigen, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT767 Parvovirus B19 IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Parvovirus B19. Parvovirus B19 antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT717 Poliovirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Poliovirus. Poliovirus (serotypes PV1-PV3) antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT768 Rabies virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Rabies virus. Rabies virus antigen, Rabies virus envelope glycoprotein IgG, nucleic acid.
L3CT (Class 3 IVDs)	**CT917 Reovirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Reovirus. Reovirus antigen, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT746 Respiratory syncytial virus (RSV) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Respiratory syncytial virus (RSV). Respiratory syncytial virus (RSV) antigen, IgA, IgG, IgM, IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT931 Rhinovirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Rhinovirus. Rhinovirus antigen, IgA, IgA/IgG, nucleic acid.
L3CT (Class 3 IVDs)	**CT769 Rift Valley Fever virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Rift Valley Fever virus. Rift Valley fever virus IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3	**CT720 Ross River virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Ross River virus.

IVDs)	Ross River virus (RRV) IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT770 Rotavirus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Rotavirus. Rotavirus antigen, IgG, IgM, nucleic acid.
L3CT (Class 3 IVDs)	**CT771 Rubella virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Rubella virus. Rubella virus antigen, IgG, IgM, IgG/IgM, nucleic acid, total antibody.
L3CT (Class 3 IVDs)	**CT911 Sandfly fever virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Sandfly fever virus. Sandfly fever virus (Naples serotype) IgG, IgM, IgG/IgM, total antibody; Sandfly fever virus (Sicilian serotype) IgG, IgM, IgG/IgM, total antibody; Sandfly fever virus (Toscana serotype) IgG, IgM, IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT721 Semliki Forest virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Semliki Forest virus. Semliki Forest virus IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT772 Severe acute respiratory sydrome-associated coronavirus (SARS-CoV) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Severe acute respiratory sydrome-associated coronavirus (SARS-CoV). SARS-CoV antigen IgG, IgM, IgA/IgG/IgM, nucleic acid.
L3CT (Class 3 IVDs)	**CT722 Sindbis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Sindbis virus. Sindbis virus IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT728 St. Louis encephalitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to St. Louis encephalitis (SLE) virus. St. Louis encephalitis (SLE) virus antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT729 Tick-borne encephalitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Tick-borne encephalitis (TBE) virus. Tick-borne encephalitis (TBE) virus antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT756 Varicella zoster virus (Human herpesvirus 3) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Varicella zoster virus (VZV), also referred to as Human herpesvirus 3. Varicella-zoster virus (VZV) antigen, IgA, IgG, IgM, IgA/IgG/IgM, total antibody.
L3CT (Class 3 IVDs)	**CT723 Venzuelan equine encephalitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Venzuelan equine encephalitis (VEE) virus. Venezuelan equine encephalitis (VEE) virus antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT773 Vesicular stomatitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Vesicular stomatitis virus. Vesicular stomatitis virus IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT730 West Nile virus (WNV) IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to West Nile virus. West Nile virus antigen, IgG, IgM, IgA/IgG/IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class	**CT724 Western equine encephalitis virus IVDs** IVDs that are intended to be used in testing to provide information about infection

3 IVDs)	with or exposure to Western equine encephalitis (WEE) virus. Western equine encephalitis (WEE) virus antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT731 Yellow fever virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Yellow fever virus. Yellow fever virus antigen, IgG, IgM, nucleic acid, total antibody, total antibody neutralization.
L3CT (Class 3 IVDs)	**CT924 Zika virus IVDs** IVDs that are intended to be used in testing to provide information about infection with or exposure to Zika virus. Zika virus IgG, IgM, nucleic acid.

Instrument and analyser IVDs

L1CT (Class 1 IVDs)	**CT943 Instrument/analyser IVDs** Manual, semi-automated or automated equipment or apparatus that are intended by the manufacturer to be used as an in vitro diagnostic medical device (IVD) for the purposes of processing, examining and/or providing information about a clinical specimen. Amino acid analyser, Antimicrobial susceptibility analyser, Atomic absorption spectrophotometer, Blood culture analyser, Laboratory blood gas analyser, Point-of-care blood gas analyser, Blood tube mixer, Cell washer, Chemiluminescent immunoassay analyser, Stationary clinical chemistry metabolic profile analyser, Portable clinical chemistry metabolic profile analyser, Laboratory coagulation analyser, Home-use/point-of-care coagulation analyser, Laboratory co-oximetry analyser, Point-of-care co-oximetry analyser, Densitometry analyser, Dry clinical chemistry analyser, Electrophoresis analyser, Enzyme immunoassay analyser, Erythrocyte sedimentation rate (ESR) analyser, Flow cytometry analyser, Portable fluorescent immunoassay analyser, Stationary fluorescent immunoassay analyser, Fluorescent spectrophotometer, Gas chromatography analyser, Laboratory glucose analyser, Home-use/point-of-care glucose analyser, Haematology analyser, Laboratory haemoglobin analyser, Point-of-care haemoglobin analyser, Haematocrit analyser, High performance liquid chromatography analyser, Immunohaematology/blood bank analyser, Ion selective analyser, Isothermal nucleic acid amplification analyser, Liquid-phase immunoassay analyser, Mass spectrometry analyser, Microarray analyser, Microplate reader, Microplate washer, Microscope slide maker, Microscope slide stainer, Microscope slide maker/stainer, Blood microscopic viewing instrument, Microorganism identification analyser, Yeast/fungi identification analyser, Microorganism identification/antimicrobial-susceptibility analyser, Laboratory multichannel clinical chemistry analyser, Point-of-care multichannel clinical chemistry analyser, Home-use multichannel clinical chemistry analyser, Multichannel immunoassay analyser, Multiplex analyser, Nephelometry immunoassay analyser, Nephelometry instrument, Microorganism-density nephelometry instrument, Osmometric analyser, pH meter, Platelet aggregation analyser, Radioimmunoassay analyser, Radioimmunoassay analyser, Sample handling instrument, Spermatozoa/semen analyser, Tissue processing analyser, Thermal cycler nucleic acid amplification analyser, Laboratory urine analyser, Point-of-care urine analyser.

Microbiological culture media IVDs

L1CT (Class 1 IVDs)	**CT922 Microbiological culture media IVDs** IVDs that are intended to be used as culture media for the selection, growth, isolation and/or differentiation of tissue cells or microorganisms including bacteria, yeast, fungi and/or viruses from a clinical specimen. Actidione agar, Aeromonas culture media, Anaerobic culture media, Antimicrobial activity testing media, Aspergillus sp culture media, BiGGY (bismuth, glycine and glucose for yeast)/Nickerson agar culture media, Bile esculin azide culture media, Bile esculin culture media, Bismuth Sulphite culture media, Bordetella species culture media, Brain heart infusion agar culture media, BCP (bromocresyl purple) agar culture media, Brucella species culture media, Burkholderia cepacia culture media, Burkholderia pseudomallei culture media, Campylobacter species (Blaser-Wang) culture media, Campylobacter species (Butzler) culture media, Campylobacter species (CAT) culture media, Campylobacter species (CCDA) culture media, Campylobacter species (Karmali) culture media, Campylobacter species (Preston) culture media, Campylobacter species (Skirrow) culture media, Candida species culture media, Candida species chromogenic culture media, Cetrimide culture media, CGB (L-Canavanine Glycine Bromthymol blue) culture media, Chocolate agar culture media, Chocolate agar with factors X + V culture media, Chocolate/Haemophillus agar culture media, Chocolate/Neisseria agar culture media, CLED (cystine, lysine, electrolyte deficient) agar culture media, Clostridium species culture media, Clostridum difficile culture media, Coletsos culture media, CNA (colistin/nalidixic acid) culture media, Colistin oxolinic acid blood agar (COBA) culture media, Columbia Agar culture media, Columbia agar culture media with 5% horse blood, Columbia agar culture media with 5% sheep blood, Corynebacterium species (Hoyle) culture media, Corn meal agar culture media, Czapek-Dox agar culture media, Dermatophyte agar culture media, Desoxycholate agar culture media, DNase agar culture media, Egg yolk agar culture media, Egg yolk tellurite culture media, Eosin-methylene blue agar culture media, ESBL (Extended Spectrum Beta-Lactamase) culture media, ESBL (Extended Spectrum Beta-Lactamase) chromogenic culture media, Drigalski agar culture media, Gardnerella vaginalis culture media, Gonorrhoea culture media, Group B Streptococus culture media, Group B Streptococus chromogenic culture media, Haemophillus species identification media, Hektoen enteric culture media, Helicobacter pylori culture media, Kligler Iron agar culture media, Lactritmel agar culture media, Legionella BCYE culture media, Legionella BMPA culture media, Legionella GVPC culture media, Loeffler agar culture media IVD, Lowenstein-Jensen culture media, Lysine Iron agar culture media, Lysine Iron agar culture media, MacConkey agar culture media, MacConkey agar without crystal violet culture media, Malt extract agar culture media, Mannitol salt agar culture media, Methicillin resistant Staph aureus (MRSA) screening agar culture media, Methicillin resistant Staph aureus (MRSA) chromogenic agar culture media, Middlebrook (Mycobacterium) agar culture media, MLCB agar (mannitol, lysine, crystal violet, brilliant green) culture media, Motility culture media, MILS (Motility Indole Lysine Sulphide) culture media, MR-VP agar (Methyl red/Vogues-Proskauer) culture media, Mycobiotic agar culture media, Mycoplasma agar culture media, New York City culture media, Nutrient Agar culture media, Peptone agar culture media, Potato dextrose agar culture media; Pseudomonas CFC (cephaloridine, fucidin and cetrimide) agar culture media, Pseudomonas CN (cetrimide and nalidixic acid) culture media, Sabouraud Actidione (cyclohexamide) Chloramphenical agar culture media, Sabouraud Dextrose agar culture media, Salmonella chromogenic culture media, Salmonella chromogenic culture media, Salmonella/Shigella species culture media, Shahadi Ferguson perfringens culture media, Simmons citrate culture media, Sulphide Indole Motility (SIM), Sorbitol-MacConkey agar culture media, Staph aureus chromogenic culture media, SXT culture media, Thayer-Martin culture media, Tinsdale culture media, Triple sugar Iron (TSI) agar culture media, Tryptic Soy Agar culture media, Tryptose blood agar culture media, Urea agar culture media, Urinary micororganisms culture media, Urinary micororganisms chromogenic culture media, Vibrio species (TCBS) culture media, Vogel-Johnson agar culture media, VRE/HLARE culture media, VRE chromogenic culture media, XLD (Xylose Lysine Deoxycholate) culture media, Yersinia (CIN) culture media, Alkaline peptone water culture media, Blood culture kit, Blood culture aerobic broth, Blood culture anaerobic broth, Blood culture brain heart infusion broth, Blood culture brain heart infusion broth and Middlebrook 7H9 media, Blood culture columbia broth, Blood culture tryptic soy broth, Blood culture thiol broth, Blood culture thioglycollate broth, Aerobic broth culture media, Anaerobic broth culture media, Antimicrobial broth culture supplement, Arcobacter species broth culture media, Brain heart infusion broth culture media, Campylobacter broth culture media, Cooked meat broth culture media, Czapek-Dox broth culture media, Group B Streptococus broth culture media, Heart infusion broth culture media, MacConkey broth culture media, Malt extract broth culture media, Middlebrook (Mycobacteria) broth culture media, MR-VP (Methyl red/Vogues-Proskauer) broth culture media, Mycoplasma broth culture media, Nutrient broth culture media, Oxidative/Fermentative (OF) broth culture media, Sabouraud broth culture media, Salt tolerance broth culture media, Schaedler anaerobe broth culture media, Selenite broth culture media, Selenite-cystine broth culture media, Selenite-mannitol broth culture media, Sterile distilled water media/diluent, Sterile saline media/diluent, Tryptic soy broth culture media, Thioglycolate broth culture media, Tissue culture media, Todd-Hewitt broth culture media, Trichomonas broth culture media,

Tryptose phosphate broth culture media, Urea broth culture media, Viral culture media, VRE/HLARE broth culture media, Diagnostic susceptibility testing media, Fastidious organism susceptibility testing media, Fungal susceptibility testing media, Haemophillus susceptibility testing media, Mueller-Hinton agar susceptibility testing media, Mueller-Hinton agar with sheep blood susceptibility testing media, Mycobacteria susceptibility testing media, Mueller-Hinton broth susceptibility testing media, Amies transport media, Anaerobic transport media, Bordetella species transport media, Chocolate agar with factors X + V transport media, Carey-Blair transport media, Helicobacter pylori transport media, Stuart transport media, Viral transport media.

Software IVDs

L1CT (Class 1 IVDs)	**CT944 Software IVDs** Software that has been developed for the purpose of being incorporated into an IVD or that is intended for use as an IVD in its own right. Software systems may be an integrated collection of items which include computer programs, procedures and any associated documentation and data. All analytes as represented in Level 2 software collective terms.
L2CT (Class 2 & 3 IVDs)	**CT1250 Analyser software IVDs** Software that is intended to be incorporated into an IVD analyser to establish or supplement operational functions which may include the processing of specimens, generation of data, interpretation, storage, display and/or reporting of results obtained from a clinical laboratory specimen. Laboratory analyser software
L2CT (Class 2 & 3 IVDs)	**CT910 Interpretive software IVDs** An interpretative software algorithm intended to be applied to a clinical result or set of results obtained through testing in order to identify and/or formulate additional clinical information which may then be used to guide patient management. First trimester screening assessment trisomy 21 (Down syndrome) risk software.
L2CT (Class 2 & 3 IVDs)	**CT1251 Laboratory information system IVDs** Software that is intended to be used either as an independent system or incorporated into an existing network to establish or supplement the functions of a clinical laboratory information system including the generation of data, interpretation, storage, and/or reporting of results obtained from a clinical laboratory specimen. Clinical laboratory information system software, Blood bank laboratory information system software.

Specimen receptacle IVDs

L1CT (Class 1 IVDs)	**CT936 Specimen receptacle IVDs** IVDs that are vessels with or without additives that are intended to be used for the collection, containment, preservation and/or transport of all clinical specimens for analysis or investigation**.**
L2CT (Class 2 & 3 IVDs)	**CT933 Blood specimen collection IVDs** Blood collection tubes or vessels and other related products, which may or may not contain additives and be under vacuum, that are intended to be used for the collection, containment and/or transport of clinical blood specimens for analysis or investigation. Blood gas syringes with various anticoagulants; Capillary blood collection tubes with various coagulants; Evacuated blood collection tubes with various anticoagulants, preservatives, gel separators, clot activators, additive free; Non-evacuated blood collection tubes with various anticoagulants, preservatives, gel separators, clot activators, additive free;
L2CT (Class 2 & 3 IVDs)	**CT1259 Non-blood specimen receptacle IVDs** IVDs that are specimen receptacles or containers that are intended to be used for the collection, containment and/or transport of specific types of clinical laboratory specimens and all other general clinical specimens other than blood. Cervical cytology specimen container, microscopy slide; Colonic cytology specimen container; Diagnostic fungal specimen envelope; Drug testing specimen collection; Faeces specimen container with preservative, additive free, DNA preservative, transport buffer, acid-alcohol fixative, polyvinyl fixative, formaldehyde/acetate fixative, Schaudinn's fixative; General specimen container - sterile, non-sterile, no additive; General specimen microscopy slide, normal saline, formalin; Nasopharageal aspirate container; Specimen container mailer, Insulated specimen container mailer; Sputum container - sterile, no additive; Sweat specimen container, Urine specimen containers for drug testing, midstream collection, 24 hour urine collection containing various additives - boric acid, sodium formate, ethyl paraben, sodium porpionate, chlorhexidine,

Tissue typing IVDs

L1CT (Class 1 IVDs)	**CT891 Tissue typing IVDs** IVDs that are intended to be used in tissue typing to provide information about human leukocyte antigen (HLA) specificities, HLA antibodies, platelet antigens and antibodies, and to determine the compatibility of white cells, platelets or tissue for transfusion or transplantation. All analytes as represented in Level 2 & 3 tissue typing collective terms.
L2CT (Class 2 IVDs)	**CT289 Human leukocyte antigen (HLA) typing IVDs** IVDs that are intended to be used in tissue typing to provide information about human leukocyte antigen (HLA) specificities. All analytes as represented in Level 3 HLA tissue typing collective terms.
L3CT (Class 3 IVDs)	**CT893 Human leukocyte antigen A (HLA-A) typing sera IVDs** Immunoglobulins that are intended to be used in tissue typing to determine specificity of antigens from the human leukocyte antigen A (HLA-A) locus. The following antigens from the HLA-A locus:HLA-A1, A10, A11, A19, A2, A23 (A9), A24 (A9), A25 (A10), A26 (A10), A28, A29, A3, A30 (A19), A31 (A19), A32, A33, A34 (A10), A36, A43, A66 (A10), A68 (A28), A69 (A28), A74 (A19), A80.
L3CT (Class 3 IVDs)	**CT894 Human leukocyte antigen B (HLA-B) typing sera IVDs** Immunoglobulins that are intended to be used in tissue typing to determine specificity of antigens from the human leukocyte antigen B (HLA-B) locus. The following antigens from the HLA-B locus: HLA-B12, B13, B15, B16, B18, B20, B27, B35, B37, B38 (B16), B39 (B16), B40, B41, B42, B44, B45, B46, B47, B48, B49, B5, B51, B52, B53, B54 (B22), B55 (B22), B56 (B22), B57 (B17), B59, B60 (B40), B61 (B40), B62 (B15), B63 (B15), B63 (B15), B64 (B14), B65 (B14), B67, B7, B71 (B70), B72 (B70), B73, B75 (B15), B76 (B15), B77 (B15), B78, B8, B81, Bw4, Bw6.
L3CT (Class 3 IVDs)	**CT895 Human leukocyte antigen C (HLA-C) typing sera IVDs** Immunoglobulins that are intended to be used in tissue typing to determine specificity of antigens from the human leukocyte antigen C (HLA-C) locus. The following antigens from the HLA-C locus: HLA-Cw1, Cw10 (Cw3), Cw2, Cw4, Cw5, Cw6, Cw7, Cw8, Cw8, Cw9 (Cw3).
L3CT (Class 3 IVDs)	**CT900 Human leukocyte antigen DP (HLA-DP) typing sera IVDs** Immunoglobulins that are intended to be used in tissue typing to determine specificity of antigens from the human leukocyte antigen DP (HLA-DP) locus. The following antigens from the HLA-DP locus: HLA-DPw1, DPw2, DPw3, DPw4, DPw5, DPw6.
L3CT (Class 3 IVDs)	**CT897 Human leukocyte antigen DQ (HLA-DQ) typing sera IVDs** Immunoglobulins that are intended to be used in tissue typing to determine specificity of antigens from the human leukocyte antigen DQ (HLA-DQ) locus. The following antigens from the HLA-DQ locus: HLA-DQ1, DQ2, DQ3, DQ4, DQ5 (DQ1), DQ6 (DQ1), DQ7 (DQ3), DQ8 (DQ3), DQ9 (DQ3).
L3CT (Class 3 IVDs)	**CT896 Human leukocyte antigen DR (HLA-DR) typing sera IVDs** Immunoglobulins that are intended to be used in tissue typing to determine specificity of antigens from the human leukocyte antigen DR (HLA-DR) locus. The following antigens from the HLA-DR locus: HLA-DR1, DR10, DR103, DR11, DR12, DR13, DR14, DR15, DR16, DR17 (DR3), DR18 (DR3), DR4, DR51, DR52, DR53, DR7, DR8, DR9.
L3CT (Class 3 IVDs)	**CT892 Multiple human leukocyte antigens (HLA) typing IVDs** IVDs that are supplied together and intended to be used in combination to provide tissue typing information about multiple human leukocyte antigens (HLA) from one or multiple loci. HLA class I & II antigen nucleic acid, HLA class I & II antigens, HLA class I antigen nucleic acid, HLA class I antigens, HLA class II antigen nucleic acid, HLA class II antigens.
L2CT (Class 2 IVDs)	**CT898 Human leukocyte antigen (HLA) antibody screening and identification IVDs** IVDs that are intended to be used in tissue typing to provide information about the presence and specificity of antibodies directed against human leukocyte antigens (HLA). HLA class 1-associated MICA antibody, HLA class I & II antibody screening, HLA class I antibody identification panel, HLA class I antibody screening, HLA class II antibody

	identification panel, HLA class II antibody screening.
L3CT (Class 3 IVDs)	**CT1038 Multiple human leukocyte antigen (HLA) antibodies IVDs** IVDs that are supplied together and intended to be used in combination to provide tissue typing information about antibodies directed against human leukocyte antigens (HLA) from multiple loci. HLA class 1-associated MICA antibody, HLA class I & II antibody screening, HLA class I antibody identification panel, HLA class I antibody screening, HLA class II antibody identification panel, HLA class II antibody screening.
L2CT (Class 2 & 3 IVDs)	**CT1041 Human neutrophil antigen (HNA) typing IVDs** IVDs that are intended to be used in tissue typing to provide information about the specificity of human neutrophil antigens (HNA). Human neutrophil antigen HNA-1a/HNA-1b/HNA-1c typing, human neutrophil antigen HNA-4a/HNA-4b typing, human neutrophil antigen HNA-5a/HNA-5b typing, multiple human neutrophil antigen (HNA) typing.
L2CT (Class 2 & 3 IVDs)	**CT1042 Human neutrophil antigen (HNA) antibody screening and identification IVDs** IVDs that are intended to be used in tissue typing to provide information about the presence and specificity of antibodies directed against human neutrophil antigens (HNA). Human neutrophil antigen (HNA) multiple antibody screening/identification kit
L2CT (Class 2 & 3 IVDs)	**CT1039 Human platelet antigen (HPA) typing IVDs** IVDs that are intended to be used in tissue typing to provide information about the specificity of human platelet antigens (HPA). Multiple human platelet antigen (HPA) typing.
L2CT (Class 2 & 3 IVDs)	**CT1040 Human platelet antigen (HPA) antibody screening and identification IVDs** IVDs that are intended to be used in tissue typing to provide information about the presence and specificity of antibodies directed against human platelet antigens (HPA). Human platelet antigen (HPA) multiple antibody screening/identification.
L2CT (Class 2 & 3 IVDs)	**CT899 Tissue typing-related IVDs** IVDs that are intended to be used alone or in combination with other IVDs to perform various tissue typing-related tests and procedures. (e.g. lymphocyte separation reagents, cell preservative solutions). B lymphocyte magnetic separation reagent, lymphocyte separation media, lymphocyte stabilization, T lymphocyte magnetic separation reagent.

Therapeutic Goods Administration

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