



# **Therapeutic Goods (Restricted Representations—Rapid Antigen Test and Nucleic Acid Amplification Test Kits) Permission 2026**

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I, Michael Shum, as delegate of the Secretary of the Department of Health, Disability and Ageing, make the following permission.

Dated 19 June 2026

Michael Shum  
Acting Assistant Secretary  
Regulatory Compliance Branch  
Health Products Regulation Group  
Department of Health, Disability and Ageing

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## 1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Rapid Antigen Test and Nucleic Acid Amplification Test Kits) Permission 2026*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is made.	20 June 2026

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under section 42DK of the *Therapeutic Goods Act 1989*.

## 4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) advertise;
- (b) health practitioner;
- (c) included in the Register;
- (d) label;
- (e) medical practitioner;
- (f) Register;
- (g) therapeutic goods;
- (h) Therapeutic Goods Advertising Code.

In this instrument

*Act* means the *Therapeutic Goods Act 1989*.

*Class 1 IVD medical device* has the same meaning as in the MD Regulations.

*Class 3 IVD medical device* has the same meaning as in the MD Regulations.

*instructions for use* has the same meaning as in the MD Regulations.

*IVD medical device* has the same meaning as in the MD Regulations.

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***IVD medical device for self-testing*** has the same meaning as in the MD Regulations.

***MD Regulations*** means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

***point of care testing*** has the same meaning as in the MD Regulations.

***prominently displayed or communicated*** has the same meaning as in the Therapeutic Goods Advertising Code.

***relevant practitioner*** means:

- (a) a health practitioner; or
- (b) a person registered under a law of a State or internal Territory to practice paramedicine.

Note: The term health practitioner is defined in subsection 3(1) of the Act to mean a person who is registered or licenced under a law of a State or internal Territory to practice in certain health professions specified in the definition, including medicine.

***restricted representation*** means a representation referred to in section 42DD of the Act.

***SARS-CoV-2 (COVID-19)*** means the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes the disease COVID-19.

***specified goods*** means a Class 3 IVD medical device that:

- (a) is included in the Register; and
- (b) is a rapid antigen test kit or a nucleic acid amplification test kit; and
- (c) has an intended purpose accepted in relation to its inclusion in the Register that relates to the detection of one or more of the following only:
  - (i) SARS-CoV-2 (COVID-19);
  - (ii) influenza A;
  - (iii) influenza B;
  - (iv) respiratory syncytial virus (RSV).

Note: The specified goods may be an IVD medical device for self-testing, or an IVD medical device for point of care testing by a relevant practitioner, or both.

## 5 Permission

For subsection 42DK(1) of the Act, in relation to each item in the table in Schedule 1, the representations specified in column 2 (to the extent that those representations are restricted representations) are permitted to be used in advertisements specified in column 3 about the specified goods, subject to the conditions (if any) specified in column 4.

## 6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

# Schedule 1—Permission

Note: See section 5.

<b>Permitted use of restricted representations</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Representation</b>	<b>Advertisement</b>	<b>Conditions</b>
1	a representation to the effect that the specified goods may be used to detect possible infection with one or more of the following: (a) influenza A; (b) influenza B; (c) respiratory syncytial virus (RSV); (d) SARS-CoV-2 (COVID-19)	an advertisement about the specified goods including, but not limited to, an advertisement that is: (a) on the label of the specified goods; or (b) on the package in which the specified goods are contained; or (c) on any material included with the package in which the specified goods are contained, including instructions for use	all of the following: (a) the advertisement must not be inconsistent with government health messaging in relation to testing for a disease, condition or ailment mentioned in column 2; (b) the advertisement must not be inconsistent with the intended purpose of the specified goods accepted in relation to the inclusion of the specified goods in the Register, or any conditions of inclusion relating to the goods; (c) if the specified goods are for point of care testing only—the advertisement must contain a statement, prominently displayed or communicated, to the effect that the goods are intended for use by a relevant practitioner and must not be used for self-testing; (d) if the specified goods are an IVD medical device for self-testing—the advertisement must contain statements, which are prominently displayed or communicated, to the effect that: (i) a negative test result may not be conclusive; and (ii) if you test negative using the goods, but are symptomatic and at higher risk of serious disease, see a medical practitioner for further

<b>Permitted use of restricted representations</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Representation</b>	<b>Advertisement</b>	<b>Conditions</b>
			<p>testing;</p> <p>(e) the advertisement must not:</p> <p>(i) include a claim that the specified goods are diagnostic; or</p> <p>(ii) state or infer that polymerase chain reaction (PCR) testing, or other laboratory testing, will never be required; or</p> <p>(iii) state that the specified goods are capable of early detection; or</p> <p>(iv) include claims relating to the accuracy, specificity, sensitivity or limit of detection of the specified goods (except where such claims are included solely in instructions for use relating to the goods); or</p> <p>(v) include comparisons with other therapeutic goods; or</p> <p>(vi) infer that the specified goods are capable of determining whether or not a person is infectious, or the degree of their infectiousness</p>
2	a representation that refers, expressly or by implication, to one or more of the diseases, conditions or ailments mentioned in column 2 of item 1, where the reference is necessary to provide information about the proper use of the specified goods	an advertisement made in accordance with item 1 that includes instructions for use relating to the specified goods (including, but not limited to, instructions in written, graphical, pictorial or video form)	

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## **Schedule 2—Repeals**

Note: See section 6.

### ***Therapeutic Goods (Restricted Representations—COVID-19 and Influenza Test Kits) Permission 2022***

#### **1 The whole of the instrument**

Repeal the instrument.