From: [redacted]
To: IRIS
Cc: [redacted]
Subject: RE: TGA Request for Information - DIR 65968 - Monash IVF Group
Date: Friday, 27 November 2020 3:46:57 PM
Attachments: image002.png
image003.png
image004.png
TGA Response to NI Questions v1.0 27Nov20.pdf
Group-Adverse-Event-and-Feedback-Policy-v5-0-09Nov20.pdf
IVD Validation Document - Next Generation Sequencing V1.0.pdf
Monash IVF Group validation of NGS summary.pdf

Please find attached Monash IVF Group's response with the information requested.

Kind regards

[redacted]

[redacted]

T. [redacted] - M. [redacted] - F. [redacted]
[redacted]

Monash IVF Group Limited
Pelaco Building 1
Level 1, 21-31 Goodwood Street
RichmondVICAustralia3121

monashivfgroup.com

From: [redacted]
Sent: Friday, 30 October 2020 1:05 PM
To: [redacted]
Subject: TGA Request for Information - DIR 65968 - Monash IVF Group - Response due by COB 26 November 2020 [SEC=OFFICIAL]

Dear [redacted]

To assist in the evaluation and resolution of the Device Incident Report (DIR 65968) you recently submitted to the TGA, please provide the information requested in the attached letter and return it to this office **within 20 working days of the date of this letter,** and no later than COB

26/11/2020.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on [redacted] or email IRIS@health.gov.au.

Yours sincerely,

[redacted]

[redacted]
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Phone: [redacted]
Email: [redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Monash IVF Group Limited
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Level 1, 21-31 Goodwood Street
Richmond VIC 3121 Australia
+61 3 9420 8235
groupenquiries@monashivf.com
monashivfgroup.com.au
ABN 90 169 302 309

27 November 2020

[redacted]
Delegate of the Secretary Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

IRIS@health.gov.au and [redacted]

Dear [redacted]

Re: DEVICE INCIDENT REPORT DIR 65968

Please find below the Monash IVF Group responses to your letter of 30 October, regarding our Adverse Event report relating to the suspension of the cell-free PGT-A test.

1. Please provide a general description of the device

[redacted]

Results of either test may indicate that the embryo:

- Is diagnosed as chromosomally normal and suitable for transfer– Euploid or NAD (No abnormality detected)
- Is diagnosed as chromosomally abnormal and unsuitable for transfer - Aneuploid
- Is unable to yield a result – inconclusive and is treated in the same way as an untested embryo

Cell-free PGT-A is screening test and is only designed to analyse whole chromosome number. The screening tool does not give any information relating to mosaicism or other genetic conditions or abnormalities including single gene disorders as well as small duplication/deletions. There is a 3-5% background population risk for birth defects or genetic conditions in any pregnancy. Cell-free PGT-A is only designed to detect abnormal chromosome number (aneuploidy) which may lead to miscarriage or serious conditions adversely effecting pregnancy and live birth and not these other conditions.

Patients are advised as part of the consenting process that for both Biopsy and cell-free PGT-A "This test is only a screening test and therefore cannot provide an absolute guarantee of the chromosome status of the embryo. In some embryos, the biopsied cell/s or culture media may not be representative of the whole embryo.

While every effort is made to ensure that the PGT-A test offered has the highest possible accuracy using the currently available technology, results are not 100% accurate. **Therefore, prenatal diagnosis is highly recommended in an ensuing pregnancy**."

2. Based upon your submitted report, you first became aware of a significant increase in aneuploidy rates in the NI-PTG tested embryos, when compared to the invasive PTG tested embryos, in June2020 as a part of your routine surveillance program. Please provide:

a) **a copy of your documented procedures for reporting adverse events –** Monash IVF Group Adverse Events and Feedback Policy v5.0 09Nov20 is attached

b) a rationale as to why this adverse event was not reported to the TGA until October 2020 – While initial concerns about the test were raised in June 2020, it was not until further investigation revealed irregularities relating to the validation data, which led to the decision to suspend the test with effect from 25 September. At that time, the TGA Reporting requirements were assessed by the team at Monash IVF but the precautionary suspension of the test did not appear to meet the Adverse Event Criteria listed on the website: **https://www.tga.gov.au/adverse-event-reporting**

Adverse event

An adverse event is an occurrence involving a medical device that meets the following criteria:

- death of a patient, health care provider, user or other person; or
- a serious injury or serious deterioration to a patient, health care provider, user or other person, including;
  - a life-threatening illness or injury;
  - permanent impairment of a body function;
  - permanent damage to a body structure; or
  - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

c) any changes you have made, or intend to make, in relation to your reporting procedures for adverse events

The Monash IVF Group Adverse Events and Feedback Policy was updated to the version provided, following a discussion with [redacted] to include the reference and link to the NPAAC document: Requirements For The Development And Use Of In-House In Vitro Diagnostic Medical Devices (IVDs).

3. **Based upon your submitted report, you stated that your post-launch surveillance sample size was 805 when you first became aware of this issue in June 2020. During our phone discussion of 22 October 2020, you advised TGA that the number of patients tested using the NI PGT-A test was in the order of 1300, of which around 60% had returned a positive result for aneuploidy. Please confirm:**

   a) **when you stopped using the test** Monash IVF Group suspended the test when investigations revealed irregularities relating to the validation data, which led to the decision to suspend the test with effect from 25 September.

   b) **how many tests were conducted after June 2020 when you identified the issue** The observations as at June 2020 were not the grounds for suspending the test. The decision to suspend the test related to the irregularities relating to the validation data, which were identified in late September 2020.

4. **Please provide details of your system for reviewing experience gained in the post-production phase for the medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied to the design or production of such devices.**

The Monash IVF Group genetics laboratory at Repromed currently participates in all available external QC programs that are available for our preimplantation genetics testing program, however an external QC program does not exist for cell-free PGT so instead we have set up an internal QC program. The results from our internal QC program have all been concordant since it was initiated.

As an additional aspect to our quality assurance programme we also monitor the false negative rates in all screening tests that we offer through the Repromed genetics laboratory. The cell free PGT-A false negative rate appears to be in line with what we see in our biopsy programme and this will continue to be monitored for embryos in storage that were previously screened and have yet to be transferred.

Learnings from our experience with this process will be incorporated into the future design of any tests implemented across Monash IVF Group.

5. **Please provide details of the design specifications for the device, including:**

   a) **any medical device standard that has been applied to the device**

   b) **the results of the risk analysis carried out**

   c) **if no medical device standard, or part of it, has been applied to the device, please provide the solutions adopted to ensure that each device complies with applicable provisions of the essential principles.**

We enclose a copy of the Monash IVF Group 'In house IVD Validation- Next generation sequencing' document, which includes this information.

6. Please provide a copy of the clinical evidence, in relation to the device, required by the clinical evaluation procedures, as described in the Part 8 of Schedule 3 of the Regulations.

We enclose a copy of the Monash IVF Group 'Summary of NGS Validation' document, which includes this information.

7. Please provide a copy of the validation report, including details of the tests or trials conducted prior to launching the device in testing clinics.

As described in the two documents provided in 5 & 6 above.

We hope that this information is sufficient to answer the questions raised, but if there is anything further that you require, please do not hesitate to contact me.

Kind regards

[redacted]

T. [redacted] - M. [redacted] - F. [redacted]
[redacted]

Monash IVF Group Limited
Pelaco Building 1
Level 1, 21-31 Goodwood Street
RichmondVICAustralia3121

Document Name: Adverse Event and Feedback Policy

Document Owner: Group Quality, Risk and Compliance Manager

In the event of a failure to or inability to comply with the process as described, users must follow the Emergency Procedures, as described in Section 4. Failure to comply with these instructions may constitute misconduct, such instances will be investigated and disciplinary action may be taken.

This Document ensures compliance with:	
Legislation / Regulations / Standards	RTAC Code of Practice 2017 AS ISO 15189:2013 Diagnostic Imaging Accreditation Scheme NSQHS Standards Second Edition Therapeutic Goods Regulations (Medical Devices) Privacy Amendment (Notifiable Data Breaches) Act 2017 Occupational Health & Safety Act 2004 NSW Private Health Facilities Act 2007 and associated regulations

Risks that this process manages	Inability to provide appropriate level of care to patients if adverse events are not escalated to appropriate people Inability to manage risk if adverse events are not communicated Lack of ability to provide continual improvement Legal action against Monash IVF Group Loss of reputation Loss of license due to non-compliance with legislation/regulations Loss of patient confidence Loss of patients Loss of revenue Workplace injury if hazards are not managed appropriately

Definitions
***MVF** - Monash IVF Group and companies within the Group*
***Events** – A thing that happens that requires reporting in Riskman: incidents, near misses, feedback (complaints and compliments), suggestions for improvement, supplier issues, equipment failure, audit findings and hazards*
***Adverse Event** - An Adverse Event is an unexpected outcome relating to the provision of services by MVF. This includes incidents, accidents and near misses and legal claims made against MVF. NSW Health further define an adverse event as an unintended injury to a patient, or a complication caused by the health care management of a patient, that results in a major permanent loss of function (being sensory, motor, physiological or psychological) for the patient or death of the patient.*
***Feedback** - Is information provided by a patient or customer that relates to their perception of the service provided my MVF. This includes complaints, compliments and suggestions for improvement.*

Critical Adverse Event or Emergency *- The occurrence of any event that causes an immediate and catastrophic interruption or disruption or the threat thereof to the business's ability to safely deliver business services.*
OHSS - Ovarian Hyperstimulation Syndrome
Hazard *- Something that has the potential to cause harm (injury or damage)*
RTAC SAE *- Is an Adverse Event that meets the Reproductive Technology Accreditation Committee definition of Serious Adverse Event. Some RTAC SAE are classified as Notifiable (RTAC SNAE)*
RTAC SNAE *- Is an Adverse Event that meets the Reproductive Technology Accreditation Committee definition of Serious Notifiable Adverse Event. Specific reporting requirements relate to these events.*
Corrective Action *- Actions taken to resolve the current event*
Preventive Action *- Actions taken to prevent the event from re-occurring*
TGA *– Therapeutic Goods Administration*
RTAC *– Reproductive Technology Accreditation Committee*
MAC *– Medical Advisory Committee*
Reportable Adverse event *– an event that meets the criteria of the relevant regulating body/ies. See Appendix 2 for details*

Related Documents	• *Emergency Plan – Delegation of Authority Policy* • *Site Specific Emergency Plans* • *IT Disaster Recovery Plan* • *IT Security Incident Plan*

Purpose and Scope

This document describes the Adverse Event and Feedback Management principles to be applied in each business unit within the Monash IVF Group (MVF).

Critical or Emergency events may require immediate management; considerations and authorities are described in the MVF *Emergency Plan – Delegation of Authority Policy*

Policy

It is MVF Policy:

That the following principles are applied and documentation kept relating to all Adverse Events and Feedback:

- ✓ Immediate assistance must be provided to the person/s affected
- ✓ In the event of personal injury, the area should be made safe, but preserved until such time as any investigation into the event, by MVF or external authorities has concluded
- ✓ An immediate assessment of the potential for continuing risk of harm to the person or others should be conducted to determine any immediate actions required
- ✓ All employees have access to Riskman to report Adverse Events and Feedback, user levels are defined in Appendix 1
- ✓ All Events are documented in RiskMan software, instructions are provided in Appendix 2.
- ✓ Clinical Adverse events must also be entered into the patient's RIMs record
- ✓ Basic information about the event should be gathered, while details are still fresh in their minds
- ✓ Escalation is made to the appropriate level
- ✓ Reports are made to regulators and/or insurers, as appropriate
- ✓ Investigation is conducted to identify the veracity of the report and to identify contributing factors
- ✓ Corrective and Preventive actions are implemented, as appropriate
- ✓ Timely responses are provided in response to complaints, in a manner agreed with the complainant (i.e. verbal / written)
- ✓ Review of all events is undertaken to facilitate continuous improvement
- ✓ Records of all events are retained
- ✓ Near misses should be reported, as well as actual events

Feedback, including complaints should:

- ✓ Be welcomed as an opportunity to review and improve services
- ✓ Be captured as and when provided
- ✓ Be actively sought from stakeholders at intervals not exceeding 12 months

Investigations should:

- ✓ Avoid blame
- ✓ Be impartial and confidential
- ✓ Include the people involved in the event
- ✓ Seek to identify facts, not opinions
- ✓ Focus on identifying the system failures that contributed to the event and ways to improve these systems
- ✓ Be documented

Documentation should:

- ✓ Be factual, not opinion
- ✓ Be legible and comprehensible after the fact
- ✓ Avoid abbreviations and jargon

Open Disclosure should:

- ✓ Be consistent with the Australian Open Disclosure framework (https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework/)
- ✓ Be documented
- ✓ Be practised on all cases, regardless of whether the patient would know that something had gone wrong
- ✓ Be timely, consideration should be given to when in their cycle a patient should be notified
- ✓ Express regret to the patient for what has happened
- ✓ Provide a factual explanation of what has happened
- ✓ Provide a plan and offer of support
    - o ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the adverse event
    - o assurance that any necessary follow-up care or investigation will be provided promptly and efficiently
    - o in the relevant settings, clarity on who will be responsible for providing ongoing care resulting from the adverse event
    - o contact details for any relevant service they wish to access
    - o information about how to take the matter further, including any complaint processes available to them

It is MVF Policy:

As a gesture of goodwill, to provide treatment at no cost to the patient to return them to where they would have been if the event had not occurred. E.g. if 3 embryos are lost as a result of an event, sufficient stimulated cycles will be provided at no out of pocket cost, until the patient has 3 more embryos available. Alternatives to a similar value can be agreed with the patient. In the event that an Event warrants a fee waive or refund, approval must be provided by the relevant General Manager in consultation with the Medical / Clinical Director.

In the event that an investigation into an Adverse Event or Feedback indicates that disciplinary action may be warranted, instructions and support should be requested from the relevant Human Resources personnel.

Compliance

Compliance with this policy must be monitored by each business unit by:

- ✓ Internal Audit/s (at intervals not exceeding 12 months). Audits must be conducted against this policy, as well as the requirements of the Legislation, Regulations and Standards listed on the front page of this document.
- ✓ Review of all Adverse Events and Feedback by the local Leadership Teams (monthly)
- ✓ Review of all patient related Adverse Events and Feedback by the MAC (at intervals not exceeding 3 months)

Non-Compliance with this policy

There is no tolerance to non-compliance to this policy.

Who:

All employees are required to:

- Report any events, feedback and hazards that they become aware of in RiskMan
- Participate in the investigation and resolution of the event, as required
- Encourage colleagues to notify incidents that have been identified

General Managers are responsible for:

- Ensuring that specific authority and responsibilities and user access levels are assigned for the management of Adverse Events and Feedback, including recording, investigation, documentation and reporting. Access levels for RiskMan are described in Appendix 1

Clinic Managers and Department Heads are responsible for:

- Ensuring that their employees have been educated about Adverse Event and hazard identification and reporting, including use of RiskMan
- The investigation and resolution of events that have occurred in their department / clinic,
- Consulting with the Medical Director / Clinic Director and other Key Personnel, as required
- Any disciplinary action to be taken in response to an event where employee conduct forms part of the investigation or is identified as a contributing factor, in consultation with HR.
- The implementation of and communication of any preventive actions to the affected teams.
- The planning of any internal audits to verify the effectiveness of preventive actions

Quality, Risk and Compliance Personnel are responsible for:

- Ensuring that Department Heads have been educated about Adverse Event identification and reporting, including use of RiskMan.
- Supporting Department Heads through the conduct of Contributing Factor Analysis Investigations, as required.
- Ensuring that notifications are made to the Insurers and/or Regulators, as described below and any follow up is provided, as requested.
- Posting all events in RiskMan
- Ensuring all events are addressed and closed out in a timely manner
- Set up and running of reports and trend identification processes, as required by the business and support Management Review Processes.

The **Group Quality, Risk & Compliance Manager** is responsible for:

- The online submission of IVD adverse events, via the TGA e Business Services portal
- Changes to RiskMan to ensure that the appropriate data is captured
- Managing access levels in RiskMan, as requested through IT Helpdesk requests

Leadership teams are responsible for**:**

- Ensuring that all events they are aware of have been reported in RiskMan
- Reviewing all Adverse Events* and Feedback to identify trends and consider additional Preventive Actions.

Medical Directors and Clinical Directors are responsible, through the MAC for:

- The review of patient related events, to ensure appropriate management of clinical cases and implementation of preventive actions.
- Recommending Corrective and Preventive actions to address clinical events

Laboratory Directors of Diagnostic Laboratories are responsible for:

- Informing the Regional Manager and the requesting doctor, if required.
- Advising and consulting with the Medical Director / APP / Designated Person to
    - Risk assess the event to determine the potential impact on results
    - Halt testing and/or reports, if required
    - Recall already released examinations, if required
    - Confirm when the examinations and reports can re-commence
    - Re-issue any results, as required

HR Team is responsible for:

- The management of workplace injuries and Worker related events
- Reporting injuries to relevant State's regulatory bodies
- Providing support to Leadership teams in the investigation of events that may lead to disciplinary action, as required.

** For privacy reasons, specifics of Worker events, including staff injuries should not be included in the Leadership review process. Trends and injury types can be reviewed.*

When:

All Events should be reported through RiskMan within 24 hours of them being identified.

Complaints should be acknowledged to the complainant within 3 business days and a timeframe for response should be given.

Events that have the potential to escalate should be brought to the immediate attention of the relevant General Manager and Group Quality, Risk and Compliance Manager; such notification to be made by telephone where possible, or alternatively automatic Alerts in Riskman ensure that these notifications occur. Such events include:

- ✓ Actual, possible or alleged breach of legislation / regulations
- ✓ Actual, possible or alleged error leading to loss of or risk to pregnancy
- ✓ Additional / unplanned medical attention required
- ✓ Adverse drug reaction
- ✓ Breach of confidentiality
- ✓ Death or hospitalisation (including ovarian torsion, blood loss or OHSS admission)
- ✓ Error relating to Patient ID with adverse clinical outcome

- ✓ Failure of recipient to attend for pregnancy test post Donor cycle
- ✓ Fire, bomb or other threatening activities in the health facility
- ✓ Loss or damage to biological material
- ✓ Medication error resulting in serious harm or death
- ✓ Patient outcomes or results could be affected by equipment failure
- ✓ Patient outcomes or results could be affected by process failure or failure to follow process
- ✓ Reported birth defects or unexpected intra-partum stillbirth
- ✓ Reported infection requiring antibiotics or surgery
- ✓ Site unsuitable for ongoing service provision
- ✓ Surgery or invasive procedure performed incorrectly resulting in serious harm or death
- ✓ Suspected incorrect or missed diagnosis
- ✓ Threatened Legal Action
- ✓ Threatened Media Involvement

How:

Internal

Monash IVF Group use Riskman to capture all Adverse events and Feedback (including complaints and compliments). As the user enters information into the fields, the form changes to reflect the relevant questions for the type of event that is being entered.

Internal reporting- RiskMan:

Full user guides are available within the RiskMan system, through Help\RiskMan Quick Guides

From within Citrix, open Windows Explorer and either follow the link from the Monash IVF Group Intranet, or navigate to http://riskman/Riskman

For any Serious and/or reportable events, the Investigating Manager can initiate the completion of an Incident Investigation and Contributing Factors Analysis form to assist in identifying the contributing factors and ensuring that any corrective/preventive actions are effective in preventing recurrence.

NSW Day Hospital only

For the NSW Day Hospital, when a "reportable incident" (see Appendix 3) is reported to the Chief Executive Officer (CEO), the CEO must appoint an Investigation Team in relation to the reportable incident. The team should include:

- o Some members who have fundamental knowledge of the care processes in the area where the incident occurred
- o People who were not involved in the incident or care of the patient, are not direct line managers of the area and who do not have any personal or non-professional connection with any clinician involved in the incident
- o Where possible, at least one person who is external to the organisation
- o Independent senior mental health clinicians, where the event relates to a suspected suicide, homicide or other serious crime

The team members must be advised of their role and obligations (see Appendix 4).

This team must use the Incident Investigation and Contributing Factors Analysis form and any other templates they deem appropriate to document their findings. Within 70 calendar days of the event, the completed report must be submitted to the CEO and the DSU MAC for approval. The CEO must ensure that the approved report is reported, in accordance with the external escalation requirements within 30 days of receipt.

Any actions identified through this process must be entered as CAPA in Riskman and the completed Incident Investigation and Contributing Factors Analysis form must be scanned into Riskman.

External Reporting –

See Appendix 3 for details of reportable event definitions

1. **Workcover –** Injury reports must be submitted within 24 hours using the relevant state Worker's compensation forms, available on their website.
2. **TGA In house IVD** registration – Reports must be made using the TGA's Medical Device Incident reporting System. Reports must include near misses and be made in the following timeframes:
    a. Information about an adverse event that presents a serious public health threat or concern must be reported to the TGA within 48 hours of the laboratory becoming aware of the event.
    b. Information about an adverse event that led to the death or serious deterioration in the state of health of a patient, a user of the in-house IVD or another person must be reported to the TGA within 10 days of the laboratory becoming aware of the event.
    c. Information about an adverse event that might lead to the death or serious deterioration in the state of health of a patient, a user of the in-house IVD or another person must be reported to the TGA within 30 days of the laboratory becoming aware of the event.
3. **TGA Medicines and Medical Device adverse events –** Reports must be made using the TGA's online form
4. **VARTA (Vic Only) – Reports must be made within** VARTA's Online Adverse Event Report form must be used, Quality Officers have access to log-in details. This will simultaneously submit the report to RTAC. The Riskman 'Exception report – Regulator' should be attached to the submission.
5. **RTAC –** RiskMan External Escalation – Exception Reports* must be sent to the [redacted]
6. **RTAC Certifying Body –** any reports made to RTAC must also be sent to our Certifying Body through our [redacted]
7. **NSW Ministry of Health Secretary (Day Surgery) -** For reportable events, the Riskman 'Exception report – Regulator' must be submitted, to MOH-PrivateHealthCare@health.nsw.gov.au as follows.
    a. Advise the Secretary, NSW Health of all reportable incidents within 2 working days of the incident's occurrence.
    b. Appoint a root cause analysis within 30 days of the incident occurring.
    c. Ensure that the root cause analysis team submits its incident report to both the Licensee and the Chair of the Medical Advisory Committee for the relevant facility within 70 calendar days of the occurrence of the reportable incident.

d. Forward a copy of the incident report within 30 days of the receipt of that report from the root cause analysis team.

8. **The Office of the Australian Information Commissioner (OAIC) –** All data breaches will be assessed for eligibility by the Quality, Risk and Compliance Manager or Group Quality, Regulatory and Risk Manager and reported to the OAIC as required, using the OAIC Notifiable Data Breach Form https://forms.business.gov.au/smartforms/landing.htm?formCode=OAIC-NDB
9. **Insurers –** Any event reported externally to the regulators listed above must also be reported to the insurers using the RiskMan – Exception Reports Insurer template* and be sent to the AON Claims Consultant:

[redacted]
Aon Risk Solutions
80 Collins Street Melbourne VIC 3000
t [redacted]
f [redacted]
m [redacted]
[redacted]

*Report templates are available in RiskMan and must be used for individual event reporting

Appendices

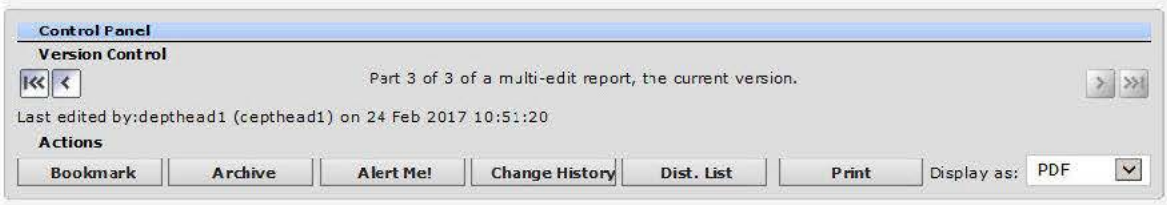
Appendix 1 – RiskMan User Access Levels

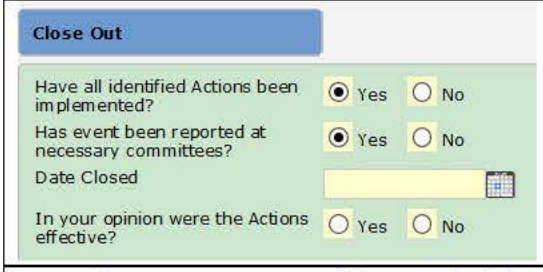
Ref	Permission Level Name	Event Register Access
1	Default	Enter Events and review own entries
2	Dept Head	As Default PLUS Investigate and resolve events reported as having occurred in or involved their department/s
3	Manager	As Department Head PLUS Investigate and resolve events reported as having occurred in or involved their Geographical Location
4	Quality Rep	As Manager PLUS Posts & Closes events in their Geographical Location
5	Corporate	As Manager, but no Geographical Location restriction
6	IT Admin	As Default PLUS User Admin rights
7	Super User	View all events reported across all business units Manage all lists and codes User Admin rights

Appendix 2 – Riskman Summary User Guide

NOTE: Full user guides are available within the RiskMan system, through Help\RiskMan Quick Guides

<table>
<tr><th colspan="2">Login</th></tr>
<tr><td> 
</td><td>Log into Riskman using your normal MVF log-in credentials. Make sure that you select the correct Login Area, either IVF, FSSC or MIVFG</td></tr>
<tr><td>If your credentials are not recognised, click on Create New log-in and follow the prompts to enter:
✓ your normal MVF credentials for Username and password
✓ where you are located (Geographical Location)
✓ Which company you work for (Company)
✓ Phone Number
✓ Which department you primarily work in (Position)
Click ‘Create the Account’</td><td> 
</td></tr>
<tr><td colspan="2">This will create a ‘Default’ Level account. If you require a higher level of access, please contact IT Helpdesk</td></tr>
<tr><th colspan="2">Entering a Report</th></tr>
<tr><td> 
</td><td>Click on New Event</td></tr>
<tr><td>Complete the Event Entry form:
✓ Hover your mouse over a field to show Tips
✓ Yellow fields are mandatory</td><td></td></tr>
</table>

✓ Fields are shown/hidden depending on the drop down selections that you make ✓ You can return to the report at any time, if further information becomes available ✓ Automatic Alerts will notify the relevant people of your report ✓ Explain what has happened and how it was identified. Avoid blame. ✓ Each patient impacted by an event must have a separate record in Riskman. These can be linked to allow a single resolution of the event and individual resolution for each patient.	**Event Entry** Submit this form to record the event. You will be able to modify this page once it is submitted.
Add Document	Supporting documents, saved to the user's desktop can be attached by clicking Add Document.
Once you have completed all of the information, click Submit. If you have missed any mandatory fields, these will be highlighted for you to complete.	Submit
Posting	
☑ Make these changes available to all Authorised Users? Post	The Quality Rep is responsible for 'Posting' reported Events (with the exception of Audit Findings and Compliments which auto-Post).
Posting involves checking the report is:	✓ Acceptable (relevant and appropriate) ✓ Unique
Where changes are made to a 'Posted' report, it will have to be posted again before those changes are visible to other users.	
An Event must be posted before it will appear on reports	
Investigating and Resolving	
The person(s) nominated as Department Head will receive an email notification requesting that they login to RiskMan to view the initial report and conduct their investigation, detailing and assigning necessary corrective and preventive actions.	
	These activities can be delegated to another user with Dept Head permissions, using the 'Distribution List' function
	

All mandatory fields must be completed and Events may be selected for reporting through Internal Committees by selecting 'Yes' next to the appropriate committee. Click Submit to Save the entry.	
Additional Information that the investigation has revealed	
This section should be used to document if the investigation has shown that this is not an isolated event and to spell out the conditions under which the event could recur. This field should not be used to document actions taken as a result.	
Preventative/Corrective Action	
Any preventative or corrective action should be documented in the Add Preventative /Corrective Action section.	
Almost every RiskMan entry should have some type of preventative or corrective action included in the RiskMan Event.	
Close Out	
	Once all Actions have been implemented and the Event has been reported at the appropriate Committees, the relevant Department Head is responsible for marking the event as Closed and assessing the effectiveness of the actions
Once the Department Head has marked the Event as Closed, the Quality Rep must check the record and formally close the Event. The Event will need to be Posted for this to take effect.	

Appendix 3 – How do I know if this event is reportable?

Regulator	Reportable events defined in	Internal Reference
Workcover	State Work Health & Safety Acts (Occupational Health & Safety Act)	Chief People & Culture Officer
TGA	NPAAC Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices Adverse events (and near misses) that lead to a serious deterioration in the state of health of a patient, a user of the in-house IVD or another person include: a) a life threatening illness or injury b) permanent impairment of a body function c) permanent damage to a body structure; or d) a condition necessitating medical or surgical intervention to e) prevent permanent impairment of a body function or permanent damage to a body structure Reporting of information about adverse patient outcomes to the TGA is not required where the adverse outcome resulted from known limitations in the design of the in-house IVD and the in-house IVD performed within its accepted design parameters. Multiple incidences may identify a problem with an in-house IVD that subsequently could require reporting to the TGA as an adverse event. https://www.tga.gov.au/reporting-adverse-events While an individual report may not be enough to determine whether a particular therapeutic good caused an adverse event. All reports help to build a picture of the safety profile of a product and assist with the TGA's safety monitoring program. The TGA particularly needs to know: • all suspected adverse events to new therapeutic goods • all suspected medicine and/or vaccine interactions • unexpected adverse events (that is, adverse events that do not appear in the Product Information, Consumer Medicine Information and/or product labelling) • serious adverse events, such as those suspected of causing: o death o danger to life o admission to hospital o prolongation of hospitalisation o absence from productive activity o increased investigational or treatment costs o birth defects. Reporters are encouraged to provide as much detail as possible, but at bare minimum are asked to provide: • contact details for the reporter (name, address, phone number) • patient identifier (such as initials, date of birth or age, but not their full name) • details of the product involved	Quality Regulatory & Risk Manager Director of Nursing for NSW DSU

	• details of the suspected adverse event. Providing as much information as possible will reduce the need for the TGA to follow up. However, it is important not to delay reporting an adverse event if some information is not available.	
VARTA	Conditions of registration available at https://www.varta.org.au/regulation/clinic-information	Designated Officer / Quality Regulatory & Risk Manager
RTAC	Code of Practice available at https://www.fertilitysociety.com.au/wp-content/uploads/2017-RTAC-ANZ-COP-FINAL-1.pdf and Technical Bulletin 5 available at https://www.fertilitysociety.com.au/wp-content/uploads/20150211-RTAC-Technical-Bulletin-Number-5.pdf	Quality Regulatory & Risk Manager
OAIC	https://www.oaic.gov.au/privacy/notifiable-data-breaches/when-to-report-a-data-breach/	Quality Regulatory & Risk Manager
NSW Day Hospitals (Ministry of Health)	A "Reportable Incident" is defined as a clinical incident which involves: • The death of a patient unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management; • Suspected suicide of a person (including an inpatient or community patient) who has received care or treatment for a mental illness from the relevant Health Services organisation where the death occurs within 7 days of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation; • Suspected homicide committed by a person who has received care or treatment for mental illness from the relevant Health Services organisation within six months of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation; • Unexpected intra-partum stillbirth; OR An **Australian Sentinel Event** being: • Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death. • Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death. • Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death. • Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death. • Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death. • Suspected suicide of a patient within an acute psychiatric unit or acute psychiatric ward. • Medication error resulting in serious harm or death. • Use of physical or mechanical restraint resulting in serious harm or death. • Discharge or release of a child to an unauthorised person. • Use of an incorrectly positioned oro- or naso-gastric tube resulting in serious harm or death.	Director of Nursing Quality Regulatory & Risk Manager

Appendix 4 – Investigation Team Appointment (NSW DSU Reportable events only)

DATE

INSERT NAME
INSERT FACILITY
INSERT ADDRESS

Dear (Insert Name)

I am writing to you to advise that in accordance with Division 6C of the Health Administration Act 1982 and the NSW Health Incident Management Policy, you have been appointed to an Investigation Team to determine the root cause and contributing factors for the reportable incident (insert the Riskman ID), as set out in the attached appointment document.

You have been selected as a member of this team because your expertise and experience is essential to the review of this incident. The work of the Investigation Team will be privileged in accordance with the Health Administration Act.

This has a number of implications, of which you should be aware:

1. **Restrictions on disclosure of information**

   You are required to maintain confidentiality in relation to your work as a member of this team, and you must not make your own record or discuss the investigation with anyone who is not part of the team, except for the purposes of exercising the function or any recommendation of an Investigation Team or for the purposes of preparing a report on the event.

2. **Statutory Privilege**

   The internal workings of RCA Teams appointed under the Health Administration Act are privileged. This means:

   - Members of the team cannot be compelled to give evidence about information obtained by them as part of their work on the RCA Team;
   - Members of the team cannot be compelled to produce to court, papers created or communications (written or verbal) made for the dominant purpose of the RCA Team carrying out its functions;
   - The final RCA report prepared by the RCA Team cannot be adduced or admitted as evidence in any proceedings (including coronial proceedings, or any proceedings in which it is claimed a procedure or practice was careless or inadequate).
   - Members of the team are protected from personal liability, including actions for defamation, provided they act in good faith as a part of the RCA Team function.
   - Team members should be aware there are limits to the privilege:
   - The privilege will not apply to pre-existing documents such as a notification in the incident management system, or medical records or other records created for general care or management reasons;

- The privilege does not prevent release of the final report outside the organisation, to the patient or family of the patient.

3. **Concerns or complaints about an individual clinician not to be investigated**

   The Investigation Team does not have any authority to investigate concerns or complaints about an individual clinician. Under the terms of the Health Administration Act, where the Investigation Team considers the reportable incident may involve professional misconduct or unsatisfactory professional performance or possible impairment issues the team must notify the CEO in writing.

   The Investigation Team may, at its discretion, notify the CEO if an incident may involve unsatisfactory professional performance. Following notification to the CEO the team will take no further action on the individual matter.

4. **Requirements for the Final RCA Report**

   The final report must contain:

   - the incident management system incident number
   - the MoH RIB number
   - a description of the incident
   - causation statements outlining root causes, where root causes have been determined
   - recommendations for change and improvement where appropriate and
   - monitoring processes for follow-up of recommended actions

The final report is to be submitted to the CEO on the (insert date) Thank you for your participation in this important patient safety activity.

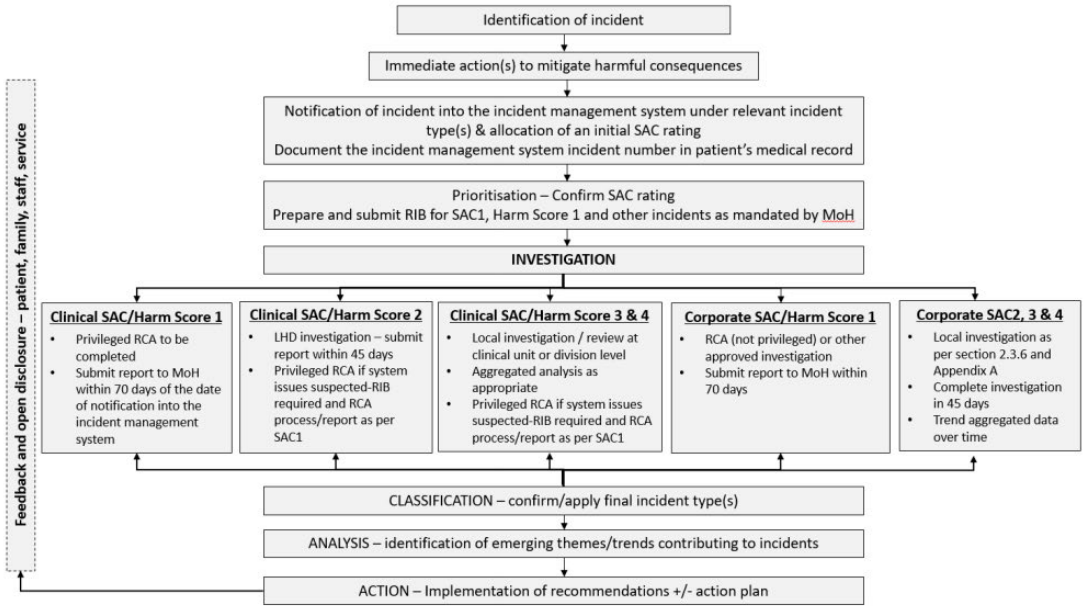
Yours sincerely

Signature

Name

Designation

Diagram 1: The NSW Health Incident Management Process



In house IVD Validation- Next generation sequencing

Document Control	
Document Type:	Validation Document – Next Generation Sequencing
Version:	Version 1.0
Author/Owner:	Monash IVF Group – Genetics Department

Aim

Outlines the validation process for design, production, utilisation, storage and transport of in house IVD.

Applicability

This document operates as an local document which relates to the overall Quality, Risk and Compliance framework across the Monash IVF Group to ensure compliance with:

- See Quality Manual

Terms and Definitions

- ART - Assisted reproductive technology - A reproductive technology used primarily for infertility treatments.
- QMS – Quality Management System
- QM – Quality Manager
- PGD – Preimplantation Genetic Diagnosis – A reproductive technology used in an IVF cycle for the genetic diagnosis of disease in early embryos prior to implantation and pregnancy.
- PGS – Preimplantation genetic screening
- NGS – Next generation sequencing
- WGA – whole genome amplification
- aCGH – array comparative genomic hybridisation
- WPD – Workplace document/Procedure/Manual

In house IVD Validation- Next generation sequencing

1. Test Name and Classification

Preimplantation Genetic Screening using Next Generation Sequencing – Class II IVD

[redacted]