**From:** [redacted]
**To:** [redacted]
**Subject:** FW: Monash IVF - media about problems with cell-free preimplantation genetic testing [SEC=OFFICIAL]
**Date:** Monday, 19 October 2020 1:14:46 PM
**Attachments:** image001.png
image002.gif

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FYI

Kind Regards
[redacted]
Devices Post Market Monitoring
Medical Devices Surveillance Branch

Phone: [redacted] Fax: [redacted]

**Therapeutic Goods Administration**
Department of Health
PO Box 100
Woden ACT 2606 Australia
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.*

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**From:** [redacted]
**Sent:** Monday, 19 October 2020 1:13 PM
**To:** [redacted]
**Cc:** [redacted]
**Subject:** RE: Monash IVF - media about problems with cell-free preimplantation genetic testing [SEC=OFFICIAL]

Thanks. The media was from Friday which includes the media response we provided (sort of)
Pls keep us informed.
[redacted]

**From:** [redacted]
**Sent:** Monday, 19 October 2020 1:11 PM
**To:** [redacted]
**Cc:** [redacted]
**Subject:** Monash IVF - media about problems with cell-free preimplantation genetic testing [SEC=OFFICIAL]

Hi [redacted] & [redacted]

I see there is more in the media today about Monash IVF and disposal of embryos.

We held a teleconference with the IVF laboratory on Friday and they have now submitted an adverse event report to us which is currently with [redacted] team for follow-up and additional questions. For your information, below are some summary notes from the teleconference.

- Testing commenced when the laboratory obtained NATA accreditation for the test in May 2019 (test was validated over 2-3 years in clinical research trials).
- The test is a screening test for chromosomal aneuploidy (abnormal chromosome number) and only performed on embryos that are not suitable for biopsy. Further prenatal genetic testing is recommended to patients.
- The nature of the testing means that monitoring and review of test performance occurs over many months. The laboratory monitors KPI's related to expected chromosomal aneuploidy rates and identified that the test was not performing as it had been in clinical trials and a higher than expected rate of positives were being identified. (We'll be asking for further info on what rate they obtained that was indicative of a problem)
- No identified impact on false negative results and commented that it remained consistent with laboratory's reported false negative rate (as reported in the fact sheet, 9.4%).
- The consequence of a false positive is that the embryo would not have been transplanted (and potentially disposed).
- 1300 patients have been tested (we'll be requesting further information on how many were positive and how and when they notified patients)
- Test was immediately suspended and the laboratory notified NATA and the relevant bodies overseeing IVF services. No notification sent to the TGA (laboratory checked the TGA's website and thought the incident did not met the criteria for a notifiable adverse event).
- Test remains suspended while the laboratory investigates the matter and revalidates the test.
- The in-house IVD regulatory requirements were briefly discussed, along with the post-market reporting requirements for adverse events. TGA advised this incident, particularly suspension of a test, would be considered an adverse event that requires reporting to the TGA.
- Laboratory to submit an adverse event report to the TGA and [redacted] will contact TGA this week to discuss the in-house IVD notification requirements.

[redacted] and I have another teleconference with the lab tomorrow to discuss the in-house IVD requirements to make sure they are fully compliant with the notification requirement.

Regards

[redacted]

[redacted]

Devices Emerging Technology & Diagnostics | Medical Devices Surveillance Branch
Medical Devices and Product Quality Division | Health Products Regulation Group
Australian Government Department of Health
T: [redacted] | E: [redacted]