From: [redacted]
To: [redacted]
Subject: RE: teleconference with Repromed re cell-free preimplantation genetic test [SEC=OFFICIAL]
Date: Monday, 19 October 2020 9:22:48 AM
Attachments: image001.gif

Happy with these [redacted]

From: [redacted]
Sent: Friday, 16 October 2020 5:58 PM
To: [redacted]
Subject: teleconference with Repromed re cell-free preimplantation genetic test [SEC=OFFICIAL]

Hi all, some notes from the teleconference before I forget. Feel free to correct, add or edit as you see fit. Once we are happy I will send to the laboratory for confirmation.
Have a good weekend
[redacted]

- 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 (low number of cells). 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 were being identified. They didn't say what rate they obtained, fact sheet states 6.2% - can ask this when they submit the adverse event report
- No identified impact on false negative results and commented that it remained consistent with laboratory's reported false negative rate (as reported in their 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 (don't think they gave a number on how many were positive and how and when they notified patients, can ask for this when they submit the adverse event)
- 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 will contact TGA next week to discuss the in-house IVD notification requirements.

From: [redacted]
Sent: Friday, 16 October 2020 3:06 PM
To: [redacted]
Subject: FW: Found the following [SEC=OFFICIAL]

In preparation for this afternoon's meeting [redacted] provided the documents above and below is a list of questions that we may want to ask:

- When testing started and when did the laboratory receive NATA accreditation
- When was the problem identified and how was it identified by the laboratory
- How many patients (embryo's) have been tested so far and what is the scope of the problem (how many tests found to be problematic)
- What was the consequence – embryo's discarded? How many?
- When were 'patients' notified
- Is the laboratory still testing and if so what are the corrective actions/risk mitigation strategies that have been put in place.
- How is the test monitored to ensure optimal performance (ie, QC or QA etc)
- Is the laboratory aware of the regulatory requirements for in-house IVDs and that they are required to notify the TGA of their in-house IVDs and report adverse events

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From: [redacted]
Sent: Thursday, 15 October 2020 3:19 PM
To: [redacted]
Subject: Found the following [SEC=OFFICIAL]

[redacted]
Medical Devices Surveillance Branch

Phone: [redacted]
Mob: [redacted]
Email: [redacted]

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