

From: [REDACTED]
To: [REDACTED]
Subject: RE: MonashIVF - PGT-A - Submitted AE report - DIR-65968 [SEC=OFFICIAL]
Date: Monday, 19 October 2020 12:10:09 PM
Attachments: [image001.gif](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)

Thanks [REDACTED]

From: [REDACTED]
Sent: Monday, 19 October 2020 10:32 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: MonashIVF - PGT-A - Submitted AE report - DIR-65968 [SEC=OFFICIAL]

Dear [REDACTED] and colleagues,

Please find attached the submitted DIR for the suspended PGT-A testing by Monash IVF, for your information.

We have not, as yet, reviewed the submitted DIR-65968

Kind regards,

[REDACTED]

From: [REDACTED]
Sent: Monday, 19 October 2020 9:44 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

Hi [REDACTED]

They have submitted the report – [REDACTED] is looking at it

Kind Regards

[REDACTED]
[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.



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From: [REDACTED]

Sent: Monday, 19 October 2020 9:12 AM

To: [REDACTED]

Cc: [REDACTED]
[REDACTED]

Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

Good morning [REDACTED]

Please find below some notes from our teleconference with your colleagues, [REDACTED] and [REDACTED]. [REDACTED] Could you please pass these on so that [REDACTED] and [REDACTED] can edit/confirm my notes are correct.

- 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.
- 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
- 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 meet 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.

Please let me know if there are any difficulties submitting the required adverse event report to the TGA and we can arrange to someone to assist.

Kind regards

[REDACTED]

[REDACTED]

Devices Emerging Technology & Diagnostics | Medical Devices Surveillance Branch
Therapeutic Goods Administration
Australian Government Department of Health

T: [REDACTED] | E: [REDACTED]

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From: [REDACTED]
Sent: Thursday, 15 October 2020 5:32 PM
To: [REDACTED]
Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

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Thanks [REDACTED]

I'll update our calendar invite as we sometimes have issues with external calendar invites coming through and I would hate for them to miss it.

Thanks

[REDACTED]

Monash IVF Group Limited
Pelaco Building 2
Ground Floor, 21-31 Goodwood Street
Richmond VIC Australia 3121

T: [REDACTED] | M: [REDACTED] | F: [REDACTED]

E: [REDACTED] | W: monashivfgroup.com.au



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From: [REDACTED]
Sent: Thursday, 15 October 2020 5:27 PM
To: [REDACTED]
Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

Hi [REDACTED] I've included the teleconference details in the meeting invite but they are also provided below

Kind regards

[REDACTED]

Audio conferencing details: MeetMe Audio Conferencing

Australia Toll free: 1800 047396
Australia Direct: 02 8017 1300 (Sydney)
Participant passcode: 25831977 then #

From: [REDACTED]
Sent: Thursday, 15 October 2020 3:27 PM
To: [REDACTED]
Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

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Thank [REDACTED]

Once you organise conference details, please just forward it to people in the invite and I will remove my calendar appointment.

Cheers

[REDACTED]
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E: [REDACTED] | W: monashivfgroup.com.au



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From: [REDACTED]
Sent: Thursday, 15 October 2020 3:02 PM
To: [REDACTED]
Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

Dear [REDACTED]

4-5pm suits. I've been told we still can't access meetings via Zoom and so I will try and set up an alternative teleconference. Will send details through soon.

I will have my colleagues from our post-market and clinical teams on the call as well

Kind regards

[REDACTED]

From: [REDACTED]

Sent: Thursday, 15 October 2020 2:51 PM

To: [REDACTED]

Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

REMINDER : Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Thanks [REDACTED]

Apologies for the time on the day but would 4pm-5pm be alright?
I will send through zoom details now.

Are there other people you would like added to the invite?

Thanks

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From: [REDACTED]

Sent: Thursday, 15 October 2020 2:44 PM

To: [REDACTED]

Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

Dear [REDACTED]

Thank you for getting back to me so quickly and sorry I missed your call. We will be available any time after 1pm tomorrow.

Kind regards

[REDACTED]

[REDACTED]

Devices Emerging Technology & Diagnostics | Medical Devices Surveillance Branch
Therapeutic Goods Administration
Australian Government Department of Health

T: [REDACTED] | E: [REDACTED]

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From: [REDACTED]
Sent: Thursday, 15 October 2020 2:07 PM
To: [REDACTED]
Subject: RE: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]

REMINDER : Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good afternoon [REDACTED]

I've just tried to phone you now to tee up a time between yourself and relevant staff.
If I could please have your availability for tomorrow afternoon and/or Monday next week, I will schedule some time.

Feel free to call me back at your earliest convenience, it would be much appreciated.

[REDACTED]

[REDACTED]

Monash IVF Group Limited
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From: [REDACTED]
Sent: Thursday, 15 October 2020 1:35 PM
To: [REDACTED]
Subject: TGA request for meeting re cell-free preimplantation genetic test and concerns raised in recent media article [SEC=OFFICIAL]
Importance: High

Dear [REDACTED]

We've become aware via a media article published in the [Herald Sun](#) on 10 October 2020, of a potential problem with a cell-free preimplantation genetic test being offered by your laboratory, Adelaide Fertility Centre Pty Ltd (trading as Repromed).

We understand that your laboratory has been accredited by [NATA](#) to provide this testing service using an in-house IVD medical device. All laboratories developing and using in-house IVDs are subject to certain regulatory requirements including a requirement to notify the Therapeutic Goods Administration (TGA) of the in-house IVDs being used and reporting of any adverse events.

We'd like to urgently speak to you about your cell-free preimplantation genetic test and the concerns raised in the media article. Please let me know your availability and I will set up a meeting to discuss.

Yours sincerely

[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]

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