From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: MonashIVF - PGT-A - Submitted AE report - DIR-65968 [SEC=OFFICIAL]
Date: Monday, 19 October 2020 10:32:24 AM
Attachments: image001.gif
image002.png
image003.png
image004.png
DIR-65968 - MonashIVF - PGT-A.pdf

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]
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.
Important: *This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission*

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] 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 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.

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]
Devices Emerging Technology & Diagnostics | Medical Devices Surveillance Branch
Therapeutic Goods Administration
Australian Government Department of Health
T: [redacted] | E: [redacted]

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]

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

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]

open attachments if you recognise the sender and know the content is safe.

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]
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

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

[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

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]
Devices Emerging Technology & Diagnostics | Medical Devices Surveillance Branch
Therapeutic Goods Administration
Australian Government Department of Health
T: [redacted] | E: [redacted]
This response is general information given to you without prejudice; it is not binding on the TGA and you should seek you own independent legal advice to ensure that all of the legislative requirements are met.

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]

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.
Kindly,

[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

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] 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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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

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Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 40 - ID : 510535

16/10/2020
UNSIGNED
Print

Released by [redacted] on 01/10/2020 16:07:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
65968		RM4949	Initial

ARTG:

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Triage	Trend	25/09/2020	16/10/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
	16/10/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor			

Event Description for Website Publication:

Clinical Event Information:

The outcome following a surveillance audit on Repromed SA Genetics laboratory's cell free (non-invasive) PGT-A program that has triggered a detailed internal investigation.
Whilst our investigation has not been completed, irregularities have been found in the Validation document that supported the implementation of this test and the accreditation granted by NATA. Consequently, Repromed have decided that the test will cease to be offered clinically to its patients, or any patients it performed the test for in the broader Monash IVF Group's network of clinics. NATA have been informed accordingly, and a repeat of the validation study performed as a matter of urgency.
Monash IVF Group will work through a process of Open disclosure with our clinicians and patients which will include remediation where found to be appropriate.
I have also included below a sample of the sort email that has been sent to patients, this one is for patients with aneuploidy only embryos.

Background
Monash IVF's NI PGT program was launched following an almost four-year long process of research and Validation trials. The program was approved by Monash IVF GMAC and had human ethical trials approval from an accredited HREC.
The research and validation, led by [redacted] focussed on whether the genetic results from NI PGT systems were as accurate as those from gold standard PGT-A with trophectoderm biopsy.
[redacted]
The validation data was obtained on a cohort of 121 embryos, and showed the two methods were very similar in their outcomes of detecting aneuploidy. There was a correlation of 98% between invasive PGT and NI-PGT; consequently the test was submitted for NATA accreditation. The NATA accreditation audit with peer review from a technical expert and review of validation report occurred in early 2019. Monash IVF Group launched the NI PGT-A program across New South Wales, Northern Territory, Queensland, South Australia, Tasmania and Victoria in May 2019. The test has also been performed on behalf of [redacted] in [redacted]

Findings
As part of our routine surveillance program, a review of the NI-PGT outcomes was undertaken in June 2020. This review considered not only how accurately the two alternatives performed in terms of detecting abnormality, but also in clinical pregnancy rates. In addition, the post launch surveillance sample size was considerably larger (n = 805) than the validation studies (n = 121). This review highlighted some variations of the performance of the test in clinical use, as compared to the validation results:
- Failed DNA amplification rates were pleasingly lower than the validation study (2.6% Surveillance vs 5.0% Validation).
- There was an increase in inconclusive rates compared to validation study (6 3% Surveillance vs 1 6% Validation); however both outcomes were within parameters experienced in routine clinical practice.
- The significant unexpected finding, was that there was a significant increase in aneuploidy rates in the NI PGT tested embryos when compared to the current invasive PGT tested embryos. This was evident across all ages and for non-delayed and delayed embryos.

The increase in aneuploidy was 20-30% higher in the NI PGT group.
- This implies a higher false positive rate compared with PGT-A with biopsy, indicating that more embryos may have been called abnormal when in fact they may be normal, compared with biopsy PGT-A.

The discordant results between Biopsy PGT and NI PGT prompted a full interrogation of the validation study data files to try and better understand these unexpected outcomes. This review revealed some discrepancies in the validation data that are not yet fully understood, but bring into question its scientific and clinical validity.

Next Steps
Monash IVF Group are working with our clinicians to prioritise patient communications and support programs, as we notify patients that the test is being suspended and the impact that our findings have on any stored aneuploidy embryos.
A further validation study is underway, under the supervision of a multidisciplinary Steering Committee, to assess the possibility of continuing to provide the test.
NATA have been advised of our decision to suspend the test and we will work with them in the event that we are in a position to repeat the accreditation process in the coming months.
If you have any questions regarding any of the information or would like further information, please do not hesitate to call me.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Health Impact

Recorded Health Impacts:

Patient Information

Sex: | Weight: | Age:

Patient Focused Corrective Action Taken: | Patient History:

Patient Outcome/Consequences: | Additional Event Description:

Describe any test (Lab, xray, etc.): | Injured - Extent of Injury: | Other medical devices currently using/implanted: | Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname: [redacted] | Reporter #: | Preferred Contact Method:

Reporter Title: [redacted] | First Name: [redacted] | Surname: [redacted]

Position: [redacted] | Company/Institution: Monash IVF Group

Address 1: Monash IVF Group, 21-31 Goodwood Street | Address 2: | Town/Suburb: Richmond | State: VIC

Country: Australia | Postcode: 3121 | Phone: [redacted] | Fax:

Mobile: | Email: [redacted] | Last External Submission By: 104241_65620 - 16/10/2020 17:03

Initial Reporter Section

As Above?: No | *If No, fill out the following:* | Initial Reporter Confidential: Yes

Search Reporter By Surname: | Initial Reporter #: | Preferred Contact Method:

Title: | First Name: | Surname:

Position: | Company/Institution: 79 631 193 489

Address 1: | Address 2: | Town/Suburb: | State:

Postcode: | Country: | Phone: | Fax:

Mobile: | Email: | Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	DV-2017-IVI-10175-1		
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
In-house IVD - cell free PGT-A	In-house IVD - cell free PGT-A		
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
			0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Monash IVF Group			
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	25/09/2020	[redacted]	[redacted]
Contact Surname:			
[redacted]			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
	No			Unassigned	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
16/10/2020					
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Screening only			
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No				
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		Yes			

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
65620	Monash IVF Group		65620
Attention To:	Address 1:	Address 2:	Town/Suburb:
[redacted]	Pelaco Building 1 Level 1 / 21-31 Goodwood Street		Richmond
State:	Postcode:	Phone:	Fax:
VIC	3121	[redacted]	
Email:			
[redacted]			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
	Ongoing
Details of Similar Events:	Additional Details (use for tables):
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:	
Rating:		Type Cause and Outcome:
Expected Rate:	Actual Rate:	

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:
Suspension of the test and working through communications with affected patients	Proposed re-validation of test under extended committee Appointment of external reviewer to completed RCA relating to validation

Additional Comments:

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:	Next Steps for Level 2 Investigation:

Click [N] to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click [N] to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3	

Health Impact

Details

Level 1	Level 2	Level 3	

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:
Investigator's Notes:		**Summary Findings:**		**Recall Number:**

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
1					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	
Injured - Extent of Injury:	**Was device directly linked to death?:**	**Was device directly linked to permanent disabiltiy?:**	**Consequence:**
Other Consequence:	**Describe any test (Lab, xray, etc.):**	**Additional Event Description:**	**Medical Problem Device Used For:**

Additional Device Information

Where did you get this device from?:	How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:

Town/Suburb:	State:	Postcode:

Flow Details DIR-REQ - Device Incident Request 283548

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
283548	DIR-REQ		Triage	[redacted]	[redacted]	19/10/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User		
Signed At		
Comment		