



Australian Government
Department of Health
Therapeutic Goods Administration

A - General Information

Review Reference Number: PMR-2020-01549

Review Description: DIR 65968 - Monash IVF - in-house IVD (NI-PGT/PGT-A)

Review Start Date: 15/10/2020 9:15 PM

Review Phase: Signal

Review Status: Inactive

Review Status Reason: Closed

Risk Rating:

Review Closed Date: 20/10/2020

Signal In-Scope: Regulatory processes and compliance requirements related to the Non-invasive preimplantation genetic testing for aneuploidy (NI-PGT or cell-free PGT-A).

Signal Out of Scope: Review of regulatory processes and compliance requirements for any other IVD tests conducted by Monash IVF for genetic screening of embryos.

Current In-Scope:

Current Out of Scope:

Reason for Closing Review: After a teleconference with Monash IVF Group, they agreed to submit a DIR. As such, this matter will be processed through the post-market investigation reporting scheme (IRIS).

Reference DIR-65968

Reason for Pausing Review:

B – Review Tasks

Task Name	Start Date	End Date

C – ARTG Entries

ARTG ID	ARTG Name	Sponsor Name	Outcomes



Australian Government

Department of Health Therapeutic Goods Administration

D – Candidates

ARTG Entry Name	ARTG ID	Model	Scope	Phase Added	Manufacturer Name

E – Notifications

Notification Name	Notification Type	Sponsor	Status Reason	Response Due Date	Date Sent