

Certificate of Analysis



Level 2, 321 Kent Street, Sydney NSW 2000, Australia

Phone: +61 2 9229 6420
Email: info@geneabiomedx.com
Website: geneabiomedx.com

Product Details

Product description: Vitrification Set
Product code VIT-01
Lot number: J000006500
Expiry date: 10 Mar. 2025

Intended Use

Gems Vitrification Set is used for the vitrification of human embryos for Assisted Reproductive Technology (ART) procedures.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician or practitioner trained in its use.

Set Contents

The Gems Vitrification set comprises of Vitsol 1, Vitsol 2 and Vitsol 3.

Product Analysis

Assay	Specification			Result
	Vitsol 1	Vitsol 2	Vitsol 3	
pH at 25 °C in air	7.30 – 7.50			Pass
MEA	MEA (1-cell): ≥80% developed to blastocyst stage or beyond by 96 hours			Pass
Endotoxin	<0.4 EU/mL		<0.05 EU/mL	Pass
Sterility	No Growth			Pass
HSA Analysis	13.7 – 22.9 mg/mL	12.2 – 20.3 mg/mL		Pass

Product passed and released by Quality

Signature:

Electronically signed by: Lalitha Kalyanaraman
Reason: QA Approval
Date: Apr 5, 2024 12:10 GMT+11

Name: Lalitha Kalyanaraman

Job Title: QA Associate

Date: 05 Apr. 2024