

Certificate of Analysis



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Product Details

Product description: Vitrification Set
Product code VIT-01
Lot number: J000006929
Expiry date: 11 Sep. 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	7.3 – 7.5			Pass
MEA	MEA (1-cell): ≥80% developed to blastocyst stage or beyond by 96 hours			Pass
Endotoxin	<0.40 EU/mL		<0.05 EU/mL	Pass
Sterility	No Growth			Pass
HSA Analysis	13.70 – 22.90 mg/mL	12.20 – 20.30 mg/mL		Pass

Product passed and released by Quality

Signature:

Electronically signed by: Lalitha
Kalyanaraman
Reason: QA Approval
Date: Oct 31, 2024 09:49 GMT+11

Name: Lalitha Kalyanaraman

Job Title: QA Associate

Date: 31 Oct. 2024







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Final Audit Report

2024-10-31

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