

Certificate of Analysis



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Product Details

Product description: Vitrification Set
Product code: VIT-01
Lot number: J000007661
Expiry date: 18 Nov. 2026

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			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: Nicole Connor
Reason: QA Approval
Date: Dec 18, 2025 08:30:17 GMT+11

Name: Nicole Connor

Job Title: Quality Assurance Associate

Date: 18 Dec. 2025

Certificate of Analysis- J000007661

Final Audit Report

2025-12-18

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