

# Certificate of Analysis



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## Product Details

**Product description:** Vitrification Set  
**Product code:** VIT-01  
**Lot number:** J000006382  
**Expiry date:** 27 Jan. 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: Elliot Atchison  
Reason: Approval  
Date: Mar 5, 2024 10:09 GMT+11

**Name:** Elliot Atchison

**Job Title:** Manufacturing QA Team Leader

**Date:** 05 Mar. 2024