Certificate of Analysis



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Product Details

Product description: GERI Medium

Product code ONE-50

Lot number: J000007112

Expiry date: 27 Nov. 2025

Intended Use

Geri Medium is used to provide necessary nutrients for embryo development *in vitro*. The embryos can remain in this solution for up to 5 days prior to being transferred to the uterus.

USA only: Gems Geri Medium is for *in vitro* culture of embryos from fertilisation to the blastocyst stage of development. This medium can be used for transfer of embryos into the uterus.

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

Product Analysis

| Assay | Specification | Result |
|--------------------------------------|--|--------|
| pH at 37 °C with 6 % CO ₂ | 7.3 – 7.5 | Pass |
| Osmolality | 285 – 295 mOsm/kg | 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 | 3.75 – 6.25 mg/mL | Pass |
| Gentamicin | 0.0075 – 0.0125 mg/mL | Pass |

Product passed and released by Quality

Signature: the signature of the signatur

Eila McGregor
Reason: QA Approval
Date: Mar 13, 2025 12:00
GMT+11

Name: Eila McGregor

Job Title: Quality Assurance Associate

Date: 13 Mar. 2025

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Final Audit Report 2025-03-13

Created: 2025-03-13 (Australian Eastern Daylight Time)

By: Eila McGregor (eila.mcgregor@geneabiomedx.com)

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"Certificate of Analysis - J000007112" History

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