

Certificate of Analysis



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

Phone: +61 2 8228 2719
Email: info@geneabiomedx.com
Website: geneabiomedx.com

Product Details

Product description: Warming Set
Product code: WRM-01
Lot number: J000007190
Expiry date: 19 Jan. 2026

Intended Use

Warming Set and its individual solutions (WarmSol 1, WarmSol 2, WarmSol 3) is used for the warming of embryos that have undergone vitrification using the Vitrification Set (VIT-01) or Gavi Medium Cartridge (GAVI-MED-20). WarmSol 1, WarmSol 2 and WarmSol 3 should not be used individually, always use as part of the Warming Set.

USA only: Gems Warming Set is used for the warming of human blastocyst stage embryos that have undergone vitrification. **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 Warming set comprises of WarmSol 1, WarmSol 2, and WarmSol 3, all supplemented with human serum albumin.

Product Analysis

Assay	Specification			Result
	WarmSol 1	WarmSol 2	WarmSol 3	
pH at 25 °C in air	7.3 – 7.5			Pass
Osmolality	1280 - 1320 mOsm/kg	780 - 820 mOsm/kg	295 - 305 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	15.00 – 25.00 mg/mL			Pass

Product passed and released by Quality

Signature:

Electronically signed by: Elliot Atchison
Reason: Approval
Date: Jun 16, 2025 16:43 GMT+10

Name: Elliot Atchison

Job Title: QA Lead

Date: 16 Jun. 2025








Certificate of Analysis - J000007190

Final Audit Report

2025-06-16

Created:	2025-06-16 (Australian Eastern Standard Time)
By:	Elliot Atchison (elliott.atchison@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAbzERaDfvqpw5NCQUvnAINzseq5THHO-h

"Certificate of Analysis - J000007190" History

-  Document created by Elliot Atchison (elliott.atchison@geneabiomedx.com)
2025-06-16 - 4:41:51 PM GMT+10- IP address: 202.67.82.173
-  Document emailed to Elliot Atchison (elliott.atchison@geneabiomedx.com) for signature
2025-06-16 - 4:42:11 PM GMT+10
-  Email viewed by Elliot Atchison (elliott.atchison@geneabiomedx.com)
2025-06-16 - 4:42:16 PM GMT+10- IP address: 68.218.165.131
-  Elliot Atchison (elliott.atchison@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2025-06-16 - 4:42:34 PM GMT+10
-  Elliot Atchison (elliott.atchison@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2025-06-16 - 4:43:04 PM GMT+10
-  Document e-signed by Elliot Atchison (elliott.atchison@geneabiomedx.com)
Signing reason: Approval
Signature Date: 2025-06-16 - 4:43:05 PM GMT+10 - Time Source: server- IP address: 202.67.82.173
-  Agreement completed.
2025-06-16 - 4:43:05 PM GMT+10