

# Certificate of Analysis



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

Phone: +61 2 9229 6420  
Email: info@geneabiomedx.com  
Website: geneabiomedx.com

## Product Details

**Product description:** Warming Set  
**Product code:** WRM-01  
**Lot number:** J000006342  
**Expiry date:** 21 Nov. 2024

## 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	7.30 – 7.50			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	<0.4 EU/mL			Pass
Sterility	No Growth			Pass
HSA Analysis	15.0 – 25.0 mg/mL			Pass

## Product passed and released by Quality

**Signature:**   
**Name:** Eila McGregor  
**Job Title:** Quality Assurance Associate  
**Date:** 17 Jan. 2024