

Certificate of Analysis



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Product Details

Product description: Warming Set
Product code: WRM-01
Lot number: J000006115
Expiry date: 07 Aug. 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:

Elliot Atchison

Job Title:

Manufacturing QA Team Leader

Date:

15 Jan. 2024