

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:	VitBase
Product code	VBS-20
Lot number:	J000006934
Expiry date:	11 Sep. 2025

Intended Use

VitBase is a HEPES buffered medium that is used to maintain embryos for a short period of time in a non-gassed environment.

USA only: Gems VitBase is a HEPES buffered medium that is used to maintain embryos for a short period of time in a non-gassed environment during embryo vitrification and warming procedures. The embryos can be placed in this medium for a maximum of 10 minutes.

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 25 °C in air	7.3 – 7.5	Pass
Osmolality	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: Lalitha
Kalyanaraman
Reason: QA Approval
Date: Oct 18, 2024 13:28 GMT+11

Name: Lalitha Kalyanaraman

Job Title: QA Associate

Date: 18 Oct. 2024







Certificate of Analysis - J000006934

Final Audit Report

2024-10-18

Created:	2024-10-18 (Australian Eastern Daylight Time)
By:	Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA9RK80LaMRfA6Ltuxgn4ASOiINBg_6fFM

"Certificate of Analysis - J000006934" History

-  Document created by Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)
2024-10-18 - 1:27:23 PM GMT+11- IP address: 58.111.90.210
-  Document emailed to Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com) for signature
2024-10-18 - 1:27:47 PM GMT+11
-  Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-10-18 - 1:28:09 PM GMT+11
-  Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2024-10-18 - 1:28:43 PM GMT+11
-  Document e-signed by Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)
Signing reason: QA Approval
Signature Date: 2024-10-18 - 1:28:44 PM GMT+11 - Time Source: server- IP address: 58.111.90.210
-  Agreement completed.
2024-10-18 - 1:28:44 PM GMT+11