

# Certificate of Analysis



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## Product Details

Product Description	GAVI TIP and SEAL
Product Code	GAVI-TIP-20
Lot Number	TS0050-001
Manufacture Date	2024-08-08
Expiry date	2025-05-13

## Product Specification

Requirement	Specification	Result
MEA	≥ 80% of 2PN's developed to Blastocyst stage by 96 hrs	Pass
Endotoxin	< 20EU/Device	Pass
Sterility	No Growth	Pass

This product complies with approved and released procedures within the Genea Biomedx EN/ISO 13485 compliant Quality Management System. This product and all its identified Part Numbers and Revisions conform to approved product specifications retained within the QMS. Where cited, lot numbers indicate traceable items within the QMS.

## Product Passed and Released by Quality Assurance

Signature:

A handwritten signature in black ink that reads 'K. Lalitha'.

Electronically signed by: Lalitha Kalyanaraman  
Reason: QA Approval  
Date: Oct 23, 2024 11:20 GMT+11

Name:

Lalitha Kalyanaraman

Job Title:

QA Associate

Date:

23 Oct. 2024







# COA - TS0050-001

Final Audit Report

2024-10-23

Created:	2024-10-23 (Australian Eastern Daylight Time)
By:	Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAALu_fjLlq0Sa8Kw8C4AFDAqifuprLa2w0

## "COA - TS0050-001" History

-  Document created by Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)  
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-  Document e-signed by Lalitha Kalyanaraman (lalitha.kalyanaraman@geneabiomedx.com)  
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