

Certificate of Analysis



MatTek
CORPORATION

289 inserts 27. May. 2016 Maintenance done by Laura

Product: EpiGingival™ Tissue Model

Lot Number: **24023**

Part#: GIN-100-PE6.5-7d

Description: Reconstructed gingival tissue containing normal human oral epithelial cells (NHOE).
This product is for research use only. Not for use in animals, humans or diagnostic purposes.

I. Cell source

All cells used to produce EpiGingival™ are purchased or derived from tissue obtained by MatTek Corporation from accredited institutions. In all cases, consent was obtained by these institutions from the donor or the donor's legal next of kin, for use of the cells or derivatives of the tissue for research purposes.

NHOE Strain: **G26**

II. Donor and Reconstructed Tissue Profile:

Donor age:	46 years
Donor sex:	Male
Donor tobacco use:	No
Age of reconstructed tissue at time of shipment:	7 days

III. Analysis for potential biological contaminants:

The cells used to produce EpiGingival™ tissue are screened for potential biological contaminants. Tests performed for each of the potential biological contaminant listed in the analysis that follows, were performed according to the test method given. The product resulted in "no detection" for the following potential biological contaminants determined by the stated test method:

NHOE:

HIV-1 virus - Oligonucleotide-directed amplification	Not detected
Hepatitis B virus - Oligonucleotide- directed amplification	Not detected
Hepatitis C virus - Oligonucleotide- directed amplification	Not detected
Bacteria, yeast, and other fungi - long term antibiotic, antimycotic free culture	Not detected

IV. Analysis of tissue:

Macroscopic observation of tissue

Appearance: **Pass**

Initials: **PK**

Date: **5/25/2016**


Paul Kearney
Quality Assurance Manager

May 25, 2016
Date

CAUTION: Whereas all information above is believed to be accurate and correct, no absolute guarantee that human derived material is non-infectious can be made or is implied by this certificate of analysis. All tissues should be treated as potential pathogens. The use of protective clothing and eyewear and appropriate disposal procedures are strongly recommended.

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