

CERTIFICATE OF ANALYSIS

PRODUCT DESCRIPTION:

EZ-Tip® (Vial) Denudation and Transfer Pipette

LOT NUMBER(S):

208695, 208697

EXPIRY DATE:

2022-08-31

INDICATIONS FOR USE:

The EZ-Tip pipettes are for denudation, i.e. removing the cumulus from an oocyte prior to Intracytoplasmic sperm injection (ICSI) and in vitro fertilization (IVF), and for

handling gametes, embryos and biopsied cells (polar bodies,

blastomeres and trophectoderm) during assisted

reproductive techniques (ART).

QUALITY ASSURANCE:

Sterilised by gamma irradiation using dose between 25 and

35kGy to a SAL of 10⁻⁶

Assay Test. Pass criteria:

1-cell MEA ≥ 80% hatched blastocysts at 120 hrs 100% PASS

Limulus Amoebocyte Lysate Test (LAL). Pass criteria

<20Eu/device. PASS

STORAGE CONDITIONS:

Temperature 10-30°C Humidity 20-80% RH

Keep away from direct sunlight (UV)

Quality Assurance:

2019

Date: 19 September

 $\mathbf{K}_{\mathsf{Only}}$ Caution: US Federal law restricts this device to sale by or on the order of a physician.

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