



Kitazato Corporation

<http://www.kitazato.co.jp/>

PRODUCT: Blastomere Biopsy Pipettes

LOT#: 405028

EXPIRY DATE: 2027-05-25

Year-Month-Date

REF: 95351

CODE: MT-BPBM-25-35

APPROVED BY:

Kazumi Shibata
Quality Control

2024-06-07

CERTIFICATE OF ANALYSIS

Indication for Use: MT-BPBM is used for removing a blastomere cell for pre-implantation genetic diagnosis.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner trained in its use.

Sterilization: The products were gamma irradiated at a minimum dose of 28.0 kGy and a maximum dose of 35.7 kGy on 5/30/2024. The validated sterile assurance level is 10^{-6} .

ASSAY	SPECIFICATION	RESULT
Endotoxin ¹	≤ 0.5 EU/device	<0.03125
MEA (2-cell) ²		
-Control	$\geq 80\%$	100
-This Lot	$\geq 80\%$	95

¹ Uses the LAL with a sensitivity of 0.03125EU/mL

² 2-cell mouse embryo testing is performed using fresh mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 72 hours in culture medium.