



**KITAZATO BioPharma Co., Ltd.**

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PRODUCT: Repro Plate


LOT#: 61007

EXPIRY DATE: 2019.10.07

Year / Month / Date

REF: 83016,83017

CODE: Repro Plate-K2(6well)

  
 APPROVED BY: Kazumi Shibata  
 Quality Assurance  
 2016.11.24

**CERTIFICATE OF ANALYSIS**

**Indication for Use:** Repro Plate is used to place vitrification or thawing media on the wells.

**Storage:** Store between 15-30 °C.

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

We certify that products manufactured by Kitazato BioPharma Co., Ltd. have been approved in accordance with current Good Manufacturing Practice (cGMP). The quality of products was tested and evaluated by quality control procedures.

ASSAY	SPECIFICATION	RESULT
Appearance	Particle Free, No Cracks	Pass
Endotoxin <sup>1</sup>	≤ 0.5 EU/unit	<0.001
MEA (One Cell) <sup>2</sup>		
-Control	≥ 80%	100%
-This Lot	≥ 80%	100%

<sup>1</sup> Bacteria Endotoxins Test, Photometric Techniques in accordance with the USP, EP and JP

<sup>2</sup> One cell mouse embryo testing is performed using fresh mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 96 hours in culture medium.