

Registered ISO 9001:2015 ISO 13485:2016 Gene Era Biotech

Certificate of Compliance

Contract Manufacturer's /Supplier's Name: Gene Era Biotech/Thomas Scientific

Catalog Numbers: AR-10-SLF
Non-sterile Products:
Sterile Products: AR-10-SLF
Product Description: 10µL Universal Tip, Racked, Sterile, Low Retention, Filter 96
Mfg. Lot Number: tips 201120-1137
Material: Virgin Polypropylene

Sterilization:

Sterile catalog numbers from this lot have been pre-sterilized and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization*. Sterility Assurance Level: SAL 10⁻⁶
This does not apply to non-sterile product catalog numbers.

Endotoxin (pyrogen) Testing:

Products are directly tested for endotoxins by the Limulus Ameobacyte Lysate (LAL) gel clot assay according to USP/FDA guidelines for medical devices. No pyrogens were detected.

Results: Test sample extraction had an undetectable level of endotoxin at **0.05 EU/mL**

RNase/DNase Testing:

This product has been tested and is free of any detectable RNase/DNase contamination.

Lot Number Designation:

The product lot number shall be 6 digits followed by a "-" and 4 digits. The first two digits of the lot number shall be the last two digits of the current year. The next two digits shall represent the current month. The last two of the six digits shall represent the current date of the month. The last four numbers are preceded by a "-" and represents the actual mold number.

GEB's practice is to recommend product use within three years from the date of manufacture. This

product lot has been sampled and tested in accordance with Standard Operating Procedures and has

been released for the following characteristics:

Visual attributes	Pass
Dimensional	Pass
Accuracy Test	Pass CV < 3%
Tip warp	Pass



Quality Manager:

Date: