Certificate of Analysis

Part Number(s):	**FT-10XL-L-R-S, FT-10XL-L-R-S-10**
Description:	**10XL ul Filter Tip**
Lot Number:	**2509232024**

This certifies that the products listed above have been manufactured in accordance with established manufacturing guidelines and product specifications. The products conform to all Quality requirements and have undergone all standard quality requirement tests.

Component Materials: Medical-grade Polypropylene, meets requirements for medical applications

Expiration Statement: For the attributes contained within this certificate,

- **Sterile product** has an expiration date of three (3) years from the date of manufacture.
- **Non-Sterile product** has an expiration date of five (5) years from the date of manufacture.

Sterilization: For sterile product, this lot has been irradiated and dosimetrically released based on Electron-beam radiation. Requirements for validation and routine control are in accordance with ISO 11137 “Sterilization of health care products.”

Endotoxin (Pyrogen)Testing:

The Product has been tested for endotoxins. No Pyrogens were detected.

- Testing has been conducted based on the gel clot test method
- FDA license limit test using USP Reference Standard Endotoxin (RSE)
- Test Sensitivity: 0.25 EU/mL

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

- Product extractions and control standards were evaluated for DNase activity by exposure with digested DNA substrate.
- Product extractions and control standards were evaluated for RNase activity by exposure with bacterial RNA substrate.
- Electrophoretic results show that no RNase or DNase activity was detected.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy (BSE/TSE): None of these products or raw materials are manufactured from or come into contact with animal material.

Novas Bio Inc. | 30514 San Antonio Street | Hayward, CA 94544 USA

Phone + 1 650.468.0887 **support@novasbio.com** **www.novasbio.com**

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Certificate of Analysis

Lot Number Designation: 9 Digit Lot Number:

Digits 1 to 2 – Year of manufacture,
Digits 3 to 4 – Month of manufacture,
Digits 5 to 6 – Start day of manufacture,
Digits 7 to 9 – Tooling Id

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure	**Results**
Visual attributes	Pass
Packaging	Pass
Dimensional	Pass

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