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Certificate of Analysis

Part Number:	**MCT-150-C**
Description:	**1.5 ml Microcentrifuge Tube, Clear. Non-sterile.**
Lot Number:	**220601121**

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,

- **Non-Sterile product** has an expiration date of 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.

Human DNA Testing: This product has been tested and is free of any detectable Human DNA contamination.

- Product samples were verified to be absent of any Human DNA above 0.1 ng.

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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.

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

Test/Procedure	Quality Requirement	Results
Visual attributes	1. Flash length ≤ 0.010” 2. Shorts and pinholes not acceptable 3. Bubbles on tube body not acceptable 4. No grease, oil, black specks are acceptable if visible from arms-length (24”). 5. Gates Length ≯ 0.010” 6. Sinks on surface not acceptable	Pass
Centrifugation Test	1. Fill full shot with Blue water (0.5g Bromophenol Blue, 0.5g Xylene Cyanol FF) 2. Add double distilled water up to 2 liters and centrifuge for 10 minutes at 14,000 RCF. 3. Check for leaks & damage to body of tube.	Pass
Boil Test	1. Turn the heat block on 2. Take one complete shot of tubes 3. Fill half way with water into each tube, and snap close the cap 4. When the temperature on block reaches 100°C, place each tube on the heat block for 20 minutes 5. Observe if any caps pop open which is not acceptable	Pass
Autoclave Test	1. Autoclave the tubes at 121°C 15psi for 15 minutes, cap and tube should be well sealed, leakage is not acceptable.	Pass
Chloroform Test	1. Take one shot of tubes 2. Fill with 1.0ml HPLC Chloroform into each Cavity and snap close the cap tightly 3. Lay a white towel paper on the surface, upside down each tube on the paper towel for 1 hour, any visible leakage is not acceptable	Pass

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