BioClean Ultra

RAININ
Pipetting 360°

CERTIFICATE
OF QUALITY

Rainin BioClean™ Ultra pipette tips labeled "Certified RNase-, DNAse-, Endotoxin- and ATP-free" have been process-tested and passed the following detection levels using the test protocols below.

Contaminants Tested	Testing Detection Levels
RNase	≤ 10^{-9} Kunitz units/µL
DNAse	≤ 10^{-7} Kunitz units/µL
Human DNA	< 0.32 pg
Bacterial DNA	< 1 pg
Endotoxin	< 0.001 EU/ml

Contaminants Tested	Testing Detection Levels
ATP	< 2 X 10^{-12} mg/µl
Protein	< 2 ng/lane
Protease	< 50 µg/liter
PCR Inhibitors	None detected

CERTIFIED BY **David Greenwood, Ph.D.**
Head of Quality Systems

Testing Procedures

RNase testing protocol
Products were rinsed in DNase-, RNase-free 0.1 µm filtered distilled water, then product extracts were exposed to an RNA standard in a fixed volume of buffer. The RNA standard was incubated at 37°C for 1 hour. RNA fluorescence was measured using an RNA fluorescent dye and evaluated for degradation.

DNase testing protocol
Products were rinsed in DNase-, RNase-free 0.1 µm filtered distilled water, then product extracts were exposed to an DNA standard in a fixed volume of buffer. The DNA standard was incubated at 37°C for 1 hour. DNA fluorescence was measured using an DNA fluorescent dye and evaluated for degradation.

DNA testing protocol
Quantitative PCR (qPCR) was used in the following fashion: A BioRad CFX96 system was used to detect amplification in 20 µL reaction volumes containing negative controls, positive controls, varying concentrations of stock DNA (human or bacterial) and tip eluate. Final primer concentration is 200-300 nM. Both human and bacterial primer sets for conserved sequences were used, and are as follows:

Human primers: Forward: 5′-TGAATGGGAGAAGGCAGAAG
Reverse: 5′-TATCCACCGGGTGTTTTCTC

Bacterial primers: Forward: 5′-CAAGGCTAAATACTCCTGAC
Reverse: 5′-CACTCCCCTCGCCGGGGTTC

Endotoxin testing protocol
Products are extracted in endotoxin-free LAL reagent water for 1 hour, then product extracts are tested by kinetic assay. The test is performed by adding LAL to the negative control, Control Standard Endotoxin, positive control and product extracts. After a fixed incubation period, the reaction mixture is measured. The sensitivity of the kinetic assay is 0.001 EU/mL.

ATP tested by the following protocol
ATP is tested by measuring the difference between baseline and product-rinsed luminescence of an ATP standard solution containing 10^{-11} mg of ATP. Perturbations in light emission of a product-rinsed ATP standard solution are evaluated to determine the presence or absence of ATP.

Protein testing protocol
Groups of tips from each production batch were rinsed with RNase/DNase/Protein-free water and an aliquot of the rinsates run on a 4-12% Novex Tris-Glycine gradient gel under denaturing conditions with appropriate controls. A BSA protein standard was prepared and 2 ng, 5 ng and 20 ng amounts run in individual lanes. Following electrophoresis, the gel was fixed and silver-stained using standard procedures and the results visualized on a light table.

Protease testing protocol.
Batches of tips are assayed for potential protease contamination using the QuantiCleave™ Protease Assay Kit (Thermo Scientific). Groups of tips from each batch were rinsed with protease-free water and the rinsates tested (in duplicate) according to the manufacturer's instructions. Trypsin was used as a proteolytic standard. Results were determined colorimetrically at 450 nm and averaged for each duplicate pair. Test sample protease levels were derived from the Trypsin Standard Curve.

Sterilized product
Rainin tip products labeled as "sterilized" are irradiated by gamma radiation (SAL=10^{-6}). Dosage level has been predetermined by bioburden testing.

Limitation of Liability
Mettler-Toledo Rainin, LLC's entire liability with respect to this product is limited to the price of the product. In no event shall Mettler-Toledo Rainin, LLC, its agents or its employees be liable for direct, indirect, special, consequential or incidental damages arising out of the use of, or inability to use, this product or arising out of any defect in the product, even if Mettler-Toledo Rainin has advised of the possibility of such damages. BioRad is a trademark of BioRad Laboratories, Inc. Rainin is a registered trademark of Mettler-Toledo Rainin, LLC.

METTLER TOLEDO