RAININ
Pipetting 360°

METTLER TOLEDO

Certificate of BioClean Quality

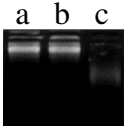
RAININ BioClean pipette tips and capillaries/pistons labeled

"Certified RNase-, DNase-, DNA-, Pyrogen-, and ATP-free"

have been process-tested and passed the following detection levels using the test protocols overleaf.

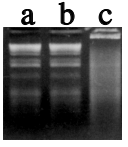
Contaminants tested	Testing detection levels
RNase	$\leq 10^{-9}$ Kunitz units/µL
DNase	$\leq 10^{-7}$ Kunitz units/µL
DNA	< 1 copy human DNA
Pyrogens	0.001 EU/mL
ATP	$< 2 \times 10^{-12}$ mg/µL

RNase tested by the following 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, then heated to 65°C for 10 minutes. RNA samples were then run on an agarose gel, photographed, and evaluated for degradation.



a: Product samples
b: unexposed RNA standard as a negative control
c: RNA standard exposed to RNase as a positive control

DNase tested by the following protocol: Products were rinsed in DNase-, RNase-free 0.1 µm filtered distilled water, then product extracts were exposed to a DNA standard in a fixed volume of buffer. The DNA standard was incubated at 37°C for 1 hour, then heated to 65°C for 10 minutes. DNA samples were then run on an agarose gel, photographed, and evaluated for degradation.



a: Product samples
b: unexposed DNA standard as a negative control
c: DNA standard exposed to DNase as a positive control

DNA tested by the following protocol: Quantitative PCR (qPCR) was utilized in the following fashion: A BioRad CFX96 system was used to detect amplification in 25 ul reactions volumes containing negative controls, positive controls, varying concentrations of stock DNA (human or bacterial), and tip eluate. Final primer concentration is 250-320 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.

Pyrogens tested by the following protocol: Products are extracted in Endotoxin screened distilled water for 1 hour, then product extracts are tested by the Kinetic Assay. The test is performed by adding LAL to the negative control, Standard Endotoxin Control, positive control, and product extracts. After a fixed incubation period, the reaction mixture is measured. The sensitivity of the Kinetic Assay is 0.001EU/mL.

ATP tested by the following protocol: The reagent used for ATP detection is allowed to contact the entire interior surface of the cuvette. Light emitted is subsequently measured using a luminometer until no signal above the instrument background is detected. The products are then rinsed in the reagent and light emitted is measured again. Finally the assay is calibrated by adding 10 microliters of a 10^{-7} moles/L ATP Standard. The light emission from the product divided by the light emission from the standard gives the ATP level of the product in pmoles.

Presterilized Product: RAININ tip products are irradiated by gamma radiation, piston and capillary products irradiated by e-beam, all labeled as "presterilized". Dosage level has been predetermined by bioburden testing.