HAMILTON®

Certificate of Conformance

March 21, 2024

P/N	Lot Number	Expiration Date	Description
235965	1057069	2027-06-24	STD VOL CO-RE TIPS CLR STACKED

Hamilton Company confirms that the products referenced are manufactured to conform to the claims listed in this certification.

Produced under Hamilton Production Specification

The Hamilton Company production process includes a 100% automated inspections. Additionally Quality Control Representatives measure and assess samples pulled from each production lot.

Produced in Clean Environment

The Hamilton Company Reno cleanroom is certified to ISO 14644-1 Class 8 for clean environment particulate load limits.

RNase-free and DNase-free

Analysis and test method used:

For each test, a substrate is reconstituted with a buffer and distributed to a 96-well plate. The test samples, negative control and positive controls are added and the plate is incubated. The results are then read on a fluorometer. Samples that noticeably fluoresce compared to the negative control are considered contaminated. The test can detect as little as 3.5 x 10-7 units (-0.5pg) or RNase A and 0.0005 U (-10pg) of DNase I.

Endotoxin/Pyrogen-free

Analysis and test method used:

FDA Guideline – USP <85>, AAMI ST72: 2011

Samples are extracted for an hour, they are tested in duplicate against a standard curve ranging from 5.0 to 0.005 EU/mL. There are two wells of sample and two wells of sample spiked with the 5.0 EU/mL standard endotoxin. A chromogen is used which changes color if endotoxin is present in the sample. The plate reader determines the amount of endotoxin based off the samples chromogen color and amount used to extract each device/product.

Human DNA-Free and PCR-Inhibitor-Free

Analysis and test method used:

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Samples are extracted in sterile DNA-free water. Part of the extracted sample is exposed to PCR reaction reagents containing primers for human genomic DNA to test for the presence of human DNA. Part of the extracted sample is added to a PCR reaction to test for PCR inhibition. PCR reactors contain Taq DNA polymerase, 10X PCR buffer, MgCl2, dNTPs and human primers. Total reaction volume is 30µL. 30 PCR cycles are run. The sample reactions are run on an agarose gel and each product result was compared to both positive and negative controls. Test sensitivity is 1pg – 2pg.

Facility and product testing is performed on a regular basis by a third party testing facility.

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