

## Test Information

VistaLab Technologies Inc. pipette tips and reservoirs labeled pyrogen-free, DNase/RNase certified, sterile have been process-tested by an independent testing laboratory according to the following specifications using the stated protocols.

Tested for	Test Sensitivity Levels
DNase	<10 <sup>-7</sup> Kunitz Units/ $\mu$ L
RNase	<10 <sup>-9</sup> Kunitz Units/ $\mu$ L
Pyrogens	<0.06 EU/mL
Sterility	<10 <sup>-6</sup> SAL

### DNase/RNase testing is according to the following protocol:

Product extracts of inner and outer tip surfaces are exposed to an appropriate standard in a fixed volume of buffer. The standards are incubated at 37° C then heated to 65° C for 5 minutes. Reactions are evaluated by agarose gel electrophoresis. The gel is photographed, and evaluated for degradation. The DNA or RNA exposed to the test sample extract must look exactly the same as the negative control that was exposed to sterile water.

### Pyrogen testing is according to the following protocol:

Endotoxin levels are tested by the limulus amoebocyte lysate (LAL) Gel Clot Assay. A representative sampling of the products is extracted according to current FDA guidelines in pyrogen-free water and the extract solutions are assayed along with positive and negative controls. The sensitivity of the LAL Gel Clot Assay is 0.06EU/mL which is the current FDA/USP guidelines endotoxin limit for medical devices which contact cerebral spinal fluid.

### Sterility testing is according to the following protocol:

Product samples are bioburdened. Product is presterilized by electron beam radiation then post-sterilization verification is performed. No growth is shown after seven days of incubation at 37° C in Tryptic Soy Broth with phenol red broth.

VistaLab Technologies, Inc.

2 Geneva Road

Brewster, NY 10509

Tel: 914.244.6226

Tel: 888.652.6520 Fax: 845.279.4620

[www.vistalab.com](http://www.vistalab.com)

L058-0034-001 Rev B

# Certificate of Analysis

*VistaLab Technologies, Inc. certifies that our pipette tips and reagent reservoirs meet acceptable industry standard performance criteria.*

*We guarantee that these products are free from defects in manufacturing, materials and workmanship. Any product that fails to perform as specified will be replaced at no charge.*



VistaLab Catalog No: 3201

Lot No: 18295P

Date of Manufacture: 10/22/18