

### Certificate of Analysis

Accumax Lab Devices Pvt Ltd is ISO 9001:2015 certified organization and all products mentioned in annexure-1 are manufactured under strictly defined and monitored conditions as per product specifications. This here by certifies that the supplied product complies with following standards of production.

**Quality System Compliance:** The product conforms to written material specifications and was manufactured under the ISO 9001/2015 quality system.

Test Report		
Material: Polypropylene		
Test	Limit	Test Result
Endotoxin	$\leq 0.06$ EU/ ml	Product is free from Endotoxin
DNase	$\leq 9.4 \times 10^{-4}$ U/Tip	Product is free from DNase
RNase	$\leq 6.5 \times 10^{-8}$ U/Tip	Product is free from RNase

**Material** Free of Bisphenol A (BPA), phthalates and cytotoxic effects. Resins are USP Class-VI certified, RoHS, FDA regulation CFR 21, and are free of Substances of Very High Concern (SVHC), REACH compliant, and are FDA approved for food contact..

**BSE/TSE Statement:** (Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy) The product above is free from and manufactured from materials that do not contain any raw materials or substances derived from animal origin as defined in EC Directive 1069/2009/EC and EC Directive 142/2011/EC.

**Latex Statement:** No Latex was used in the manufacturing of the product. This also includes all the packaging and shipping materials used in the production of the items.

**Sterilization Process:** Products marked as sterile are processed by irradiation. This dosage is enough to ensure a sterility assurance level (SAL) of  $10^{-6}$ . Our sterilization program is an ISO 11137 validated process.(Sterilization validity is 3 years from the date of manufacturing)

**Pyrogen Testing:** Endotoxin levels were tested by the Limulus Amoebocyte Lysate (LAL) 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 & negative controls.

**DNase Test:** Samples were rinsed one after another with DNA-free water. These solutions were mixed with DNase-buffer containing DNA-ladder in a DNase-free tube. A positive control was spiked with DNase, a negative control contains DNA-free water. All tubes were incubated at 37 °C. The presence of DNase was analysed by agarose-gel electrophoresis. DNase contamination is indicated by degradation of the DNA ladder.

**RNase Test:** Samples were rinsed one after another with RNA-free water. These solutions were mixed with RNase-buffer containing RNA-ladder in a RNase-free tube. A positive control was spiked with RNase, a negative control contains RNA-free water. All vessels were incubated at 37 °C. The presence of RNase is analysed by agarose-gel electrophoresis. RNase contamination is indicated by degradation of the RNA ladder.

**Quality Assurance Department**

**Date: 20/10/2018**

### **ANEXURE-1**

<b>Sr. No.</b>	<b>Product Name</b>	<b>Catalogue No.</b>	<b>Batch No.</b>	<b>Quantity in Packs</b>
1	1000ul Universal Grad tip, Sterile, Low retention, Filter	XR-1000-SLF	3LCG1111R	150
2	1000ul Universal Grad tip, Sterile, Low retention	XR-1000-SL	3LCG1110R	100
3	1250ul Universal Grad tip, Sterile, Low retention, Filter	XR-1250-SLF	6LCG1311R	100
			6LCG1011R	50
4	1250ul Universal Grad tip, Sterile, Low retention	XR-1250-SL	6LCG1010R	100
5	100ul Universal Grad tip, Sterile, Low retention, Filter	XR-100-SLF	2LCG1413R	50
6	10ul Universal Grad tip, Sterile, Low retention, Filter	XR-10-SLF	1LCG1511R	100
7	10ul Universal Grad tip, Sterile, Low retention	XR-10-SL	1LCG1510R	80
8	10ul Long Universal Grad tip, Sterile, Low retention, Filter	XR-10XL-SLF	4LCG0211R	100
9	10ul Long Universal Grad tip, Sterile, Low retention	XR-10XL-SL	4LCG0210R	80
10	200ul Universal Grad tip, Sterile, Low retention, Filter	XR-200-SLF	2LCG1414R	120
11	200ul Universal Grad tip, Sterile, Low retention	XR-200-SL	2LCG1010R	80
12	300ul Universal Grad tip, Sterile, Low retention, Filter	XR-300-SLF	8LCG0411R	60
13	300ul Universal Grad tip, Sterile, Low retention	XR-300-SL	8LCG0410R	60
14	20ul Universal Grad tip, Sterile, Low retention, Filter	XR-20-SLF	2LCG1411R	100
15	50ul Universal Grad tip, Sterile, Low retention, Filter	XR-50-SLF	2LCG1412R	50

16	10ul Super slim Universal Grad tip, Sterile,Low retention, Filter	XR-10N-SLF	7LCG1011R	50
17	10ul Super slim Universal Grad tip, Sterile,Low retention, Filter	XR-10N-SL	7LCG1010R	50