

## Certificate of Analysis

The manufacturer 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
<b>Endotoxin</b>	≤ 0.03 EU/ ml	Product is free from Endotoxin
<b>DNase</b>	1.0 X 10 <sup>-6</sup> Kunitz Units	Product is free from DNase
<b>RNase</b>	1.0 X 10 <sup>-9</sup> Kunitz Units	Product is free from RNase
<b>Human DNA free</b>	< 2 pg	Product is free from Human DNA
<b>PCR Inhibitory free</b>	Less than 2 CT variation	Product is free from PCR inhibitors

**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<sup>-6</sup>. Our sterilization program is an ISO 11137 validated process.

**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 Nuclease-free water. These solutions were mixed with DNase-buffer containing DNA-ladder or DNA sample 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 or DNA Sample.

**RNase Test:** Samples were rinsed one after another with Nuclease-free water. These solutions were mixed with RNase-buffer containing RNA-ladder or RNA sample 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 or RNA sample.

**Human DNA Contamination Test:** The quantitation procedure was carried out using standard quantification in Real time PCR/droplet digital PCR using Sybr green dye /Eva green. The Replicate analysis of Fluorescence was carried out, for sample to pass the test no fluorescence should be observed comparable to results of Non-Template control.

**PCR Inhibitory Test:** Standard quantification procedure was performed using real time PCR/ droplet digital PCR using Sybr green dye /Eva green. The replicate analysis of fluorescence was carried out. For sample to pass verification, CT values of sample has to match that of known concentration of positive controls, if there is change in CT values more than 2 cycles, it is deemed to be PCR inhibitory.

**Quality Assurance Department**

**Date:20.09.2023**

### ANEXURE-1

Sr. No.	Product Name	Catalogue No.	Batch No.	Quantity in Packs	Mfg. date	Expiry date
1	100UL UNIVERSAL GRAD TIP, STERILE, LOW RETENTION, FILTER	100-FLR-S	2LCL1513R29	80	09/2023	09/2026
2	10µL LONG UNIVERSAL GRAD TIP, STERILE, LOW RETENTION, FILTER	10X-FLR-S	4RCK1311R36	160	09/2023	09/2026
3	10000 µL TIP SUITABLE TO SMART10 ML & 1000-10000 µL PIPETTE	10ML-B	P-241492	50	09/2023	NA
4	1000 µL UNIVERSAL GRAD TIP BLUE COLOR	1000B-B	10RBL2700B27	60	09/2023	NA
5	20µL UNIVERSAL GRAD TIP, STERILE, LOW RETENTION, FILTER	20-FLR-S	12LCL0911R73	120	09/2023	09/2026
6	CLEAR VA/FA TIPS 5000µL,	5ML-B	JS-170723	50	09/2023	NA
7	1000UL LONG UNIVERSAL GRAD TIP, STERILE, LOW RETENTION, FILTER	1250-FLR-S	6LCL1411R19	150	09/2023	09/2026
8	200µL UNIVERSAL GRAD TIP	200B-N	12RCL0700B75	100	09/2023	NA
9	200UL UNIVERSAL GRAD PIPETTE TIP, YELLOW	200B-Y	12RYL0500B70	160	09/2023	NA
10	1000UL UNIVERSAL GRAD TIP, STERILE, LOW RETENTION, FILTER	1000-FLR-S	10LCL3011R28	270	09/2023	09/2026
11	200µL UNIVERSAL GRAD TIP, STERILE, LOW RETENTION, FILTER	200-FLR-S	12LCL0914R65	230	09/2023	09/2026