

Certificate of Analysis

Oxford Lab Products 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(Tips & Tubes), Polyethylene (Cap)		
Test	Limit	Test Result
Endotoxin	≤0.06 EU/ ml	Product is free from Endotoxin
DNase	≤9.4 x 10 ⁻⁴ U/Tip	Product is free from DNase
RNase	≤6.5 x 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: 01/10/2018

ANEXURE-1

Sr. No.	Product Name	Catalogue No.	Batch No.	Quantity in Packs
1	1000ul Universal Grad tip, Sterile, Low retention, Filter	XR-1000-SLF	3LCG1111R	150
2	1000ul Universal Grad tip, Sterile, Low retention Reload	XRE-1000-SL	3LCG1110K	140
3	1000ul Universal Grad tip, Sterile, Low retention	XR-1000-SL	3LCG1110R	100
4	1250ul Universal Grad tip, Sterile, Low retention, Filter	XR-1250-SLF	6LCG0511R	50
			6LCG1011R	100
5	1250ul Universal Grad tip, Sterile, Low retention Reload	XRE-1250-SL	6LCG1010K	140
6	1250ul Universal Grad tip, Sterile, Low retention	XR-1250-SL	6LCG1010R	100
7	100ul Universal Grad tip, Sterile, Low retention, Filter	XR-100-SLF	2LCG1011R	80
8	10ul Universal Grad tip, Sterile, Low retention, Filter	XR-10-SLF	1LCG1011R	80
9	10ul Universal Grad tip, Sterile, Low retention, Reload	XRE-10-SL	1LCG1010K	80
10	10ul Universal Grad tip, Sterile, Low retention	XR-10-SL	1LCG1010R	50
11	10ul Long Universal Grad tip, Sterile, Low retention, Filter	XR-10XL-SLF	4LCG0211R	70
12	10ul Long Universal Grad tip, Sterile, Low retention, Reload	XRE-10XL-SL	4LCG0210K	70
13	10ul Long Universal Grad tip, Sterile, Low retention	XR-10XL-SL	4LCG0210R	50
14	200ul Universal Grad tip, Sterile, Low retention	XR-200-SLF	2LCG1011R	110
15	200ul Universal Grad tip, Sterile, Low retention, Reload	XRE-200-SL	2LCG1010K	200
16	200ul Universal Grad tip, Sterile, Low retention	XR-200-SL	2LCG1010R	80



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17	300ul Universal Grad tip, Sterile, Low retention, Filter	XR-300-SLF	8LCG0111R	70
18	300ul Universal Grad tip, Sterile, Low retention, Reload	XRE-300-SL	8LCG0110K	80
19	300ul Universal Grad tip, Sterile, Low retention	XR-300-SL	8LCG0110R	50
20	20ul Universal Grad tip, Sterile, Low retention	XR-20-SLF	2LCG1011R	70