

CERTIFICATE OF ANALYSIS

A33073 PureLink™ Expi Endotoxin-Free Maxi Sample Kit

Packaging Lot: 2829658

Expiry Date: 30.09.2024 (DD.MM.YYYY)

Storage: at room temperature

Filling lots for components in package:

Lot	Quantity	Description
2823947	0.65 mL	RNase, 20 mg/ml
2822475	30 mL	TE Buffer (TE)
2822695	72 mL	Resuspension Buffer (R3)
2815299	330 mL	Wash Buffer (W8)
2823499	72 mL	Lysis Buffer (L7)
2824643	72 mL	Precipitation Buffer (N3)
2824322	132 mL	Elution Buffer (E4)
2823595	25 mL	Endotoxin Removal Buffer
2821369	1 mL	Lysis Indicator
2822611	21 mL	Endotoxin Free Water
2803846	1 pack	Maxi DNA binding Column
2801669	4 each	Lysate Clarification Column
2811118	1 pack	Endotoxin Free, 2 mL Tubes
2799982	1 pack	50 mL Collection tubes

QUALITY CONTROL

Parameter	Method	Requirement	Result
Rnase A Specific Activity	One unit is the amount of the enzyme which produces an increase in soluble reaction products by 1.0 A260 using yeast RNA as substrate in 15 minutes at 37°C. Fifty units are approximately equivalent to 1 Kunitz unit.	≥ 5000 U/mg	Conforms
pH	Ph.Eur. 2.2.3.	Solution specific	Conforms
Density	Measured using a densitometer.	Solution specific	Conforms
Refractive Index	Measured using a refractometer.	Solution specific	Conforms
Conductivity	Measured using a conductometer.	Solution specific	Conforms
Endotoxin Levels	Endotoxin levels in Elution Buffer and Endo Free Water are measured using a Gel-Clot Limulus Amebocyte Lysate (LAL) assay.	<0.25 EU/mL	Conforms
Yield of purified control plasmid DNA	PureLink™ Expi Endotoxin-Free Maxi Sample Kits qualified by isolating a high copy number control plasmid DNA from 100 mL of overnight E. coli culture following the protocol outlined in the manual.	≥ 750 µg	Conforms
Purity	A260/A280 ratio.	≥1.8	Conforms

ISO CERTIFICATION

Manufactured by Thermo Fisher Scientific Baltics UAB, in compliance with ISO 9001 and ISO 13485 certified quality management system.

Quality authorized by QC:

J. Žilinskienė

