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CERTIFICATE OF ANALYSIS

4458688 **BigDye™ Direct Cycle Sequencing Kit**

Packaging Lot: **2807238**

Expiry Date: 30.06.2024 (DD.MM.YYYY)

Storage: at -20±5°C in the dark

Note: **For Research Use Only. Not for use in diagnostic procedures.**

Filling lots for components in package:

Lot	Quantity	Description
2772209	5 mL	BigDye™ Direct PCR Master Mix
2772213	2 x 1 mL	BigDye™ Direct Sequencing Master Mix
2792501	20 µL	Control DNA CEPH 1347-02
2772212	1 mL	BigDye™ Direct M13 Reverse Primer
2756426	1 mL	BigDye™ Direct M13 Forward Primer

QUALITY CONTROL

Parameter	Method	Requirement	Result
pH (PCR Master Mix, Sequencing Master Mix)	Measured using a pH meter at 25 °C.	Within range of target pH	Pass
Mg^{2+} Concentration (PCR Master Mix)	Determined by analytical method.	Within range of target concentration	Pass
dATP Concentration (PCR Master Mix)	Determined by analytical method.	Within range of target concentration	Pass
dCTP Concentration (PCR Master Mix)	Determined by analytical method.	Within range of target concentration	Pass
dGTP Concentration (PCR Master Mix)	Determined by analytical method.	Within range of target concentration	Pass
dTTP Concentration (PCR Master Mix)	Determined by analytical method.	Within range of target concentration	Pass
DNase (PCR Master Mix)	Determined by analytical method.	≤ 155 pg / 1U	Pass
RNase (PCR Master Mix)	Determined by analytical method.	≤ 1.15 pg / 1U	Pass
E. coli Ori (PCR Master Mix)	Bacterial DNA Burden.	≤ 4.000 copy	Pass
Functional test (PCR Master Mix)	PCR amplification of specific fragment from human genomic DNA and analysis on E-Gel.	Reaction produces 1 specific PCR product, which is correct length and yield	Pass
Functional test (Sequencing Master Mix)	Product is tested for DNA Sequencing functional performance on a Genetic Analyzer.	• Contiguous Read Length (KB-QV20) ≥ 580 bp • Base Calling Accuracy (98.5%) ≥ 580 bp	Pass

Purity (M13 forward primer, M13 reverse primer)	Determined by HPLC.	Meet predetermined specifications	Pass
Concentration (M13 forward primer, M13 reverse primer)	Determined by analytical method.	Meet predetermined specifications	Pass
Physical inspection	Components are inspected for correct label and lot number. Caps are tightened to manufacturer's recommended torque.	• Tube label inspection • Torque check	Pass

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