



CERTIFICATE OF ANALYSIS

Product: OptiPrep™ Catalogue no. (REF): 1114542
Package size: 1 x 250 mL
Lot no.: 00118 Internal lot no.: 10196198
Expiry date: 2021-06

Quality Control Results

Test	Requirement	Result
Density, g/cm ³	1.320 ± 0.001	1.321
Endotoxins, EU/mL	< 1.0	< 0.3
Sterility test. Acc. to Ph.Eur	Sterile	Pass

The procedures and specifications used in the Quality Control are defined in approved and authorized Quality Control Procedures and Specifications, filed in the Device Master Records and maintained by the manufacturer's Quality System. The Quality Control of the lot is performed and documented by the Quality Control (QC) department. The lot is released for sale by the Quality Assurance (QA) department.

Alere Technologies AS hereby certifies that the above lot information is authentic and accurate.

Approved by:

Alere Technologies AS, Quality Assurance
Stig Ramsvik (STRA) 2018-11-26 07:56:57 (YYYY-MM-DD hh:mm:ss)

This document is electronically signed and is valid without a handwritten signature.