



CERTIFICATE OF ANALYSIS

Product: Lymphoprep™ Catalogue no. (REF): 1114547
Package size: 6 x 500 mL
Lot no.: 00219 Internal lot no.: 10202949
Expiry date: 2022-02

Quality Control Results

| Test | Requirement | Result |
|--------------------------------|---------------|--------|
| Density, g/cm ³ | 1.077 ± 0.001 | 1.078 |
| Osmolality, mOsm | 290 ± 15 | 294 |
| Endotoxins, EU/mL | < 1.0 | < 0.1 |
| Sterility test Acc. to Ph Eur. | Sterile | Pass |

The product is manufactured in compliance with GMP and ISO13485.

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) 2019-06-04 14:33:04 (YYYY-MM-DD hh:mm:ss)

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

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