



## CERTIFICATE OF ANALYSIS

Product: Lymphoprep™ Catalogue no. (REF): 1116508  
Package size: 10 x 500 mL  
Lot no.: 00119 Internal lot no.: 10200390  
Expiry date: 2022-01

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### Quality Control Results

Test	Requirement	Result
Density, g/cm <sup>3</sup>	1.077 ± 0.001	1.077
Osmolality, mOsm	290 ± 15	284
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) 2019-03-15 12:12:11 (YYYY-MM-DD hh:mm:ss)

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

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Template: 1116508 Lymphoprep, 10x500 mL, version 3