



Bio-Rad
Laboratories

Diagnostics Group
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CERTIFICATE-OF-ANALYSIS

Product Name: Lyphocek Coagulation Control
Master Batch Number: 84780
Product Base: Human Plasma
Physical Form: Lyophilized
Date of Manufacture: 2024-06-30

Description	Material Number	Batch Number	Expiration Date
Level 1	744	84781	2027-06-30
Level 2	745	84782	2027-06-30
Level 3	746	84783	2027-06-30
MiniPak	745X	84780	2027-06-30

Testing Results:

Each human donor unit used to manufacture this product was tested and found non-reactive at the donor level per current applicable FDA requirements using FDA-accepted methods including testing for HIV-1/HIV-2 antibody, HBsAg, HCV Antibody, HIV-1 and HCV by a nucleic acid test (NAT).

	Level 1	Level 2	Level 3
Water Activity: Specification: < 0.200 aw	< 0.030 aw	< 0.030 aw	< 0.030 aw

Homogeneity Claim:

"Testing has been conducted to verify sufficient homogeneity in accordance with established requirements."

ADDITIONAL TESTING:

This product has been manufactured under applicable guidelines/standards and meets all established Bio-Rad quality requirements.

Approved By:

Date:

A. Ragnan

(QC Supervisor/Manager)

10-08-2024

[Signature]

(QA Supervisor/Manager)

10-9-24

