



Bio-Rad
Laboratories

Diagnostics Group
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CERTIFICATE-OF-ANALYSIS

Product Name: Lyphochek® Tumor Marker Plus Control
Master Batch Number: 54680
Product Base: Human Serum
Physical Form: Lyophilized
Date of Manufacture: 2019-05

Description	Material Number	Batch Number	Expiration Date
Level 1	367	54681	2022-08-31
Level 2	368	54682	2022-08-31
Level 3	369	54683	2022-08-31
Trilevel MiniPak	368X	54680	2022-08-31

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).

The bovine source material(s) of this product is collected in USDA licensed establishments. These animals received ante and post mortem inspections at the abattoir by a US veterinary service inspector.

Water Activity: Specification: <0.200 aw

Level 1	Level 2	Level 3
0.050 aw	0.049 aw	0.050 aw

Homogeneity Claim:

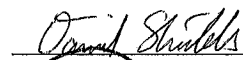
"Testing has been conducted to verify sufficient homogeneity in accordance with established requirements."

ADDITIONAL TESTING:

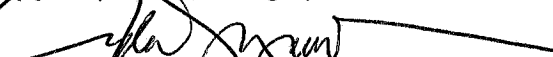
This product has been manufactured under applicable guidelines/standards and meets all established Bio-Rad quality requirements.

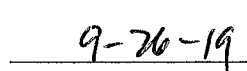
Approved By:

Date:


(QC Supervisor/Manager)


09/17/2019


(QA Supervisor/Manager)


9-26-19

