

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k042324

B. Purpose for Submission:

New Device

C. Analyte:

Quality Control Material (Assayed and unassayed)

D. Type of Test:

Quantitative

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Lyphochek Elevated Immunosuppressant Control

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1660 Quality control material (assayed and unassayed).
2. Classification:
I (Reserved)
3. Product Code:
JJY
4. Panel:
75

H. Intended Use:

1. Intended use(s):
Lyphochek Elevated Immunosuppressant Control is intended for use as a whole blood quality control to monitor the precision of laboratory procedures for cyclosporine testing.
2. Indication(s) for use:
Lyphochek Elevated Immunosuppressant Control is intended for use as a whole blood quality control to monitor the precision of laboratory procedures for cyclosporine testing.
3. Special condition for use statement(s):
For Prescription Use only

4. Special instrument Requirements:
None Reported

I. Device Description:

Lyphochek Elevated Immunosuppressant Control is a bi-level (levels 4 and 5) with 2 mL per level of solution containing cyclosporine. The base matrix for these solutions is processed human whole blood lysate. The human donor unit used to produce this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAG), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Lyphochek Whole Blood Control
2. Predicate K number(s):
k022041
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Lyphochek Elevated Immunosuppressant Control is intended for use as a whole blood quality control to monitor the precision of laboratory procedures for cyclosporine testing	Lyphochek Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Matrix	Human Whole Blood	Human Whole Blood
Stability	14 days at 2 to 8 °C after reconstituting	14 days at 2 to 8 °C after reconstituting
Shelf-Life	3 years and 3 months expiration	3 years and 3 months expiration
Differences		
Item	Device	Predicate
Levels	Bi-level control 4 and 5	Tri-level control 1,2 and 3
Components	Cyclosporine Only	Cyclosporine, Led, Red Cell Folate, Tacrolimus and Sirolimus

K. Standard/Guidance Document Referenced (if applicable):

None Referenced

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not Applicable

b. *Linearity/assay reportable range:*

Not Applicable

c. *Traceability (controls, calibrators, or method):*

Cyclosporine raw material was purchased at a predetermined concentration and the concentration is verified and the control is gravimetrically prepared.

Stability

Real-time stability studies have been performed to determine the reconstituted stability and shelf life for the Lyphochek Elevated Immunosuppressant Control. Product claims the control material is stable when reconstituted for 14 days at 2-8 °C and has a shelf life of 3 years and 3 months when stored at 2-8 °C.

d. *Detection limit:*

Not Applicable

e. *Analytical specificity:*

Not Applicable

f. *Assay cut-off:*

Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Not Applicable

b. *Matrix comparison:*

Not Applicable

3. Clinical studies:

a. *Clinical sensitivity:*

Not Applicable

b. *Clinical specificity:*

Not Applicable

c. Other clinical supportive data (when a and b are not applicable):
Not Applicable

4. Clinical cut-off:
Not Applicable

5. Expected values/Reference range:
The concentrations in the Lyphochek Elevated Immunosuppressant Control has lot specific values. The concentrations for level 4 that has a target concentration of 700 ng/mL fall within the range of 586-880 ng/mL. The concentration for level 5 that has a target concentration of 1500 ng/mL fall with the range of 1112- 1668 ng/mL.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.