

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

A. 510(k) Number:

k072721

B. Purpose for Submission:

New control material

C. Measurand:

Control material for sirolimus, tacrolimus, cyclosporine

D. Type of Test:

Not applicable, control material

E. Applicant:

Bio-Rad Diagnostics Group

F. Proprietary and Established Names:

Lypochek® Whole Blood Immunosuppressant Control

Abbott Immunosuppressant MCC

G. Regulatory Information:

1. Regulation section: Clinical Toxicology Control Material, 862.3280
2. Classification: Class I, reserved
3. Product code: DIF
4. Panel: 91 (Toxicology)

H. Intended Use:

1. Intended use(s):
Lyphochek Whole Blood Immunosuppressant Controls are 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. The following analytes are listed in the package insert: Sirolimus, Tacrolimus, and Cyclosporine.

Abbott Immunosuppressant MCC 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. The following analytes are listed in the package insert: Sirolimus, Tacrolimus.

2. Indication(s) for use:

See intended use

3. Special conditions for use statement(s):

For prescription use

Biological Source material should be treated as potentially infectious. In accordance with good laboratory practice all human source material should be considered potentially infectious and handled with the same precautions used for human specimens.

4. Special instrument requirements:

None

I. Device Description:

The device consists of control materials prepared from human whole blood, with added chemicals and stabilizers, in lyophilized form. The Lypocheck® Whole Blood Immunosuppressant Control is available at 5 concentration levels. Abbott Immunosuppressant MCC is a tri-level control. Each human donor unit used to manufacture the control was tested by the manufacturer by FDA accepted methods and found non-reactive for HBsAg, antibody to HCV and antibody to HIV-1/HIV-2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Lypocheck® whole blood control tri-level

2. Predicate K number(s):

k022041

3. Comparison with predicate:

The new device has a similar intended use and similar components as the predicate device. The differences are that the predicate control material also contained folate, lead, and serotonin analytes which are not contained in the new material. The predicate material contained citrated whole blood; The new device contains EDTA whole blood.

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 for control material.

b. *Linearity/assay reportable range:*

Not applicable for control material.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Value assignment for the levels of control materials are generated by the manufacturers of the test kits or instruments or by multiple reference laboratories. The protocol Bio-Rad recommends to manufacturers performing the testing includes a *minimum* of 20 replicates over a period of *at least* 10 days, using various lots of reagents.

The manufacturer states that the ranges listed in the package insert are provided for informational use, and that each laboratory should establish its own acceptable ranges.

Bio-Rad did not provide traceability information for these materials.

Stability is performed for opened vial and for shelf life and are performed to mimic handling of the product in the customer's hands. Protocols and acceptance criteria were reviewed and found to be acceptable.

d. *Detection limit:*

Not applicable for control material.

e. Analytical specificity:

Not applicable for control material.

f. Assay cut-off:

Not applicable for control material.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable for control material.

b. Matrix comparison:

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable for control material.

b. Clinical specificity:

Not applicable for control material.

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

4. Clinical cut-off:

Not applicable for control material.

5. Expected values/Reference range:

Not applicable for control material.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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