

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

A. 510(k) Number:

k051074

B. Purpose for Submission:

Notification of intent to manufacture and market the device: MAS Immunosuppressant Control Kit into interstate commerce.

C. Measurand:

Three assayed levels of cyclosporine, tacrolimus and sirolimus

D. Type of Test:

Quality Control Material

E. Applicant:

Microgenics Corporation

F. Proprietary and Established Names:

Proprietary – MAS Immunosuppressant Control Kit

Established Name – Toxicology Quality Control Material

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3280 Clinical Toxicology Control Material

2. Classification:

Class I , reserved

3. Product code:

LAS

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The MAS Immunosuppressant Controls, consisting of Levels 1 through 3, are in-vitro diagnostic devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine, sirolimus and tacrolimus.

3. Special conditions for use statement(s):

The MAS Immunosuppressant Controls are for professional use only.

4. Special instrument requirements:

I. Device Description:

The MAS Immunosuppressant Controls are prepared from whole blood with stabilizers added to increase stability. The MAS Immunosuppressant Controls include three separate controls known as Level I, Level II, and Level III with approximately 70, 200, 350 ng/mL of cyclosporine, 5.5, 10, and 15 ng/mL of tacrolimus, and 5.5, 10 and 15 ng/mL of sirolimus.

Human source material from which this product has been derived has been tested at the donor level for the Human Immunodeficient Virus (HIV1, HIV2) antibody, Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus (HCV) and found to be non-reactive. FDA approved methods have been used to conduct these tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Lyphochek Whole Blood Control

2. Predicate 510(k) number(s):

k022041

3. Comparison with predicate:

Device Characteristics	Subject Device	Predicated Device (K022041)
Intended Use	The MAS Immunosuppressant Controls, consisting of levels 1 through 3, are in-vitro diagnostic medical devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine, sirolimus, and tacrolimus.	Lyphochek® Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine, lead, red cell folate, tacrolimus, and sirolimus.
Matrix	Processed Human Whole Blood	Processed Human Whole Blood
Form	Liquid	Lyophilized
Analytes	Cyclosporine, Sirolimus, Tacrolimus	Cyclosporine, Lead, Red Cell Folate, Tacrolimus, Sirolimus
Levels	Three (3) Levels	Three (3) Levels
Open Vial Claim	14 days at 2°C to 8°C	14 days at 2°C to 8°C. Exception: Red cell folate is stable for 3 days at 2°C to 8°C
Storage	-20°C until expiration date	2°C to 8°C until expiration date
Stability	Until expiration date noted on vial label.	Until expiration date noted on vial label.

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

None stated

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, Stability, Expected values (controls, calibrators, or methods)*

Target values are set to create three distinct levels, which are obtained by spiking each level to different analyte concentrations. Target values take clinical needs, assay range, imprecision profile and CEDIA specifications into account. Control targets are traceable to gravimetrically prepared primary reference standards and are confirmed by LC-MS/MS.

The MAS Immunosuppressant Controls open vial stability was established by thawing each control level and testing the controls on day 0 and day 14 using the CEDIA Cyclosporine Plus, Sirolimus and Tacrolimus assays. The thawed controls were stored at 2 - 8°C between days 0 and 14; Controls tested on day 14 recover within the established range of the respective CEDIA immunoassay as compared to day 0.

Real-time stability of the controls is established by periodically testing samples to determine recovery. The mean of the LC-MS/MS result on test recovery must fall within ± 2 SD of the LC-MS/MS initial value. Real-time stability studies support a claim of 24 months when stored as directed.

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:

Not applicable

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.