

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

**A. 510(k) Number:**

k072257

**B. Purpose for Submission:**

New device

**C. Measurand:**

None – submission is for clearance of control material

**D. Type of Test:**

Control materials

**E. Applicant:**

More Diagnostics

**F. Proprietary and Established Names:**

Mycophenolic Acid Control

**G. Regulatory Information:**

1. Regulation section:

21 CFR § 862.3280 – Clinical Toxicology Control material

2. Classification:

Class I, reserved (control—assayed and unassayed)

3. Product code:

LAS – Drug Specific Control Materials

4. Panel:

Toxicology (91)

**H. Intended Use:**

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

More Diagnostics' Mycophenolic Acid Control is intended to be used as an assayed precision control product in monitoring accuracy and precision for quantitative methods that measure mycophenolic acid.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:  
Liquid Chromatography/Mass Spectrometry (LC/MS)

**I. Device Description:**

The Mycophenolic Acid (MPA) control is a four-level ready-to-use liquid serum based product. The kit contains 4 (2ml) vials for each level. The product was prepared from human blood to which the purified MPA, preservatives, and stabilizers were added. The product is provided in four concentration ranges that are relevant in a clinical setting. The unopened products are stored frozen at -14°C or below and the opened products are thawed and stored at 2-8°C. The human source material was tested and found to be negative for Hepatitis B, Hepatitis C, HTLV (1 and 2); HIV (1 and 2) using FDA approved tests. The labeling states that no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with caution.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Roche Diagnostics Mycophenolic Acid Control
2. Predicate K number(s):  
k063520
3. Comparison with predicate:

| <b>Similarities</b> |   |           |
|---------------------|---|-----------|
| Item                | Device  | Predicate |
| Intended Use        | Control to monitor accuracy and precision for quantitative MPA assays | Same      |
| Form                | Liquid  | Same      |
| Analytes            | Mycophenolic Acid   | Same      |
| Matrix              | Human serum   | Same      |
| Storage             | Frozen or thawed (refrigerated)                                       | Same      |

| <b>Differences</b>  |                         |                          |
|---------------------|-------------------------|--------------------------|
| Item                | Device                  | Predicate                |
| Levels              | Four                    | Three                    |
| Open vial stability | 45 days thawed at 2-8°C | 6 months thawed at 2-8°C |

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

Traceability

The controls are prepared by the gravimetric addition of drug to human serum.

The controls are traceable to a primary reference method, LC-MS/MS.

Stability

The stability protocols and acceptance criteria were reviewed and found to be acceptable. Current real-time studies support the claim of a frozen shelf life at -14°C or below for at least 2 years. Open vial aging supports the claim of an opened (thawed), refrigerated (2-8°C) shelf life of 45 days.

Value Assignment

The product is provided in 4 different concentration ranges. Lot specific mean values and ranges are provided to the user via the product insert for LC/MS instruments. These values are obtained from at least 20 replicates assayed on a representative sampling of the manufactured lot over 4 days. The labeling includes the recommendation that ranges are provided as guidelines only and that laboratories should determine the range based upon their test system.

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:

Lot specific ranges are provided in the labeling for use on LC/MS instruments. The labeling includes the recommendation that ranges are provided as guidelines only and that laboratories should determine the range based upon their test system.

**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.