

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

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

k080459

**B. Purpose for Submission:**

New control materials

**C. Measurand:**

Control materials for Cyclosporine, Sirolimus, and Tacrolimus.

**D. Type of Test:**

Not applicable, control materials.

**E. Applicant:**

Chromsystems Instruments and Chemicals, GmbH

**F. Proprietary and Established Names:**

MassCheck Immunosuppressants Whole Blood Control

**G. Regulatory Information:**

1. Regulation section: 21 CFR 862.3280
2. Classification: Class I, reserved (for assayed controls)
3. Product Code: DIF- Drug Specific Control Materials
4. Panel: 91 (Toxicology)

**H. Intended Use:**

1. Intended use(s):  
See Indications for use, below.
2. Indication(s) for use:

The Chromsystems Immunosuppressants Whole Blood Calibrators are in vitro diagnostic devices intended to verify performance of various laboratory assay systems that measure cyclosporine, sirolimus and tacrolimus.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

**I. Device Description:**

The control materials consist of CPD (Citrate Phosphate Dextrose) human whole blood with immunosuppressants added to it (see concentrations below). These solutions are lyophilized to increase stability. The user must reconstitute these materials prior to use. The target concentration ranges (i.e., the ranges of assigned values the manufacturer allows for each lot) is shown below.

Name of device	Analyte (µg/L)		
Immunosuppressants Whole Blood Controls			
Level I	83.2-125	2.00 – 3.71	2.07 - 4-31
Level II	197 - 295	5.55 – 9.25	8.38 – 12 6
Level III	410 - 616	13.0 – 19.6	16.9 – 25.3
Level IV	1385 - 2077	29.3 – 43.9	33.4 – 50.2
Blank Control	<1.0	<1.5	<0.05

The manufacturer includes the following in the product insert: The product contains pooled human whole blood tested and found non-reactive against HIV 1+2 antibodies, HIV-, HCV-, and HBV-DNA (PCR), HBs antigen, HBc antibodies, HCV antibodies and by TPHA. Because no test method can give absolute assurance that materials will be free of infectious agents, a possible danger of infection should be taken into account. This product may also contain unknown agents or other pathogens for which there are no approved tests. We therefore recommend considering all products containing human source material as potentially infectious. As a consequence exercise the same care in the handling of the product as in the handling of potentially infectious patient samples.

**J. Substantial Equivalence Information:**

1. Predicate device name(s): Bio-Rad Laboratories Lypocheck Whole Blood Immunosuppressant Control.
2. Predicate 510(k) number(s): k072721. (The sponsor also identified the calibrators within the Waters MassTrak Immunosuppressants Kit k063868.)
3. Comparison with predicate:  
The predicate and proposed devices are similar in the following ways:
  - Same intended use - in vitro diagnostic devices intended for the calibration and control of laboratory assay systems used in the determination of immunosuppressant drug specific analytes in patient whole blood.
  - Same analytes
  - Consist of similar matrices (human whole blood)
  - Predicates and proposed devices are supplied as lyophilized material and must be reconstitutedThese devices differ in the following ways:
  - The numbers of concentration and levels are different.

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

CEN EN 980: 2001, Graphical Symbols for Use in the Labeling of Medical Devices

ISO 14971: 2007, Application of Risk Management to Medical Devices

**L. Test Principle:**

Not applicable for control materials

**M. Performance Characteristics (if/when applicable):**

Performance characteristics such as precision, linearity, detection limit and method comparison are not applicable for control materials.

1. Analytical performance:

*a. Precision*

Not applicable

*b. Linearity/assay reportable range:*

Not applicable

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

Value assignment for controls:

Value assignment, which was described fully in the 510(k), is based on purified

materials (> 98%-99% purity) used to calibrate an LCMS/MS System. Multiple control materials were reconstituted by multiple operators and replicates were measured for each level. The labeling includes the recommendation that individual laboratories should establish their own mean values and ranges.

**Stability:**

Stability testing was performed to support the manufacturer's storage recommendations of 2-8 degrees C for up to one week for reconstituted materials, or -18 degrees C for up to 6 months for lyophilized materials.

Materials stored at -18 degrees C were compared to materials stored at -80 degrees C and "time zero" measurements. Measurements were conducted using a well-validated LCMS method. (Information regarding the method was provided in the 510(k)). At each time multiple samples of each control were measured. Calculated slopes of change in percent recovery per month were all within 0.3%.

For in-use stability testing freshly measurements of reconstituted samples were compared to samples held under the manufacturer's recommended conditions. Calculated slopes of change in percent recovery per week were < 1.6% relative to the newly reconstituted samples.

*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:

Not applicable

a. *Clinical Sensitivity:*

b. *Clinical specificity:*

c. Other clinical supportive data (when a. and b. are 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.