

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

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

k103271

**B. Purpose for Submission:**

Addition of two analytes: Apolipoprotein AI (Apo AI) and Apolipoprotein B (Apo B) to previously cleared quality control material k082067

**C. Measurand:**

Control material for analytes: HDL-C, LDL-C, Cholesterol, Triglycerides, Apolipoprotein AI (Apo AI) and Apolipoprotein B (Apo B)

**D. Type of Test:**

Quality control material

**E. Applicant:**

Maine Standards Company

**F. Proprietary and Established Names:**

MSC Lipid Control

**G. Regulatory Information:**

| Product Code | Classification    | Regulation Section | Panel                 |
|--------------|-------------------|--------------------|-----------------------|
| JJY          | Class I, reserved | 21 CFR862.1660     | 75 Clinical Chemistry |

**H. Intended Use:**

1. Intended use(s):

See "Indications for Use" below.

2. Indication(s) for use:

The MSC Lipid Control is intended for use as an assayed quality control material to monitor the ongoing precision of clinical laboratory systems for the following analytes: High-density Lipoprotein Cholesterol (HDL-C), Low-density Lipoprotein Cholesterol (LDL-C), Total Cholesterol (CHOL), Triglycerides (TRIG), Apolipoprotein AI (Apo AI), and Apolipoprotein B (Apo B) on instruments listed in the value sheet.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Instruments listed on the value sheet include the following: Roche Integra 400, Roche Cobas c501, Ortho Clinical Vitros 5,1 FS, Beckman Coulter Immage 800

**I. Device Description:**

The MSC Lipid Control is a human serum based liquid quality control containing stabilized HDL-C, LDL-C, CHOL, TRIG, Apo AI and Apo B of human origin. The device consists of a total of six vials with each vial representing two levels: Level 1 at 3 x 10mL and Level 2 at 3 x 10mL. Material of human origin was tested at the donor level using FDA approved methods and found to be non-reactive for HBsAg and to antibodies to HCV and HIV-1/2.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Bio-Rad Liquichek™ Lipids Control, Level 1 and 2
2. Predicate 510(k) number(s):  
k012513
3. Comparison with predicate:

**Similarities**

| Item         | Device: MSC Lipid Control   | Predicate: Bio-Rad Liquichek™ Lipids Control |
|--------------|---|--|
| Similarities |   |  |
| Intended Use | Assayed quality control material to monitor the ongoing precision of clinical laboratory analysis for the listed analytes | Same   |
| Levels       | Two   | Same   |
| Matrix       | Human serum based liquid  | Same   |

**Differences**

| Item                   | Device: MSC Lipid Control   | Predicate: Bio-Rad Liquichek™ Lipids Control  |
|------------------------|---|---|
| Differences            |   |   |
| Number of constituents | Six   | Eight   |
| Constituents           | Cholesterol<br>Triglycerides<br>HDL Cholesterol<br>LDL Cholesterol<br>Apolipoprotein AI<br>Apolipoprotein B | Cholesterol<br>Triglycerides<br>HDL Cholesterol<br>LDL Cholesterol<br>Apolipoprotein AI<br>Apolipoprotein B<br>C-Reactive protein<br>Lipoprotein(a) |

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

1. ISO 14971:2007 Medical Devices – Application of risk management to medical devices
2. CLSI C24-A3 Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions: Approved Guidelines – Third Edition
3. Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s
4. Guidance for Industry and FDA Staff: Assayed and Unassayed Quality Control Material
5. Guidance for Industry and FDA Staff: Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

**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:

Values assigned to the assayed quality controls are traceable to the reference standards used by the assay manufacturer to establish instrument response in their assays.

Stability:

Shelf-life – The sponsor provided accelerated stability data demonstrating that the MSC Lipid Control can be stored for 12 months at -10° to 20°C.

Open vial – The sponsor provided data demonstrating that upon opening a vial of MSC Lipid Control, the material is stable for 30 days at 2 - 8°C.

Real-time stability studies are on-going, but current data is supportive of the above claims.

Value assignment:

The two level MSC Lipid Control was tested at independent laboratories using different clinical systems: Roche Integra 400, Roche Cobas c501, Ortho Clinical Vitros 5,1 FS, and Beckman Coulter Immage 800. At least 20 independent runs were performed in singlicate. Data were collected, statistically analyzed, and the range calculated for each clinical platform (n>20 per platform). The range represents  $\pm 2SD$  (95.5% CI) around the system mean recovery. The mean and range are provided in tabular and graphical form in the value assignment sheet.

- 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:  
Expected values are provided in the value assignment sheets provided with the package insert

**N. Proposed Labeling:**

The labeling is sufficient and 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.