

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

A. 510(k) Number:

k082067

B. Purpose for Submission:

New device

C. Measurand:

Control material for Multi-Analytes: Cholesterol, Triglycerides, HDL Cholesterol and LDL Cholesterol

D. Type of Test:

Control Materials

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 CFR§ 862.1660	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 control material to monitor the ongoing precision of clinical laboratory analysis for Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol. This material is intended for use on automated, semi-automated, and manual clinical chemistry analyzer systems.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Instruments listed in the package insert include the following: Roche Hitachi 911, Roche HitachiModP, Roche Hitachi 917, Dade Dimension Expand, and the Beckman Coulter LX.

I. Device Description:

The MSC Lipid Control is a human serum based liquid control containing stabilized Cholesterol, Triglycerides, HDL Cholesterol and LDL Cholesterol of human origin. The device consists of six vials total, three vials at each of two levels (Level 1: 3 x 7mL and Level 2: 3 x 7mL). All human source materials were tested by FDA approved methods and found to be negative for HIV-1, HIV-2, HCV, and HBsAg.

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
Intended Use	Assayed control material to monitor the ongoing precision of clinical laboratory analysis for Cholesterol, Triglycerides, HDL Cholesterol and LDL Cholesterol	Assayed control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert
Levels	Two	Two
Matrix	Human serum based liquid	Human serum based liquid
Differences		
Number of Constituents	Four	Eight
Constituents	Cholesterol Triglycerides HDL Cholesterol LDL Cholesterol	Cholesterol Triglycerides HDL Cholesterol LDL Cholesterol Apolipoprotein A-1 Apolipoprotein B C-Reactive Protein Lipoprotein Lp(a)
Target Range	Different assigned values	Different assigned values

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

- ISO 14971:2000, Medical Devices – Application of risk management to medical devices.
- FDA Guidance: Format for Traditional and Abbreviated 510(k)s (2005).
- FDA Guidance: Points to Consider for Review of Calibration and Quality Control Labeling for *in vitro* Diagnostic Devices (1996).
- CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.
- CLSI C24-A3: Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions: Approved Guideline – Third Edition.
- CDRH: Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material (2007).

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

Stability:

Stability and acceptance criteria were reviewed and the stability claims for the MSC Lipid Control are as follows. Unopened – stable until expiration date at -10° to -20°C, Opened – stable for 30 days at 2° to 8°C. The device is under continuing real-stability testing, but current data is supportive of the aforementioned claims.

Value Assignment:

The two level MSC Lipid Control was tested at independent laboratories using different clinical systems. Twenty runs were performed in singlet at each location. The analytes were tested on the following platforms: Roche Hitachi 911, Roche Hitachi ModP, Roche Hitachi 917 (the Roche Hitachi 917 laboratory does not run LDL Cholesterol), Dade Dimension Expand and the Beckman Coulter LX. Data for Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol were collected, statistically analyzed, and the range calculated for each clinical platform (n = 20 per platform).

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.