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

A. 510(k) Number:

k103403

B. Purpose for Submission:

New device

C. Measurand:

Multi-analyte calibrator

D. Type of Test:

Not applicable.

E. Applicant:

Abbott Laboratories

F. Proprietary and Established Names:

Abbott Clinical Chemistry Multiconstituent Calibrator

G. Regulatory Information:

1. <u>Regulation section:</u>

21 CFR §862.1150, Calibrator

2. Classification:

Class II

3. <u>Product code:</u>

JIX - Calibrator, Multi-Analyte Mixture

4. <u>Panel:</u>

75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

The Abbott Clinical Chemistry Multiconstituent Calibrator (MCC) is an in vitro diagnostic product intended for use as a calibration serum in clinical chemistry assays. The MCC contains 13 analytes in a liquid human serum based matrix. The concentrations and activities are suitable for calibration of the Abbott ARCHITECT *c*8000 System. Constituent concentrations are available at two levels.

3. <u>Special conditions for use statement(s):</u>

For *in vitro* diagnostic use. For prescription use only.

4. <u>Special instrument requirements:</u>

The Abbott Clinical Chemistry Multiconstituent Calibrator is intended for use with the Abbott ARCHITECT c8000 System.

I. Device Description:

The Abbott Clinical Chemistry Multiconstituent Calibrator is prepared from a humanbased matrix containing the following analytes: albumin, total protein (made from human sourced albumin material), calcium, creatinine, glucose, iron, lactic acid, magnesium, phosphorus, urea nitrogen, uric acid, cholesterol, and triglyceride. The product consists of two levels. Sodium azide is present as a preservative.

The human serum albumin used in the calibrators has been tested and found to be nonreactive for HBsAg, anti-HIV-1/HIV-2, anti-HCV, and syphilis.

J. Substantial Equivalence Information:

1. <u>Predicate device name(s)</u>:

MC Calibrator Levels 1 and 2

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

k981706

3. <u>Comparison with predicate:</u>

Item	Device	Predicate
	(k103403)	(k981706)
Indications	For use as a calibration serum in	Same
for use	clinical chemistry assays.	
Format	Liquid, ready for use	Same
Matrix	Human serum	Same
Analytes	Albumin, calcium, cholesterol,	Albumin, calcium, cholesterol,
	creatinine, glucose, iron, lactic acid,	creatinine, glucose, phosphorus,
	magnesium, phosphorus, total	total protein, triglyceride, urea
	protein, triglyceride, urea nitrogen,	nitrogen, and uric acid
	and uric acid	
Stability	Unopened	Same
	Store at 2-8°C until expiration date	
	Opened	
	2-8°C for 7 days	
	15-30°C for 24 hours	
Levels	2	Same

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

Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrator; Final Guidance for Industry

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 Abbott Clinical Chemistry Multiconstituent Calibrator is prepared and

standardized as described in the table below.

Analyte	Reference Material	Method
Albumin	ERM-DA470	Gravimetric
Calcium	NIST SRM 956	Coulometric Titration
Cholesterol	Human Cholesterol (Abell-	Volumetric
	Kendall verification)	
Creatinine	NIST SRM 967 and 914	IDMS
Glucose	NIST SRM 965	IDMS
Iron	NIST SRM 3126	Gravimetric
Lactic Acid	Reagent grade lactate	Gravimetric
Magnesium	NIST SRM 956	IDMS
Phosphorus	NIST 186-I/2186-I	Gravimetric
Total Protein	NIST SRM 927	Gravimetric
Triglyceride	ACS Grade Glycerol	Gravimetric
Urea Nitrogen	NIST SRM 909	IDMS
Uric Acid	NIST SRM 909	IDMS

Expected Values and Value Ranges

Expected values for the Abbott Clinical Chemistry Multiconstituent Calibrator are determined by analyses of 20 replicates at each calibrator level using one Abbott Architect c8000 System. Pre-determined acceptance criteria for analyte recovery must be met for each calibrator lot. Calibrator assigned values are lot dependent and are listed in the lot-specific Multiconstituent Calibrator value sheet.

Stability

Stability testing data support the manufacturer claims that the Abbott Clinical Chemistry Multiconstituent Calibrator is stable until the expiration date printed on the vial when stored unopened at 2-8°C. Accelerated stability testing supports the target shelf life claim of 20 months. The manufacturer has an on-going real-time stability study design to support the recommended storage conditions for the life of the product. Real time stability studies were performed to evaluate the open vial stability of the calibrator. Data supports an open vial stability claim of seven days at 2-8°C or 24 hours at 30°C. The opened vials (on-board) are stable for five days at 2-8°C.

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. <u>Clinical studies</u>:
 - 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:

The expected values are provided in the labeling for each specific lot.

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.