

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

A. 510(k) Number:

k060878

B. Purpose for Submission:

Notification of intent to manufacture and market the device: addition to the Indication for Use to include risk stratification of patients

C. Measurand:

Troponin I

D. Type of Test:

Quantitative, Microparticle Enzyme Immunoassay

E. Applicant:

Abbot Laboratories

F. Proprietary and Established Names:

Proprietary Name – Abbott AxSYM[®] Troponin-I ADV
Established Name – Cardiac Troponin-I

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1215

2. Classification:

Class II

3. Product code:

MMI

4. Panel:

75 - Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

The Abbott AxSYM[®] Troponin-I ADV reagent is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of cardiac Troponin-I (cTnI) in human serum or plasma on the AxSYM System. Troponin-I values are used to assist in the diagnosis of myocardial infarction (MI) and in the risk stratification of patients with acute coronary syndromes (including unstable angina and non-ST angina) with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events.

3. Special conditions for use statement(s):

For in vitro diagnostic use only

4. Special instrument requirements:

Abbot AxSYM Analyzer

I. Device Description:

The Abbott AxSYM[®] Troponin-I ADV assay is supplied as a 100 test reagent pack consisting of Reagent Bottles 1 – 4 as follows:

Reagent Bottle 1	Conjugate 2 Anti-biotin (mouse monoclonal): alkaline phosphatase (E.coli) conjugate in TRIS buffer with protein (mouse and bovine) stabilizers.
Reagent Bottle 2	Microparticles, Anti-troponin-I (mouse monoclonal) coated microparticles in TRIS buffer with protein (mouse, goat, and bovine) stabilizers.
Reagent Bottle 3	Conjugate 1, Anti-troponin-I (mouse monoclonal): biotin conjugate in TRIS buffer with protein (mouse and bovine) stabilizers

Reagent Bottle 4 Pre-incubation diluent, diluent containing protein (mouse, goat, bovine, and E coli lysate) stabilizers in TRIS buffer.

Abbott AxSYM® Troponin-I ADV Standard Calibrators are supplied as 6 x 4 mL bottles, Calibrator A contains gelatin (porcine) solution and Calibrator B through F contain a recombinant human cardiac troponin – I – C complex in a protein (bovine) solution.

Abbott AxSYM® Troponin-I ADV Controls are supplied as 3 x 8 mL bottles containing a recombinant human cardiac troponin – I – C complex in a protein (bovine) solution.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Beckman Coulter Access AccuTnl

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

k021814

3. Comparison with predicate:

Assay Characteristics	Predicate	AxSYM Troponin-I ADV
Indications for use	Assisting in the diagnosis of MI and risk stratification of patients with acute coronary syndromes	Same
Analyte Measured	Cardiac Troponin I	Same
Assay Principle	Chemiluminescent Immunoassay	Microparticle Enzyme Immunoassay (MEIA)
Instrumentation	Access Immunoassay System	AxSYM System
Sample Type	Serum or heparinized plasma	Serum or heparinized plasma including separator tubes
Assay Range	0.01 to 100 ng/mL	0.02 to 22.78 ng/mL
Detection of Immunocomplex	Enzyme labeled anti-troponin-I binds to cTnl of the antigen – antibody complex	Enzyme labeled anti-troponin-I binds to T-I of the antigen-antibody complex
Reagent Storage	2 to 10 degrees C	2 to 8 degrees C

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

National Academy of Clinical Biochemistry Laboratory Medicine Guidelines: Biomarkers of Acute Coronary Syndrome and Heart Failure – 2004

The American College of Cardiology/American Heart Association Task Force on Practice Guidelines, (Committee on the Management of Patients with Unstable Angina). ACC/AHA Guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction – 2002: Summary Article. Circulation, 2002; 106: 1893-1900.

L. Test Principle:

Microparticle Enzyme Immunoassay (MEIA) – small particles are coated with antibodies to Cardiac Troponin I. See k041811

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision data were submitted with original submission k041811. This request for modification of Intended Use has no change in performance characteristics.

b. Linearity/assay reportable range:

See k041811.

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

See k041811.

d. Detection limit:

Se k041811.

e. Analytical specificity:

See k041811.

f. Assay cut-off:

See k041811.

2. Comparison studies:

a. *Method comparison with predicate device:*

See k041811.

Method comparison with predicate device in previous submission shows similar precision and qualitative comparison with WHO diagnosis, establishing risk stratification claims per practice guidelines. (The American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on the Management of Patients with Unstable Angina). ACC/AHA Guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction – 2002: Summary Article. Circulation, 2002; 106: 1893-1900.)

b. *Matrix comparison:*

See k041811.

3. Clinical studies:

a. *Clinical Sensitivity:*

See k041811

b. *Clinical specificity:*

See k041811

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

See k041811. The clinical cut-off for AMI is 0.04 ng/mL.

5. Expected values/Reference range:

See k041811.

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.