

K963934

Summary of 510(k) Safety and Effectiveness

DEC 16 1996

1. General Information

Device Generic Name: Enzyme Immunoassay, Troponin I
Device Trade Name: ACCESS® Troponin I assay
Applicant's Name and Address: Sanofi Diagnostics Pasteur, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

2. Predicate Device

Baxter Stratus® Cardiac Troponin-I Fluorometric Enzyme Immunoassay
Baxter Diagnostics, Inc.
Deerfield, IL 60015-4633

3. Device Description

The ACCESS® Troponin I assay is a paramagnetic-particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I levels in human serum, using the ACCESS® Immunoassay System.

4. Comparison of Technological Characteristics

The ACCESS® Troponin I test and the Stratus® Cardiac Troponin-I test are for the measurement of cardiac Troponin I in human serum. Both tests utilize the binding of cardiac Troponin I to specific monoclonal antibodies in a two site "sandwich" immunoassay. Both tests utilize alkaline phosphatase enzyme conjugated to monoclonal antibody. The ACCESS® Troponin I test uses a dioxetane-based chemiluminescent substrate, while the Stratus® Cardiac Troponin I test uses 4-Methylumbelliferyl Phosphate as the substrate. The ACCESS® Troponin I test measures light production from a chemiluminescent reaction while the Stratus® Cardiac Troponin I test measures front surface fluorescence. The ACCESS® Troponin I test uses lyophilized calibrators prepared from buffered human serum matrix with human cardiac troponin I at specified levels, while the Stratus® Cardiac Troponin I test uses liquid calibrators (shipped frozen on dry ice) prepared from buffered bovine protein matrix and human cardiac troponin I at specified levels.

5. Summary of Analytical Studies

Precision study: Total imprecision ranges from 5.97% CV (high human serum based control) to 13.53% CV (low human serum based control).
Dilution Recovery: Linearity studies performed by diluting four human serum samples containing Troponin I with Troponin I Diluent gives an average recovery of 93.5%.
Correlation: A comparison of serum Troponin I values from 189 samples run in both the ACCESS® Troponin I assay and the Stratus® Cardiac Troponin I test gives the following statistical data: $r = 0.87$, $y = 0.136x - 0.088$.
Analytical Sensitivity: The lowest detectable level of troponin I distinguishable from zero (Troponin Calibrator S0) with 95% confidence is 0.03 ng/ml.

6. Summary of Clinical Performance

The purpose of this multi-site prospective study was to 1) establish the clinical performance characteristics of the ACCESS® Troponin I assay, and 2) demonstrate substantially equivalent performance to a previously cleared troponin I assay and to the current gold standard biochemical marker, CK-MB.

For this study, 289 subjects presenting to the emergency department with chest pain of 20 minutes duration were followed serially to rule-in or rule-out AMI. Each patient contributed a minimum of two serum samples to establish the diagnosis. Forty five (45) subjects ruled-in for AMIs.

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ROC curve analysis of all subject results demonstrated an optimal cutoff of 0.15 ng/ml for this clinical indication. Using 0.15 ng/ml as a decision level, the ACCESS® Troponin I assay demonstrated a clinical sensitivity of 89% and a clinical specificity of 91%. Results from 201 patients in which both the ACCESS® Troponin I and the Stratus® Troponin I assays were used, demonstrate 90% concordance. ACCESS® Troponin I assay results were 90% concordant with CK-MB results in 208 subjects tested with both devices.

The sensitivity and specificity of the ACCESS® Troponin I assay was similar to both CK-MB and Stratus® Troponin I when analyzed as a function of time. All assays showed peak sensitivity at 5-11 hours after the onset of chest pain. Both troponin I assays demonstrated peak specificity at 12-23 hours after the onset of chest pain.

ACCESS® Troponin I demonstrated a high degree of specificity in subjects with skeletal muscle injuries and renal disease, two clinical groups that can confound the diagnosis of AMI. The specificity of ACCESS® Troponin I in 58 skeletal injury patients was 86%, which is similar to that of Stratus® Troponin I. For renal disease patients, the specificity of ACCESS® Troponin I assay was 96% for 81 subjects tested.

In conclusion the data demonstrate acceptable diagnostic efficiency of the ACCESS® Troponin I assay reagents when utilized with the ACCESS® Immunoassay Analyzer.

7. Conclusion

The ACCESS® Troponin I reagents when utilized with the ACCESS® Immunoassay Analyzer are substantially equivalent to another test currently in commercial distribution for the measurement of cardiac Troponin I.