

# Evaluation of a new chemiluminescent, microparticle-based assay for Troponin I on the ARCHITECT® instrument system

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## Objective of study

Cardiac Troponin (cTn) is regarded as the most sensitive and specific marker in aiding the diagnosis of myocardial infarction. ARCHITECT® Stat Troponin I is an assay for the quantitative measurement of Troponin I in plasma and serum, developed as part of a cardiovascular panel on the integrated ARCHITECT® ci8200 system. We present here the results of our analytical assessment of the assay.

## Material and Methods

### Instrument and assay description

The Abbott ARCHITECT® ci8200 system is a fully automated, random access, clinical chemistry/immunoassay integrated workcell for the rapid quantitative analysis of tests commonly performed in clinical chemistry and immunoassay sections of the laboratory. For immunoassays, it uses paramagnetic microparticle chemiluminescent technology. Concerning the assay, the ARCHITECT® Stat Troponin I is a two-step sandwich configured with monoclonal antibodies for both the microparticles and the acridinium-derivative conjugate:

### Precision testing

Precision was determined using the 5-day NCCLS protocol. Low, medium and high assay controls have been tested by duplicate per run, two runs per day, over five days period.

### Limit of detection

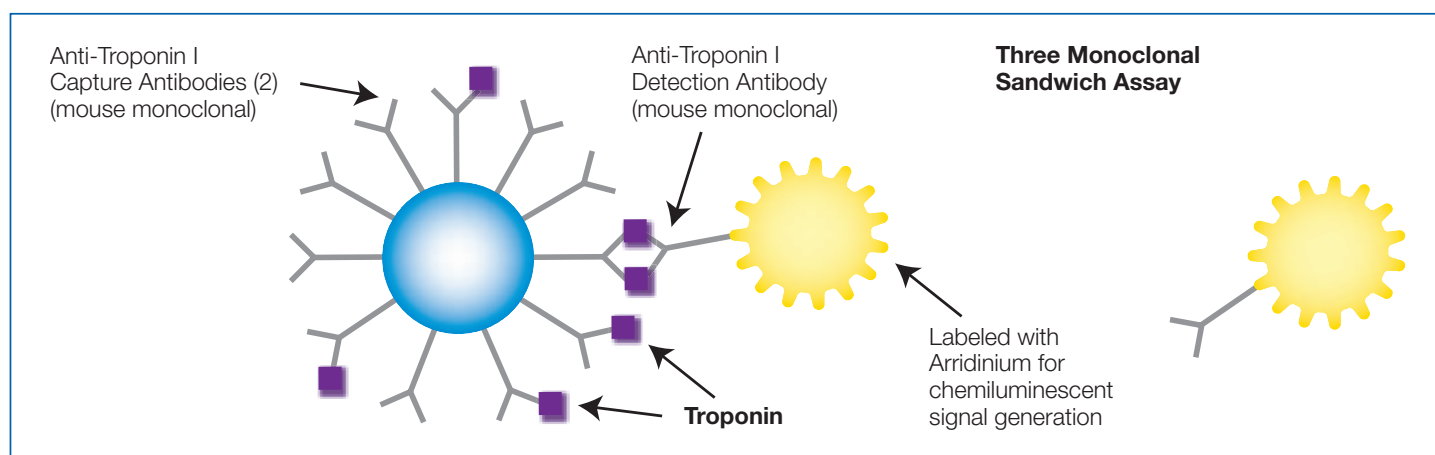
A 95% confidence interval was determined with 10 replicates of Calibrator A (0 ng/mL troponin I) and 4 replicates of Calibrator B (0.006 ng/mL Troponin I) per run. A total of 4 runs were used.

### Functional sensitivity

Functional sensitivity at a 10% total CV was determined by IFCC protocol. Serum panels were prepared using elevated Troponin I samples diluted with healthy patient sample. Each of ten panels obtained was tested once per day over ten days period.

### Specimen correlation

Values for 212 serum specimens were determined for the ARCHITECT® Stat Troponin I assay and the AxSYM™ Troponin I assay (both from Abbott Laboratories). Passing-Bablok regression analysis was used to determine slope and Y-intercept and Spearman method to determine coefficient of correlation.

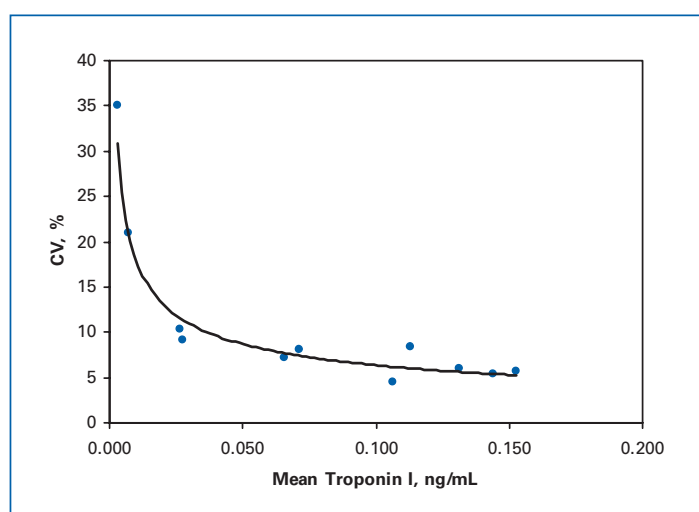


## Results

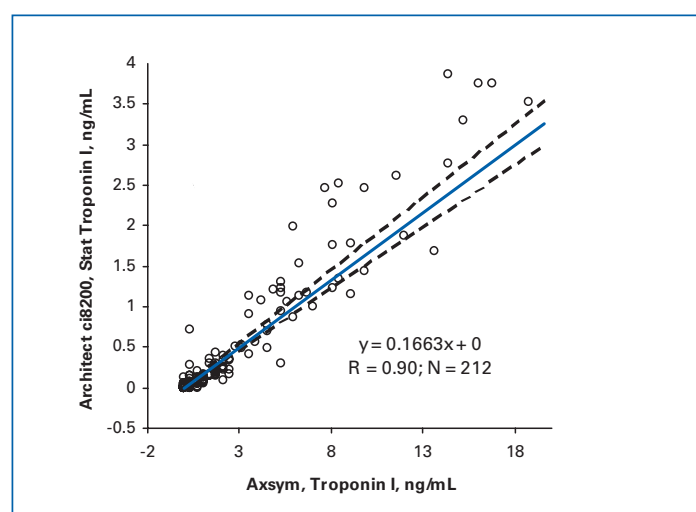
During precision testing, within run and total coefficient of variation ranged from 2.4 to 3.9% and from 3.5 to 5.0%, respectively across the controls levels:

Control Level	N	Mean (ng/mL)	Within run (% CV)	Between day (% CV)	Total (% CV)
Low	20	0.146	3.9	0.0	4.9
Medium	20	0.594	2.4	2.8	3.8
High	20	16.340	2.5	2.4	3.5

The limit of detection obtained was 0.007 ng/ml as upper limit of the 95% interval of confidence. Functional sensitivity at a 10% total CV was 0.026 ng/mL, with a 95% interval of confidence from 0.024 to 0.028 ng/mL:



When comparing ARCHITECT® with AxSYM™ analyzers for Troponin I assay, Passing-Bablok regression analysis showed a slope of 0.16 (95% CI from 0.15 to 0.18) and an Y-intercept of 0.0 (95% CI from -0.005 to 0.0). Spearman coefficient of correlation was 0.90 (95% CI from 0.87 to 0.92):



## Conclusions

ARCHITECT® Stat Troponin I assay is highly precise (total CVs less than 5%) and sensitive (analytical sensitivity of 0.007 ng/ml) assay for the detection of cardiac Troponin I. This assay has a 10% CV at 0.026 ng/mL which provides for greater precision at the low-end in support of the guidelines of ACC/ESC for IM diagnosis.