Performance Evaluation of Atellica IM High-Sensitivity Troponin I Assay at Clinic Barcelona

B. González de la Presa[1], X. Filella[1], N. Rico[1], L. Macías[1], C. Domingo[1], A. Mira[2], J. L. Bedini[1]

[1]Servicio de Bioquímica y Genética Molecular. Área Operativa Core
[2]Centro Diagnóstico Biomédico.
Hospital Clínic. Barcelona. Spain.

Background: The objective of this study was to verify the precision of the Siemens Healthineers Atellica IM TnIH Assay* on the Atellica® IM Analyzer and perform method comparison vs. ADVIA Centaur® High-Sensitivity Troponin I (TNIH) Assay, and Dimension EXL® High-Sensitivity Troponin I (TNIH) assay. In addition, the effects of hemolysis and biotin were assessed.

Methods: The assay is a dual-capture sandwich immunoassay using preformed magnetic latex particles, a proprietary acridinium ester for chemiluminescence detection, and three monoclonal antibodies. Precision studies were performed according to CLSI protocol EP05-A3 using two sample pools of lithium heparin plasma (SP), and three control materials (Biorad Cardiac Markers). One aliquot of each sample pool and each QC material was tested in replicate in two runs per day on each analyzer for a minimum of ten days with one lot of reagent and calibrator. Each run was separated by at least a two hour time interval. A total minimum of 40 replicates were generated per sample. Interference studies were performed according to CLSI protocol EP 7-A2. Hemolyzed samples (1500 and 5000 mg/L) and samples spiked with biotin (30 and 1500 µg/L) were run in duplicate on the Atellica IM TnIH Assay. For the method comparison, 40 samples were processed in the three analyzers on the same day in 3 different series. Non-parametric Passing–Bablok regression method was used for method comparison.

Results: Table 1 contains the results of the precision study. Method comparison are shown in Table 2. Figure 1 shows the comparison of Atellica IM TnIH Assay vs Dimension EXL TNIH assay. All hemolysis (up to 5000 mg/L) and biotin (up to 1500 µg/L) samples tested with the Atellica IM TnIH Assay demonstrated ≤10% change in results.

Fig 1 Dimension EXL TNIH assay vs Atellica IM TnIH Assay method comparison

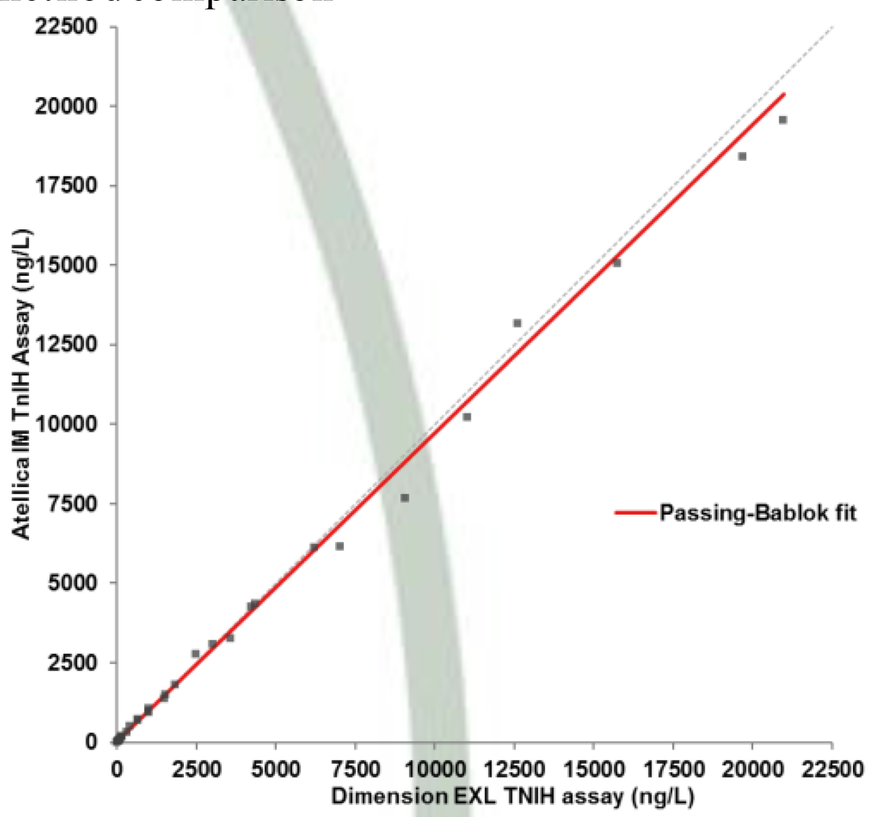

Table 1 Imprecision results

	n	Pool 1 (11.43 ng/L)	Pool 2 (25.57 ng/L)	QC 1 (98.48 ng/L)	QC 2 (259.22 ng/L)	QC 3 (5808.88 ng/L)
Repeatability imprecision-CV % (SD)	40	3.1 (0.36)	2.7 (0.69)	1.7 (1.66)	2.2 (5.60)	1.5 (84.62)
Within-Lab imprecision-CV % (SD)	40	5.8 (0.66)	4.5 (1.15)	2.6 (2.60)	2.8 (7.20)	1.5 (85.29)

Table 2 Method comparison results

Field Method = slope (0.95 Conf Interv)* **Ref Method** + Intercept (0.95 Conf Interv) (**Correlation coefficient, n**)
Atellica IM TnIH = 0.88 (0.86 to 0.90)* **Centaur TNIH** + 0.77 (0.33 to 2.61) (*r* = 0.997, n=39) Range: Atellica IM TnIH = 11.84 to 18397.5 ng/L; ADVIA Centaur TNIH = 12.04 to 19136.6 ng/L
Atellica IM TnIH = 0.97 (0.93 to 1.00)* **Dimension EXL TNIH** - 0.24 (-6.12 to 9.47) (*r* = 0.998, n=40) Atellica IM TnIH = 11.84 to 19566.0 ng/L; Dimension EXL TNIH = 12.5 to 20975.0 ng/L

Conclusions: The Atellica IM TnIH Assay has demonstrated good precision for detecting low cardiac troponin I concentrations and good correlation with the Dimension EXL TNIH assay. A slight negative bias was observed with the ADVIA Centaur TNIH Assay which may be due to a limited number of samples used across a subset of the assay range. At levels of biotin up to 1500 µg/L and hemolysis up to 5000 mg/L, there was ≤10% change in results.

CLÍNIC BARCELONA
Hospital Universitari
Centre de Diagnòstic Biomèdic

http://cdb.hospitalclinic.org