Beckman Coulter DxI 9000 Immunoassay Analyzer's High Sensitivity Troponin I achieves >90% Six Sigma performance when assessed against CLIA 2024 goals

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INTRODUCTION

In July 2024, the Clinical Laboratory Improvement Act (CLIA) proficiency testing (PT) criteria, set by the College of American Pathologists (CAP), will directly regulate Troponin I performance with a goal of 0.9 ng/mL or 30%, whichever is greater. Previously, CLIA had not directly regulated the proficiency testing criteria of Troponin I. Globally, the European Federation of Laboratory Medicine biological variation database provides a desirable goal of 19.1% and minimum goal of 29.0%. The College of American Pathologists PT survey previously set a goal of 30% or 3 * the group SD.

Estimates derived from current instrument group performance of an international proficiency testing (PT) survey have shown none of the 5 major diagnostic platforms can achieve the EFLM minimum goal at a 6 Sigma level, and 4 of the 5 platforms were 3 Sigma or below. None of the platforms could achieve the desirable goal at 4 Sigma or higher; 4 of 5 platforms were 2 Sigma or below. The College of American Pathologists goals applied on these same samples would generate allowable total errors ranging from 30% to 300%.

The DxI 9000 Troponin I method was assessed whether or not it could achieve the new CLIA 2024 goal.

Instrument Platform	Sigma metric across 5 samples, EFLM desirable goal	Sigma metric across 5 samples, EFLM minimum goal	CAP goal range
Abbott ARCHITECT i	3.60	3.12	30 to 300%
Beckman Unicel DxI	3.56	3.07	30 to 175%
Roche e600 Ser/E170	2.92	2.15	30 to 218%
Siemens Atellica IM HS	1.57	1.43	30 to 51%
Vitros 36/56/76,Eci/Q	3.54	3.05	30 to 106%

Table 1. The group standard deviations from 5 samples of an international proficiency testing sample were assessed on the Six Sigma scale, using the EFLM desirable and minimum goals, as well as the CAP goal, which is dependent on the group SD. There are no analytical Sigma metrics in the 6 or 5 or even 4 Sigma zone. The CAP goals are included to highlight their extreme variability across the range of each test. The methodology of using PT data to estimate analytical Six Sigma metrics are described in references 1-2.

MATERIALS AND METHODS

The Beckman Coulter Access high sensitivity Troponin I method was assessed on DxI 9000 Immunoassay Analzyer* with three reagent lots, using both serum samples and Lithium heparinized samples, following Clinical Laboratory Standards Institute (CLSI) guidelines EP05 and EP09 to estimate imprecision and bias. The new CLIA 2024 goal of 0.9 ng/mL or 30% was used as the benchmark.

Six Sigma strives to reduce the defect ratio via providing "a common language and a common approach to problem solving" [3]. The analytical Sigma Metric relates performance specifications (bias and imprecision) to tolerance limits to provide a measure to represent defect rate. James O. Westgard, Ph.D., adapted the industrial Sigma-metric formula into an approach appropriate for the medical laboratory [4]:

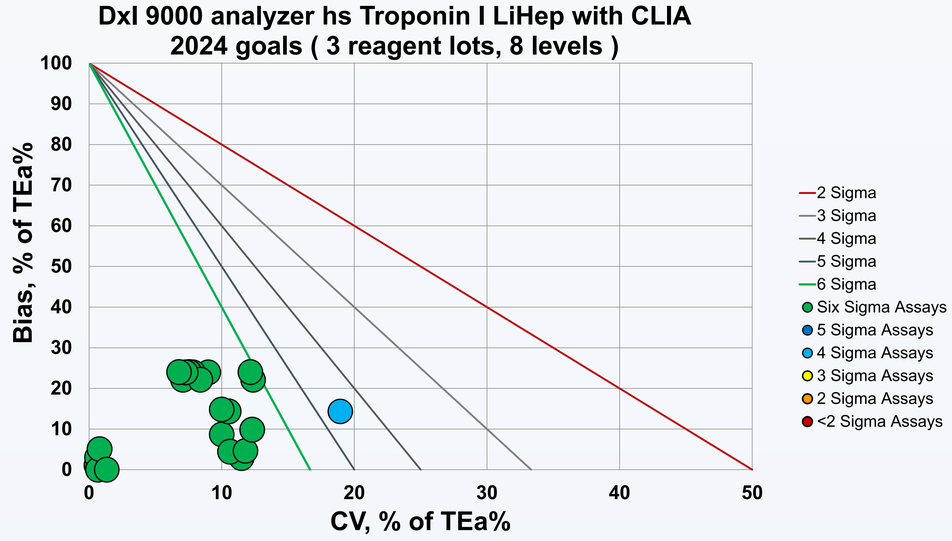
Sigma-metric = (TEa - |Bias|)/SD.

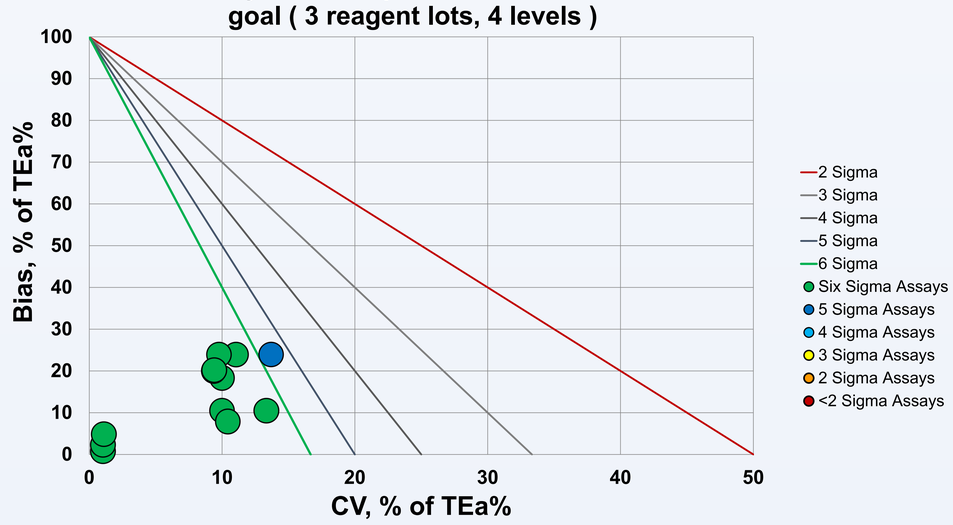
The analytical Sigma-metric predicts not only future problems with PT, but also potential optimization of QC procedures, including fewer Westgard Rules, control levels, even reduced QC frequency.[5]

Performance of an assay can be visually assessed using a Six Sigma Normalized Method Decision Chart (Normalized MEDx, commonly referred to as a "Bull's-eye graph").[6] The imprecision for the method becomes the x-axis coordinate, the bias becomes the y-axis coordinate, and diagonal lines are imposed across the graph to delineate the different Six Sigma "zones" of performance.

RESULTS

Over 90% of the DXI 9000 analyzer hs Troponin I performance achieved 6 Sigma, for both serum as well as LiHep samples. The Normalized Method Decision Charts display excellent performance.





DISCUSSION

Direct CLIA regulation of Hs Troponin I is long overdue. However, the pain of these new CLIA regulations will not be felt equally across methods, instruments and laboratories. While some proficiency testing organizations assert that the number of labs failing the new goals will not be significant, it remains the responsibility – and anxiety – of each individual laboratory to determine whether or not it is one of the "insignificant" laboratories that will fail the new standards.

CONCLUSION

The Access hs Troponin I assay on DxI 9000 analyzer easily achieves CLIA 2024's new PT criteria. Where laboratories confirm this performance, the assay can be optimized to reduce the use of "Westgard Rules", control levels, and potentially even QC frequency.

REFERENCES

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*Full name is DxI 9000 Access Immunoassay Analyzer