Analytical technologies and applications

Cod: M024

PERFORMANCE OF DIAGAM IMMUNOTURBIDIMETRIC ASSAY FOR SERUM ALBUMIN ON ABBOTT ARCHITECT C16000 PLATFORM

E. Aloisio [2], S. Pasqualetti [1], A. Carnevale [1], S. Birindelli [1], A. Dolci [1], M. Panteghini [2]

[1]Clinical Pathology Unit, 'Luigi Sacco' University Hospital, ASST Fatebenefratelli-Sacco, Milan, Italy

[2]Research Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Italy

(Italy)

elena.aloisio@unimi.it

BACKGROUND: Immunoassays are the most specific methods for measuring albumin in serum (SA). Accordingly, in October 2015, we introduced the DiAgam immunoturbidimetric assay for measuring SA on the Abbott Architect c16000 platform. We however observed an average uncertainty of the measurement that was constantly higher than the minimum goal derived from SA biological variation ($\leq 2.4\%$). Furthermore, we failed to reach the minimum total error (TE) goal ($\pm 6.1\%$) in the majority of performed EQAS exercises. Consequently, in agreement with DiAgam and Abbott, we carried out a study to evaluate the assay performance under standardized conditions.

METHODS: The study was performed between July and September 2016. The assay was calibrated three times (every 4 weeks), using calibrators from two different lots. Fresh aliquots of the 3-level DiAgam calibration control material (MPCO) were employed twice daily to check alignment of analytical runs and the fresh-frozen BioRad Liquichek Unassayed Chemistry Control level 2 (lot no. 16772), previously shown commutable for SA, was measured once a day for evaluating long-term imprecision. MPCO lots never changed throughout the study.

RESULTS: When compared with the manufacturer's assigned target values, MPCOs showed for all the study period a changeless positive bias of, in average, +9.3%, +5.9% and +5.8% at MPCO target concentrations of 24.8, 50.4 and 68.5 g/L, respectively. Total CV on BioRad material, obtained from 72 runs, was 4.0% at a mean SA concentration of 49.7 g/L. Three EQAS exercises performed during the study period showed a TE of +1.9% (Jul), +15.9% (Aug) and +20% (Sep), when our laboratory results were compared with the reference value derived from results of all participants (n=330).

CONCLUSIONS: Despite the strictly controlled conditions employed in this study, the performance of DiAgam immunoturbidimetric SA assay when applied to Abbott Architect c16000 platform did not fulfil the minimum quality specifications for the clinical use of this important test. In particular, it seems that two different issues are contributing to this situation: the inadequacy of calibrator value-assignment protocol by manufacturer and the unacceptably high imprecision of the measuring system.