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Dosages of tumor markers with higher demands for automated biochemical equipment for clinical laboratory

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Abstract:

Background: The measurement of tumor markers (TM) provided by clinical laboratories can be useful in the management of cancer patients, assisting in the processes of diagnosis, staging, evaluation of therapeutic response, detection of relapses and prognosis, due to the direct correlation between the change in levels of these markers with clinical status[1,2]. The results of TM tests by different methods are not harmonized, therefore, the values obtained by different methods cannot be used interchangeably. In the change of analytical platform, educational measures and dissemination to the clinical staff it´s necessary to previously change to minimize the impact on the patient´s clinical follow-up. If during the monitoring of a patient there is a change in the test method used to determine the serial levels of TM, the laboratory should inform the clinician of the need to restart monitoring[3]. In this study, the authors aimed to evaluate the proposed TM for the change of platform and the impacts in a large clinical laboratory in Brazil. **Methods:** The assays were evaluated: CEA, CA 15-3, CA19-9, CA125, PSA and free PSA on the Atellica IM Siemens Healthineers Analyzer. Evaluation Verification of Precision and BIAS estimation peer groups were performed through the repeatability (%CV_R) and within-laboratory precision (%CV_{WL}), according to EP15-A3; with a total of 25 samples per quality control (QC) level. The coefficient of variation (CV%) obtained was compared with the manufacturer's and the analytical quality specifications (TEa) metrics. Comparison studies were performed between the Atellica IM 1600 Analyzer and Architect Abbott according to EP09, using at least 40 serum samples. For the evaluation of the Sigma's Metric, the precision and bias components were used for each level of QC. The first choice of the TEa's metric for the proposed study was based on the VB2014. **Results:** The results obtained in the studies reached and exceeded the specification goals. The % CV_{WL} were from 2.6% to 6.6% and the BIAS from 1.39% to 11.60% and all QC levels obtained a Sigma's metric greater than 3 , with 8 out of 12 levels with results 6 Sigma (world class) and 2 out of 12 with results above 4 Sigma (good) and 2 out of 12 above 3 Sigma (desirable). In the comparison study, R^2 were 0.99 to 1.0 for all TM showing excellent correlation, despite the excellent correlation. **Conclusion**: For the CA 125 and CA 19-9 assays, special attention is needed in the implementation with the clinical staff, due to the BIAS of -24.57% and -43.91%, TE 29.36% (TEP=35.36) and 53.68% (TEP=46.07%) respectively, however when evaluated through Sigma's metrics with peer group, these assays presented world class performance (6 sigma and up) suggesting the existence of methodological differences. The assays tested on Atellica IM demonstrated excellent analytical performance. Imprecision and BIAS are consistent and demonstrate acceptable Sigma levels, like those found in previous studies and can provide a basis for understanding the quality performance of the Atellica Solution tumor marker assays. **Siemens Healthineers supported the studies by providing systems, and reagents.*

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