ASSESSMENT OF KRIBIOLISA™ ECULIZUMAB ELISA ON THE ADLTIS™ ANALYZER

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Background: Therapeutic drug monitoring of Eculizumab (ECU) is necessary to determine appropriate therapy. Aim: To assess KRIBIOLISA™ ECU ELISA on the Personal LAB™ fully automated 2 microplate analyzer ELISA/IFA (ADLTIS™ analyzer) for measuring human serum ECU concentrations.
Methods: The study was conducted in line with the CLSI protocol: Within-day imprecision: 20 replicated analyses of 3 patient samples and of KRIBIOLISA™ ECU low and high controls (40 and 320 ng/mL). Between-day imprecision: over a 20-day period using the 2 controls and 3 patient samples; each sample was tested using 2 reagent lots and 2 runs per day. Limit of blank (LoB) and limit of detection (LoD): 10 replicates of an analyte-free sample (zero-calibrator) and low concentration calibrator (10 ng/mL). LoD= LoB+ 1.645 ($SD_{\text{low concentration calibrator}}$). Lower limit of quantification (LLoQ): a low concentration serum sample was diluted with an ECU-free sample to 10 different concentrations in 5 different analytical runs. Dilution linearity: 5 high ECU concentration serum patients' pools were serially diluted with calibrator A. Analytical recovery: addition of concentrated ECU into ECU-negative samples. Calibration curve was tested all days using calibrators A-F (0-640 ng/mL) and the two controls in duplicate, as were patient samples. Therapeutic range: 50-150 ng/mL. A statistical analysis was carried out on SPSS.
Results: Within-assay coefficient of variation (CV) was 7.2%, and 4.5% for the 2 controls. The total CV for patients' pool was 6.2%, 7.9% and 6.4% respectively. Between-day imprecision for the controls was 9.4% and 6,8% respectively. LoB and LoD were 4 and 8 ng/mL respectively. LLoQ was 10 ng/mL. Dilution linearity displayed a high degree in the range studied (40- 450 ng/mL, r= 0.8). Recovery was 85%.
Conclusions: The KRIBIOLISA™ ECU ELISA adapted to the ADLTIS™ analyzer displays good precision, reproducibility, sensitivity and specificity. This technology could be suitable for monitoring ECU in routine clinical practice.
Keywords: KRIBIOLISA™ ECULIZUMAB ELISA, ADLTIS ™ Analyzer