



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.

PATIENTS AND METHODS

Precision

Following CLSI protocol.

- **Within-day imprecision:** 20 replicated analyses of three patient samples and of KRIBIOLISA™ ECU low (40 ng/mL) and high (320 ng/mL) controls.
- **Between-day imprecision:** over a 20-day period using the two controls (low, high) and 3 patient samples; each sample was tested using two reagent lots and two runs per day.

Sensitivity

- **Limit of blank (LoB) and limit of detection (LoD):** ten replicates of an analyte-free sample (zero-calibrator) and low concentration calibrator (10 ng/mL). $LoD = LoB + 1.645 (SD_{low\ concentration\ calibrator})$.
- **Lower limit of quantification (LLoQ):** a low concentration serum sample was diluted with an ECU-free sample to ten different concentrations in 5 different analytical runs.

Therapeutic range: 50-150 ng/mL.

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:** tested all days using calibrators A-F (0-640 ng/mL) and the two controls (low, high) in duplicate, as were patient samples.

Statistical analysis was carried out on SPSS.

RESULTS

	WITHIN-ASSAY		BETWEEN-DAY IMPRECISION	
	CONTROLS	PATIENTS	CONTROLS	PATIENTS
PRECISION	CV(%)	CV(%)	CV(%)	CV(%)
Low	7.2	6.2	9.4	10.2
Medium		7.9		8.5
High	4.5	6.4	6.8	9.1

CV: Coefficient of variation

SENSITIVITY LoB= 4 ng/mL; LoD= 8 ng/mL; LLoQ was 10 ng/mL

DILUTION LINEARITY High degree in the range studied (40-450 ng/mL; r=0.80). Recovery was 85%.

CONCLUSION

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.