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Comparisons of the CEDIA® , MEIA® and LC/MS/MS Assays for the Measurement of Tacrolimus in Organ Transplant Recipients

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Objectives: This study evaluated two immunoassays, the CEDIA® assay and the MEIA® assay, used for the measurement of whole blood levels of tacrolimus in organ transplant recipients.

Design and Methods: We report on the performance characteristics (total precision, limit of quantitation (functional sensitivity), limit of detection (analytical sensitivity), linearity, accuracy) for each assay. Patient correlation studies were performed, and the results were analyzed using Bland-Altman plots and Passing-Bablok analysis.

Results: Total precision for the MEIA assay, corresponding to two mean concentrations of 5.76 and 21.41 ng/mL, was 12 and 5.9 %, respectively. The limit of detection was determined to be 0.932 ng/mL and the limit of quantitation was 4.79 ng/mL. The analysis of proficiency material demonstrated good agreement with the MEIA peer mean with a slight positive bias. Results for the CEDIA assay showed a total precision, corresponding to a mean concentration of 4.34 and 18.16 ng/mL, of 21.1 and 3.5 %, respectively. The limit of detection was found to be 0.752 ng/mL, with a limit of quantitation of 4.66 ng/mL. The analysis of proficiency material for CEDIA demonstrated acceptable agreement when compared with the group of “all other methods”, since the corresponding peer group for CEDIA is not available. Both assays were acceptably linear over the reportable range of the assay. Patient correlation studies demonstrated a positive average bias for both assays versus results from LC-MS measurement.

Conclusion: Based on this evaluation, both assays demonstrated acceptable performance for use in clinical monitoring of tacrolimus.