ARK™ Linezolid Assay for the Beckman AU480® Automated Clinical Chemistry Analyzer

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Background: Linezolid is an antibiotic used for treatment of infections caused by Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci. Minimum trough levels in plasma >3 µg/mL are important for efficacy, and plasma concentrations >8 µg/mL are associated with increased incidence of thrombocytopenia. Long duration of treatment and renal impairment contribute to higher levels and associated adverse events. Here a prototype ARK enzyme immunoassay for therapeutic drug monitoring (TDM) of linezolid is described.
Methods: The ARK™ Linezolid Assay is a liquid stable homogeneous enzyme immunoassay, consisting of two reagents, 6 calibrators (0.0, 1.0, 2.5, 5.0, 15.0 and 30.0 µg/mL) and 3 controls (2.0, 10.0 and 20.0 µg/mL). The performance of the ARK assay was evaluated on the Beckman AU480® Automated Clinical Chemistry Analyzer. Precision, limit of quantitation, recovery, cross-reactivity and method comparison were studied.
Results: Total precision for the 3 quality controls ranged from 2.8% to 4.2% CV and within-run precision ranged from 1.5% to 2.0% CV in a 5-day study. The limit of quantitation was 0.75 µg/mL. Linezolid was spiked into serum throughout the calibration range (1.5 µg/mL to 28.0 µg/mL) and recovered accurately (97.8% to 103.7% nominal). Over 50 different compounds were tested for potential cross-reactivity, including vancomycin and meropenem. No cross-reactivity was observed with any of the compounds. Thirty-six specimens were tested by the ARK assay and by HPLC (concentrations ranged from 0.6 to 18.8 µg/mL). Passing Bablock regression results: ARK = 0.98 HPLC -0.06 (r^2=0.92).
Conclusions: The ARK Linezolid Assay measures linezolid in human plasma with excellent run-to-run precision at low concentrations, which supports long-term monitoring of patients. Accuracy, precision, sensitivity and specificity with fast turnaround times make this method clinically useful for TDM.