

K955422

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510(k) Summary  
Abbott AxSYM N-Acetylprocainamide

Summary of Safety and Effectiveness Information Supporting a  
Substantial Equivalent Determination

The following information as presented in the Premarket Notification 510(k) for AxSYM N-Acetylprocainamide constitutes data supporting a substantially equivalent determination.

Substantial equivalence has been demonstrated between the AxSYM N-Acetylprocainamide assay and the TDx/TDxFLx N-Acetylprocainamide assay. Both assays are automated fluorescence polarization immunoassays (FPIA). The intended use of both assays is for the quantitative determination of N-acetylprocainamide in human serum or plasma (sodium heparin, tripotassium EDTA, potassium oxalate, and sodium citrate). Both assays are calibrated with Abbott calibrators. Abbott controls are assayed controls used for verification of the accuracy and precision of the AxSYM system. Correlation studies indicated the following results:

Slope: 1.05  
Y-Intercept: -0.1  
Correlation Coefficient: 0.993  
Std. Error of the Y estimate: 0.081  
Number: 205

The AxSYM N-Acetylprocainamide standard calibrators and controls are to be used with the AxSYM N-Acetylprocainamide reagents. The calibrators and controls are prepared gravimetrically using purified material obtained from commercial sources. The calibrators and controls are verified using protocols involving multiple instrument testing. AxSYM N-Acetylprocainamide reagent, calibrator and control expiration dates are based on real time stability testing.

Prepared and Submitted :

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