**OVERVIEW**

- Validation of a new reagent kit for the LC/MS/MS analysis of Tacrolimus in whole blood in CAP laboratories.
- The kit contains calibrators, controls, and standard solutions, and is designed for use with HPLC/MS/MS methods to monitor Tacrolimus levels in whole blood samples.
- The performance characteristics were found to be acceptable for the intended use of the kit.

**INTRODUCTION**

- HPLC with tandem mass spectrometry (MS/MS) detection is becoming increasingly common in clinical laboratories.
- The sensitivity and selectivity of HPLC/MS/MS allow for accurate and precise quantification of parent drug in clinical laboratories.

**METHODS**

- Whole blood calibrators, quality controls and internal standards were prepared by diluting the appropriate solution as described in the user manual.
- Calibrators, QC’s, and patient samples were prepared for analysis as outlined in Table 1.
- Samples were analyzed using the MassTrak TDM peak eluting a step gradient.
- Tacrolimus concentrations in test samples were determined by reference to the calibration curve.

**RESULTS**

- Within run and total imprecision evaluated over 20 days at three separate test centers were <10% in the range 2.0—29.5ng/mL.
- When compared to independent, validated HPLC/MS/MS methods at three test centers using a reversion of 50 samples from each center, patient samples from kidney transplant patients and 5 samples from kidney transplant patients (<100 individual samples) the MassTrak reagent kit provided results that differed by ±10% at the lower and upper medical decision points.
- Accuracy was assessed by analyzing Tacrolimus /PPT samples (71) at two centers. All results were within the acceptable limits of the scheme (mean ± 2 SD). Passing-Bablok analysis gave a slope and intercept that were not statistically significantly different 1.0 and 0, respectively.
- Mean recovery from drug-free whole blood and from spiked patient samples analyzed twice per day for 20 days as per CLSI EP-7.

**CONCLUSIONS**

- The performance characteristics of the MassTrak™ reagent kit are acceptable for the routine therapeutic drug monitoring of Tacrolimus in kidney and liver transplant recipients.
- The reagent kit may provide the potential for harmonization of results between laboratories using HPLC/MS/MS.
- The MassTrak kit provides a turn-key solution for those laboratories wanting to monitor Tacrolimus in kidney and liver transplant patients using HPLC/MS/MS.

**REFERENCES**