**Evaluation of the Analytical Performance of Seven Therapeutic Drug Monitoring Assays on the Atellica CI 1900 Analyzer**


**Abstract**

The Atellica® CI 1900 Analyzer is an automated, mid-throughput integrated chemistry and immunoassay analyzer employing both Atellica® CH and Atellica® IM assays. This study was designed to evaluate the analytical performance of the Atellica CH Vancomycin (Vanc), Carbamazepine (Carb), Gentamicin (Gent), Phenytoin (Phny), Tobramycin (Tob), Valproic Acid (VPA), and Theophylline (Theo) assays on the Atellica CI 1900 Analyzer.

**Methods:** The Atellica CI 1900 Analyzer uses the same reagents and calibrators as the Atellica CH 930 Analyzer. Precision and method comparison (MC) were used as performance indicators for the Atellica CI 1900 Analyzer. Precision studies were performed according to CLSI EP05-A3 using native and controlled human serum samples. One aliquot of each sample pool was tested in duplicate in two runs per day after 24 hours apart on each analyzer for 20 days. MC studies were performed according to CLSI EP05-A3. Individual native and controlled human serum samples were analyzed using the Atellica chemistry assays on both the Atellica CH 930 and Atellica CI 1900 Analyzers. Precision and MC were evaluated on each assay separately.

**Results:** Representative precision and MC results observed from one reagent lot across indicated sample range are listed in the tables below for each assay. Over the seven assays tested, repeatability and within-laboratory % CVs were <0.5% and <1.0%, respectively. Slopes determined by Deming linear regression model were approximately equal to 1.

**Background**

Quantitative measurement of Vanc, Carb, Gent, Phny, Tob, VPA, and Theo in serum samples is routinely performed in clinical laboratories to monitor therapeutic drug levels to ensure appropriate therapy.

**Material and Methods**

Precision evaluation was performed according to CLSI EP05-A3. Two runs were performed each day for 20 nonconsecutive days, with a minimum of 2 hours between runs. Samples were tested in duplicate, producing a total of n = 80 measurements for each system/lot combination. For each assay, one representative system/lot combination result across all lot and system combinations was chosen. Precision studies included two calibration levels per assay. A panel of human serum samples, and controls were tested as indicated in the precision table for each analyte (Tables 1A to 1G). Samples across the assay range were prepared using individual native patient samples or normal samples spiked with positive stock made of vancomycin powder (Vanc), carbamazepine, gentamicin,gentamicin concentrated solution (Gent), 5,5-Dihydropyrimidinyl sodium salt (Phny), tobramycin concentrated solution (Tob), valproic acid sodium salt (VPA), or theophylline concentrated solution (Theo). Samples were frozen in aliquots and stored at ≤ –20°C prior to the start of the study. Each testing day, new aliquots were thawed and used for each run. Calibrators and QC materials were handled according to the manufacturer's instructions.

**Method Comparison**

Method comparison (MC) studies were performed according to CLSI EP05-A3. Individual native human serum samples were tested on the Atellica CI 1900 Analyzer and Atellica CI 930 Analyzer. MC was evaluated by comparison to the parent analyzer, which is the Atellica CH 930 Analyzer, using three reagent lots. One replicate was processed for each sample and each reagent lot on each analyzer. The total of native samples tested for each assay is indicated in Table 2. For each assay, one representative system/lot combination result across all lot and system combinations is shown in Table 2. Samples with a result outside the measurement interval were excluded from the analysis. MC studies for each assay were completed in more than 3 nonconsecutive days using a single calibration curve. Slope and intercept were calculated using weighted Deming regression for Theo and Tob and regression analysis for all other assays tested as indicated in Figure 2.