Performance Evaluation of Five Reproductive Endocrinology Assays on the Atellica CI 1900 Analyzer


Abstract

The Atellica CI 1900 Analyzer is an automated, mid-throughput, integrated chemistry and immunoassay system for laboratories with a mid to high volume laboratory flow. This study describes the performance of the Atellica IM Luteinizing Hormone (LH), Progesterone (PRGE), Follicle Stimulating Hormone (FSH), Prolactin (PRL), and Total hCG (ThCG) assays on the Atellica CI 1900 Analyzer.

Methods: The Atellica CI 1900 uses the same reagents and calibrators as the Atellica IM Analyzer. Precision studies were performed according to CLSI EP07-A3 using quality control material and simulated human serum samples. Sample aliquots were prepared according to CLSI EP07-A3. Individual human serum samples were analyzed using the Atellica IM assays on all five analyzers.

Results: Representative precision and MC results are listed for each assay in the table. The precision profiles for each assay were then fitted using a power function to give a precision profile. LoQ for each reagent lot was determined as the analyte concentration that is below the linear range.

Conclusions

The Atellica IM LH assay on the Atellica CI 1900 Analyzer demonstrated ≤2% repeatability CV and ≤3.5% within-laboratory precision CV across the sample interval. The Atellica IM ThCG assay on the Atellica CI 1900 Analyzer demonstrated ≤4% repeatability CV and ≤5.5% within-laboratory precision CV across the sample interval. The Atellica IM PRGE assay on the Atellica CI 1900 Analyzer demonstrated ≤3% repeatability CV and ≤10% within-laboratory precision CV across the sample interval. The Atellica IM FSH assay on the Atellica CI 1900 Analyzer demonstrated ≤5.5% repeatability CV and ≤13.2% within-laboratory precision CV across the sample interval. The Atellica IM PRL assay on the Atellica CI 1900 Analyzer demonstrated ≤4% repeatability CV and ≤12.2% within-laboratory precision CV across the sample interval.

Material and Methods

Performance Evaluation of Five Reproductive Endocrinology Assays on the Atellica CI 1900 Analyzer. Two runs were performed each day for 20 consecutive days, with a minimum of 2 hours between runs. Samples were tested in duplicate, producing a total of n = 80 replicates for each system-run combination. For each run, one representative system-run combination was run across all five reagent lots. The performance of each assay was evaluated by comparison to the parent analyzer, which is the Atellica IM assay on the Atellica IM Analyzer. The Atellica IM (mIU/mL) and Atellica CI 1900 (mIU/mL) were used for the LH, PRGE, FSH, PRL, and ThCG assays on the Atellica CI 1900 Analyzer.

Method Comparison

The Atellica IM FSH assay on the Atellica CI 1900 Analyzer demonstrated ≤5.5% repeatability CV and ≤13.2% within-laboratory precision CV across the sample interval. The Atellica IM PRL assay on the Atellica CI 1900 Analyzer demonstrated ≤4% repeatability CV and ≤12.2% within-laboratory precision CV across the sample interval. The Atellica IM ThCG assay on the Atellica CI 1900 Analyzer demonstrated ≤4% repeatability CV and ≤5.5% within-laboratory precision CV across the sample interval. The Atellica IM PRGE assay on the Atellica CI 1900 Analyzer demonstrated ≤3% repeatability CV and ≤10% within-laboratory precision CV across the sample interval.

Detection Capability

The Atellica IM LH assay on the Atellica CI 1900 Analyzer demonstrated ≤2% repeatability CV and ≤3.5% within-laboratory precision CV across the sample interval. The Atellica IM ThCG assay on the Atellica CI 1900 Analyzer demonstrated ≤4% repeatability CV and ≤5.5% within-laboratory precision CV across the sample interval. The Atellica IM PRGE assay on the Atellica CI 1900 Analyzer demonstrated ≤3% repeatability CV and ≤10% within-laboratory precision CV across the sample interval. The Atellica IM FSH assay on the Atellica CI 1900 Analyzer demonstrated ≤5.5% repeatability CV and ≤13.2% within-laboratory precision CV across the sample interval. The Atellica IM PRL assay on the Atellica CI 1900 Analyzer demonstrated ≤4% repeatability CV and ≤12.2% within-laboratory precision CV across the sample interval.

Conclusions

All results indicate that the Atellica IM LH, PRGE, FSH, PRL, and ThCG assays demonstrated analytical performance capable of measuring LH, PRGE, FSH, PRL, and ThCG in serum with good accuracy and precision when run on the Atellica CI 1900 Analyzer. In addition, good concordance was observed between the assays on the Atellica CI 1900 Analyzer and the Atellica IM Analyzer. Overall, these results support that the Atellica CI 1900 Analyzer when used with the Atellica IM LH, PRGE, FSH, PRL, and ThCG assays, has performance capability comparable to the Atellica IM Analyzer as a low- to mid-volume integrated clinical chemistry and immunoassay analyzer.