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Atellica LumIQ Analyzer Performance Compared to CLINITEK Status+ Analyzer for CLINITEST hCG Pregnancy Testing

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Background

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In a typical pregnancy, hCG can be detected in the blood as early as 7 days post-conception.[1-4] Recent studies have shown that hCG concentrations in urine are generally about half, or even less than half, of those in serum.[5-8] As a result, hCG can likely be detected in urine at about 14 days after conception (~28 days after the last mentrual cycle), doubling every 2 days until it peaks around 8–10 weeks after the last menstrual period. The early appearance and rising levels of hCG make it a reliable marker for the early detection of pregnancy.

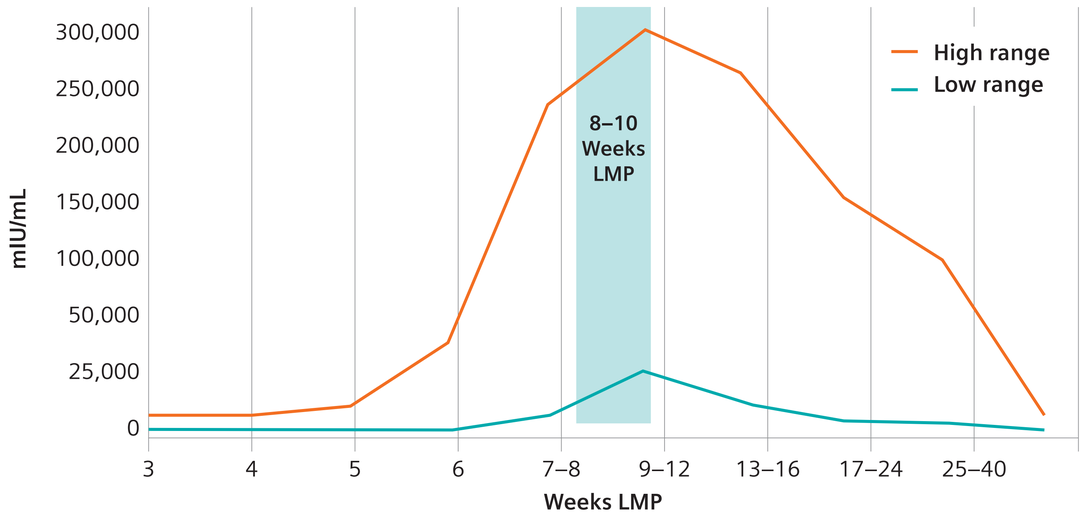

Figure 1. hCG Levels during pregnancy, shown in weeks since last menstrual period. hCG is a hormone released by the developing placenta during pregnancy. In pregnant women, hCG can be detected in urine 14 days after conception. The rapid rise, as seen here, makes hCG a reliable marker for early diagnosis of pregnancy.[9]

The CLINITEST hCG Pregnancy Test is a rapid chromatographic immunoassay designed to qualitatively detect hCG in urine.[10] A result greater than 25 mIU/mL is considered positive. Samples that are borderline are classified as indeterminate, and it is recommended to repeat the test in 48–72 hours.[10] The test utilizes monoclonal antibodies to specifically identify elevated hCG levels in urine samples. Its high immunological specificity significantly reduces cross-reactivity with other structurally similar glycoprotein hormones, such as human FSH, LH, and TSH, at physiological concentrations.

The CLINITEST hCG Pregnancy Test is used as a qualitative method in rapid detection of human chorionic gonadotropin (hCG) in urine. The purpose of this study is to show the CLINITEST hCG assay's analytical performance when tested using the new Atellica LumIQ Analyzer compared to the CLINITEK Status+ Analyzer.

Previously, the CLINITEST hCG Pregnancy Test was developed and commercialized for use on the CLINITEK Status+ Analyzer. Recently, the Atellica LumIQ Analyzer (Figure 2) was added to the Atellica Solution portfolio.[11] The Atellica LumIQ Analyzer is a portable, easy to use, semi-automated analyzer designed to read Siemens Healthineers Reagent Strips and hCG cassettes, producing results intended for in vitro diagnostic use only, in point-of-care and clinical laboratory settings. Its footprint width has been significantly reduced from 6.7 inches to just 4.25 inches, optimizing valuable countertop space in point-of-care settings and making it one of the most compact and lightweight urinalysis analyzers available.[12]

Figure 2. The Atellica LumIQ Analyzer. Panel A shows three interlocked systems, while Panel B shows that one unit is easily carried by hand.

Uniquely, the Atellica LumIQ Analyzer is the only dual-purpose point-of-care analyzer capable of performing both urinalysis testing and urine hCG pregnancy testing using the same hardware.[11]

To evaluate the analytical performance of the CLINITEST hCG Pregnancy Test on the new Atellica LumIQ analyzer, a method comparison study was performed comparing results of the hCG assay on the Atellica LumIQ Analyzer vs. the CLINITEK Status+ Analyzer.

Principles of the Procedure

The CLINITEST hCG Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid determination of hCG in urine. The membrane is precoated with anti-hCG capture antibody on the test line region (T) and goat anti-mouse IgG antibody on the control line region (C). During testing, the urine specimen reacts with the colloidal gold particles coated with anti-β hCG monoclonal antibody. The mixture then chromatographically moves along the membrane by capillary action. A positive or borderline result is indicated with a pink line. Absence of a pink-colored line in the T region indicates a negative result. The appearance of a colored line in the C region and the reference region serves as verification that sufficient volume has been added and that proper flow has occurred.[12]

Material and Methods

Material

- Urine samples were acquired through specimen acquisition or anonymous internal donation, no contrived samples were used.

Samples were assayed in duplicate (two replicate measurements) for n= 1089 samples with three lots of CLINITEST hCG cassettes.

Table 1. Clinical Urine Specimens Breakdown of Positive or Negative for hCG Pregnancy Test

Sample Type	Clinical Result	n
Urine	Negative	505
Urine	Positive	564 (77 low positive)

Methods

- Method comparison (MC) studies compared the CLINITEST hCG Pregnancy Test performance on the Atellica LumIQ Analyzers and the CLINITEK Status+ Analyzers.
- 12 CLINITEK Status+ Analyzers, 13 Atellica LumIQ Analyzers, and one IMMULITE 2000 Systems Analyzer (secondary reference device) were used.

Analysis

The first result was used for analysis, except in cases of missing results due to user error, instrument errors, or discrepant results.

- Samples that were discrepant across analyzers were tested using the IMMULITE 2000 Analyzer HCG assay to quantitatively measure the hCG concentration of the sample and determine status of positive or negative.
- Negative and Positive agreement was calculated to determine the specificity and sensitivity of the CLINITEST hCG Pregnancy Test using the Atellica LumIQ Analyzer as compared to the CLINITEK Status+ Analyzer.

Results of Method Comparison

The following results are representative of the performance of the assay.

- Urine testing was performed on 1089 samples (505 negative and 564 positive samples; inclusive of 77 low-positive samples) using the CLINITEST hCG cassettes on the Atellica LumIQ Analyzer with 1069 total results and 1068 results matching the predicate device.
- 20 results were excluded (indeterminate, N=6; no paired result, N=8; barcode detection errors, N=5; calibration bar error, N=1).

Negative and Positive Agreement

Negative and positive agreement were calculated as follows:

Percent Negative agreement (specificity) = TN ÷ (TN + FP) * 100

Percent Positive agreement (sensitivity) = TP ÷ (TP + FN) * 100

Table 2. Percent Agreement of hCG Pregnancy Test

	Predicate (CLINITEK Status+ Analyzer)	
Atellica LumIQ Analyzer Result	**Negative**	**Positive**
Negative	**504**	0
	99.80%	0%
Positive	**1**	**564**
	0.20%	100%
Total	505	564

Overall, the agreement of testing was substantial, resulting in the percent negative agreement and percent positive agreement to be 99.8% and 100%, respectively.

Discrepant Samples

- A single result was found to be discrepant between Atellica LumIQ Analyzer and the predicate device, CLINITEK Status+ Analyzer, when evaluating the first and second replicates of this sample on the Atellica LumIQ Analyzer.
- This sample was not found to be erroneous and is included in all agreement calculations. This sample was also evaluated on the secondary reference device, the IMMULITE 2000 HCG immunoassay (Table 3).

Table 3. Discrepant Sample Review. One discrepant sample was evaluated using both replicate 1 and 2. Results from IMMULITE 2000 Analyzer hCG testing indicates sample was negative for pregnancy.

Instrument	Rep 1	Rep 2
CLINITEK Status+ Analyzer	Negative	Negative
Atellica LumIQ Analyzer	Positive	Positive
IMMULITE 2000 Analyzer (mIU/mL)	**6.68**	**5.65**

Analytical study results on the Atellica LumIQ Analyzer demonstrated similar performance to claims for the CLINITEK Status+ Analyzer.

Conclusions

Evaluation of the CLINITEST hCG cassette Urine Pregnancy Test using the Atellica LumIQ Analyzer demonstrated acceptable performance compared to the same assay on the CLINITEK Status+ Analyzer.

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Atellica LumIQ Analyzer is not commercially available in all regions. Future availability cannot be guaranteed.

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