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# Evaluation of the Analytical Performance of the Hepatitis B Surface Antigen and Confirmatory Assays on the Atellica CI Analyzer

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## Background

Hepatitis B virus (HBV) causes major liver disease and despite widespread vaccination, HBV infection, often asymptomatic, remains a global health issue. Serological detection of HBV biomarkers, including hepatitis B surface antigen (HBsAg), is recommended to identify new or chronic HBV infection. HBsAg assays are also part of a triple serological panel (HBsAg; anti-HBs, antibody to HBsAg; anti-HBc total) recommended for routine testing by Centers for Disease Control and Prevention (CDC) in all adults aged ≥18 years at least once during a lifetime to identify most people living with HBV infection, reduce HBV prevalence and support the goal of worldwide viral hepatitis eradication.[1]

The Atellica IM Hepatitis B surface Antigen II (HBsII) and the Atellica IM HBsII Confirmatory (HBsII Conf) assays were previously developed and commercialized for use on the Atellica IM Analyzer.[2,3] The HBsII assay allows the qualitative determination of the HBsAg while the HBsII Conf assay, an antibody neutralization assay used as sample pretreatment step, allows the qualitative confirmation of the presence of HBsAg in samples. HBsII results are reported using Index values and samples are classified as reactive (Index value≥1.00) or nonreactive (Index value<1.00) based on the clinically established 1.00 Index cutoff. HBsII repeatedly reactive duplicate samples with Index value≥1.00 but ≤50.0 need to be confirmed with the Atellica IM HBsII Conf assay, additional HBV marker assays, or another approved confirmatory method. The regulatory approved secondary 50.0 Index cutoff was established clinically and is unique to the HBsII assay. It is a single-value rule-in (the "Hot Zone") that eliminates the need for repeat testing in duplicate when initial reactive sample is greater than 50.0 Index. The Atellica IM Analyzer is also powered by a SMART algorithm, which automatically retests samples requiring further analysis and (if one or both repeats are reactive) confirm with neutralization without the requirement for operator intervention. These two features can improve workflow efficiencies and mitigate delays in reporting HBsAg results (Figure 1).[1]

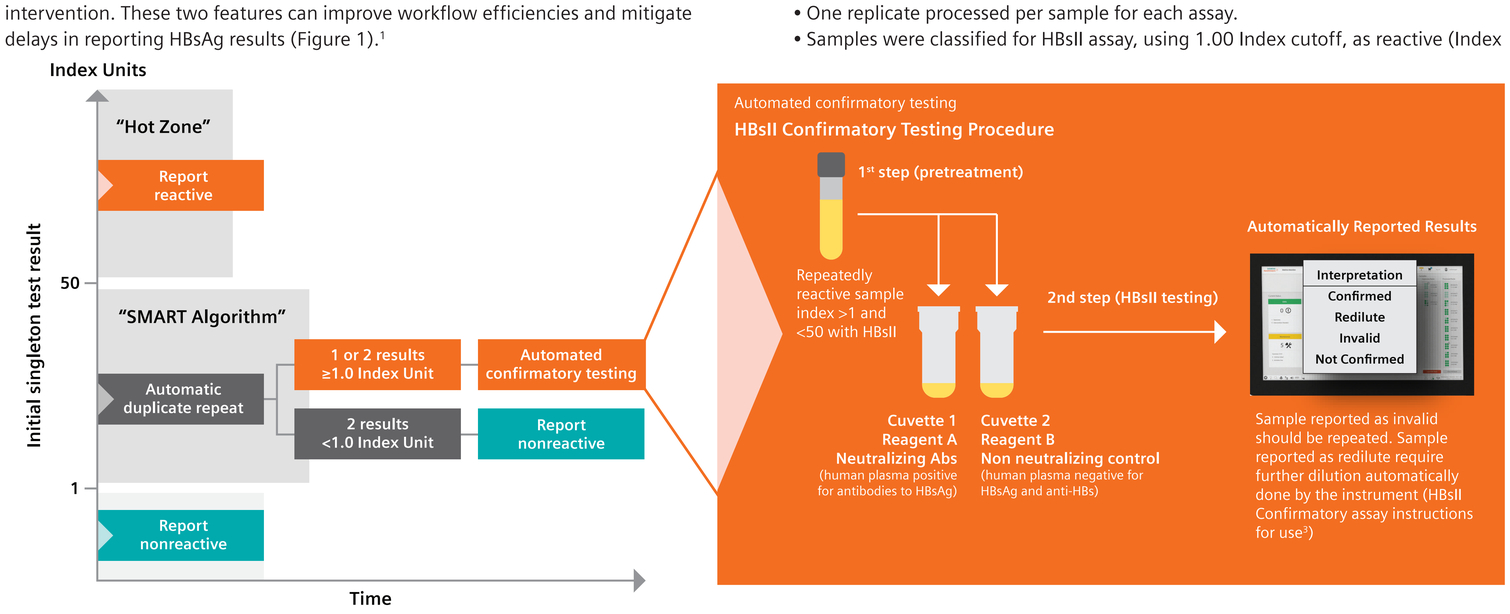


**Figure 1. Overview of HBsAg testing on the Atellica Analyzers, an automated sample journey**

For over three years, the Atellica CI Analyzer (Figure 2) has been part of the Atellica portfolio, offering a reduced footprint of 1.9 square meters. It is an integrated clinical chemistry and immunoassay analyzer designed for low- to mid-volume laboratories and features the same reagents,*consumables,* and sophisticated user interface as the Atellica IM Analyzer.[4] Consistent results across the Atellica Portfolio gives confidence when monitoring patients, no matter where in the network they have their blood drawn.

To evaluate the analytical performance of the Atellica IM assays using the Atellica CI analyzer, precision and method comparison (MC) were assessed as performance indicators for the Atellica IM HBsII and HBsII Conf assays.

**Figure 2. The Atellica CI Analyzer**

## Material and Methods

### Precision (CLSI EP05-A3)

- Sample types: pooled and contrived native human serum samples, and quality control (QC) sample.
- One aliquot/sample; tested in duplicate; two runs/day >2 hours apart for 20 days.
- One reagent lot; two analyzers; total n = 80 replicates for each system/lot combination.
- One representative system/lot combination result across all lot and system combinations tested is shown for HBsII (Table 1).
- Each testing day, new frozen aliquots were thawed and used for each run. Calibrators and QC materials were handled according to the manufacturer's instructions; two calibration events for 20-day-precision study.

### Method comparison (CLSI EP12-A2)

- MC for HBsII was evaluated using individual native serum samples stored frozen in aliquots at ≤-20°C. For HBsII Conf assay, contrived human serum samples (each HBsAg-reactive sample was mixed with an individual HBsAg-negative human serum sample to an Index of 1.00–50.00) were tested. Samples were thawed and centrifugated before tested on the Atellica CI Analyzer and the Atellica IM Analyzer using three reagent lots for each assay.
- Samples were acquired from Siemens approved vendors from HBV positive individuals and negative normal individuals.
- MC was completed over 10 non-consecutive days using two calibration events for HBsII and 8 non-consecutive days for HBsII Conf using one calibration event.
- One representative system/lot combination result across all lot and system combinations tested is presented for each assay (Tables 2 and 3).
- One replicate processed per sample for each assay.
- Samples were classified for HBsII assay, using 1.00 Index cutoff, as reactive (Index ≥1.00) or nonreactive (Index <1.00) specimens for the presence of HBsAg. Samples were classified for HBsII Conf assay as confirmed (> RLU (Relative Light Unit) cutoff and ≥50% neutralization) or not confirmed (> RLU cutoff and <50% neutralization). The system calculates the RLU cutoff value and percent neutralization automatically. RLU cutoff value for HBsII Conf assay is based on the RLU values obtained with the HBsII assay calibrators diluted with the control reagent B (non-neutralizing reagent) to account for volume dilution when adding respective confirmatory reagent into each separate cuvette as shown in Figure 1.
- Negative, positive, and overall agreement are reported and were calculated as followed:

| | | Atellica IM Result | |
|---|---|---|---|
| | | Reactive | Nonreactive |
| Atellica CI Result | Reactive | A | B |
| | Nonreactive | C | D |

Positive percent agreement = 100 × A / (A + C)

Negative percent agreement = 100 × D / (B + D)

Overall Percent Agreement = 100 × (A + D) / (A + B + C + D)

## Results

### Precision

**Table 1. Precision for the Atellica IM HBsII assay on the Atellica CI Analyzer**

| Specimen Type | Mean (n=80) (Index) | Repeatability | | Within-laboratory Precision | |
|---|---|---|---|---|---|
| | | SD (Index) | CV (%) | SD (Index) | CV (%) |
| Serum A | 0.73 | 0.039 | 5.3 | 0.045 | 6.2 |
| Serum B | 1.28 | 0.044 | 3.4 | 0.057 | 4.5 |
| Serum C | 2.83 | 0.069 | 2.4 | 0.134 | 4.7 |
| Serum D | 23.20 | 0.499 | 2.2 | 0.750 | 3.2 |
| Serum E | 45.54 | 1.181 | 2.6 | 2.024 | 4.4 |
| Serum F | 224.23 | 6.118 | 2.7 | 14.351 | 6.4 |
| Serum G | 811.87 | 15.304 | 1.9 | 24.496 | 3.0 |
| QC 1 | 2.37 | 0.074 | 3.1 | 0.119 | 5.0 |
| QC 2 | 4.73 | 0.135 | 2.9 | 0.181 | 3.8 |

The Atellica IM HBsII assay on the Atellica CI Analyzer demonstrated ≤5.3% repeatability CV and ≤6.4% within-laboratory precision CV across the sample interval.

### Method Comparison

**Table 2. Qualitative method comparison for the Atellica IM HBsII assay on the Atellica IM and Atellica CI Analyzers**

| 1.00 Index Cutoff | | Atellica IM HBsII on the Atellica IM Analyzer | | |
|---|---|---|---|---|
| | | Reactive | Nonreactive | Total |
| Atellica IM HBsII on the Atellica CI Analyzer | Reactive | 101 | 0 | 101 |
| | Nonreactive | 0 | 104 | 104 |
| | Total | 101 | 104 | 205 |

Positive percent agreement: 100% (101/101); 95% confidence interval: 96.34–100%

Negative percent agreement: 100% (104/104); 95% confidence interval: 96.44–100%

Overall percent agreement: 100% (205/205); 95% confidence interval: 98.22–100%

The design requirements for method comparison were met with 100% negative and 100% positive agreement when comparing the Atellica IM HBsII assay using the Atellica CI Analyzer to the Atellica IM Analyzer. No discordant results were observed between the compared devices.

**Table 3. Qualitative method comparison for the Atellica IM HBsII Conf assay on the Atellica IM and Atellica CI Analyzer**

| | | Atellica IM HBsII Conf on the Atellica IM Analyzer | | |
|---|---|---|---|---|
| | | Confirmed | Not Confirmed | Total |
| Atellica IM HBsII Conf on the Atellica CI Analyzer | Confirmed | 101 | 0 | 101 |
| | Not Confirmed | 0 | 0 | 0 |
| | Total | 101 | 0 | 101 |

Positive percent agreement: 100% (101/101); 95% confidence interval: 96.34–100%

The design requirements for method comparison were met with 100% positive agreement with the determination of reactive samples when comparing the Atellica IM HBsII Conf assay using the Atellica CI Analyzer to the Atellica IM Analyzer.
No discordant results were observed between the compared devices.

## Conclusion

All results indicate that the Atellica IM HBsII and HBsII Conf assays demonstrated comparable analytical performance for the serological determination of HBsAg when tested on the Atellica CI Analyzer. In addition, strong qualitative agreement was observed between the assay on the Atellica CI Analyzer and the Atellica IM Analyzer. Altogether, these results support that the Atellica CI Analyzer has comparable performance capability to the Atellica IM Analyzer.

### References

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The Atellica IM HBsII and HBsII Conf assays for use on the Atellica CI Analyzer are not yet commercially available in the United States.

**The products/features mentioned here are not commercially available in all countries. Their future availability cannot be guaranteed.*



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