PP1143

Real-World Atellica LumIQ Analyzer Performance Compared to CLINITEK Status+ Analyzer for Seven Routine Urine Tests

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Background

How does the Atellica LumIQ Analyzer perform in the Real-World? Urinalysis plays a vital role in the detection and monitoring of renal, metabolic, and genitourinary disorders. As point-of-care testing continues to evolve, new analyzers must demonstrate strong agreement with existing technologies to ensure continuity of patient care. We evaluated the performance of Multistix 8SG strips testing on the Atellica LumIQ Analyzer against the established CLINITEK Status+ Analyzer using routine clinical samples from a **Real-World Validation** (Waikato Hospital, N=30 samples) and an **Independent Controlled Evaluation** (N=486–764 samples across analytes). Agreement was assessed across seven key urinalysis parameters to determine the analytical comparability of the two POCT systems with further analysis to determine how the real-world data compared to the Independent Controlled Evaluation by Siemens Healthineers. Reagent strip evaluations included test parameters for blood, glucose, ketones, leukocytes, nitrite, pH, and protein. In the clinical setting, these test results are used along with other diagnostic information to rule out certain disease states.[1-7]

This method comparison supports the use of the Atellica LumIQ Analyzer as a reliable, space-saving alternative for point-of-care urinalysis. Previously, the Multistix 8SG strips, 10SG strips, PRO 10LS strips, and CLINITEK Microalbumin 2 assays were developed and commercialized for use on the CLINITEK Status+ Analyzer. Recently, the Atellica LumIQ Analyzer (Figure 1) was added to the Atellica Solution portfolio.[8] 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.[9]

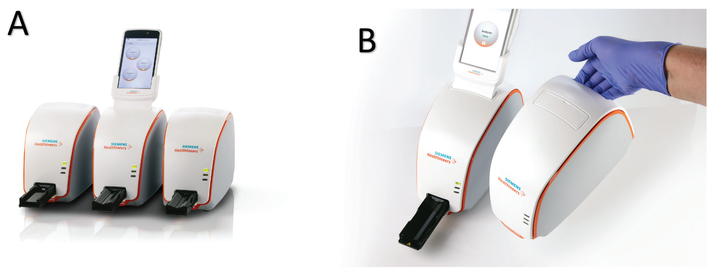


Figure 1. The Atellica LumIQ Analyzer. Panel A shows three interlocked systems, while Panel B shows one unit that is easily carried by hand.

Material and Methods

Real-World Validation (Waikato Hospital). The comparison of Multistix 8SG strips (testing of 7 analytes: blood, glucose, ketones, leukocytes, nitrite, pH, and protein) urine testing on both the Atellica LumIQ Analyzer and CLINITEK Status+ Analyzer was performed by testing 30 remnant clinical urine samples.

- Samples (N=30 clinical urine samples, natural and contrived) were tested in singlicate and analyzed.
- Method comparison (MC) studies compared the testing results from the Atellica LumIQ Analyzer and CLINITEK Status+ Analyzer (one replicate each) using Multistix 8SG strips testing the seven analytes indicated.
- One lot of reagent strip type was used, using the same lot to test each sample on the Atellica LumIQ Analyzer and CLINITEK Status+ Analyzer.

Independent Controlled Evaluation. A comparison of Multistix 10SG strips (leukocyte, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketone, bilirubin, and glucose), the CLINITEK Microalbumin 2 strips (albumin, creatinine, and A:C ratio), and the Multistix PRO 10LS strips (protein and P:C ratio) Urine Testing on both the Atellica LumIQ Analyzer and CLINITEK Status+ Analyzer was performed through testing clinical urine samples acquired through specimen acquisition or anonymous internal donation.

- Samples (N=486–764) clinical urine samples, natural and contrived) were tested in singlicate and analyzed.
- MC studies compared the testing results from the Atellica LumIQ Analyzers and CLINITEK Status+ Analyzers (one replicate each) using Multistix 10SG, Multistix PRO 10LS, and CLINITEK Microalbumin 2 reagent strips, 12 reagents total and both A:C and P:C ratios were analyzed.
- 3 lots of each reagent strip type were used, using the same lot of each type of reagent strip to test each sample on the Atellica LumIQ Analyzer and CLINITEK Status+ Analyzer. Approximately equal numbers of samples were tested on each strip lot.

The results of this larger study were previously presented, IFCC WorldLab 2025. These results were then used in comparison to the 7-analyte study conducted during routine **Real-World Validation** at Waikato Hospital.

Analysis

Real-World Validation. Each Atellica LumIQ Analyzer result was compared to the CLINITEK Status+ Analyzer result and the agreement was evaluated.

- Results from all samples for the 7 analytes were evaluated to determine overall agreement.
- The acceptable limit of agreement determined by the manufacturer is ±1 level for blood, glucose, ketones, leukocytes, nitrite, and protein; whereas for pH it was set at ± 1 pH unit or 2 levels, per manufacturer.[8]
- Comprehensive characterization of agreement was evaluated using:
  - Primary or exact agreement, within ±1 category, and
  - Directional disagreement, results on the Atellica LumIQ Analyzer were higher or lower than CLINITEK Status+ Analyzer, and
- Ordinal agreement was further assessed using quadratic weighted Cohen's kappa (κ) and polychoric correlation (ρ).

Independent Controlled Evaluation. Each Atellica LumIQ Analyzer result was compared to the CLINITEK Status+ Analyzer result and the agreement was evaluated. Analysis of agreement was performed as described above.

Results

Real-World Validation. At Waikato Hospital, the agreement between analyzers for glucose, ketones, blood, protein, nitrites, leukocytes was high, with exact agreement ranging from 90.0% to 100% and 100% agreement within ±1 category.

Directional disagreement was minimal (0.0%–6.7% higher on Atellica LumIQ Analyzer; 0.0%–10.0% lower on Atellica LumIQ Analyzer). For pH, exact agreement was lower at 63.3% (95% CI: 43.9%–80.1%), although agreement within one category remained 100%. All discrepancies for pH reflect lower Atellica LumIQ Analyzer readings (36.7%). Strong ordinal association was observed across all analytes, with quadratic weighted kappa values of 0.90–1.00 and polychoric correlations of 0.98–1.00. See Table 1.

Overall, the test agreement was substantial.

Independent Controlled Evaluation. Strong ordinal association was observed across all analytes, with quadratic weighted kappa values of 0.90–1.00 and polychoric correlations of 0.98–1.00. This level of performance was equivalent to that from the Internal Controlled Evaluation. See Table 1 and Figure 3.

Conclusion

The **Real-World Validation**, conducted by Waikato Hospital's evaluation of Multistix 8SG strips testing on the Atellica LumIQ Analyzer demonstrated a very strong agreement with the CLINITEK Status+ Analyzer, supporting its robust analytical performance. The power of comparing the smaller subset to the larger independent controlled evaluation was substantial, showing that all observed results by Waikato Hospital were congruent with the larger **Independent Controlled Evaluation,** within statistical allowance of the Atellica LumIQ Analyzer for the testing performed, and were in specification limits of agreement 100% of the time.

In a real-world clinical setting, Multistix 8SG strips testing on the Atellica LumIQ Analyzer demonstrated a very strong agreement with the CLINITEK Status+ Analyzer, supporting its robust analytical performance.

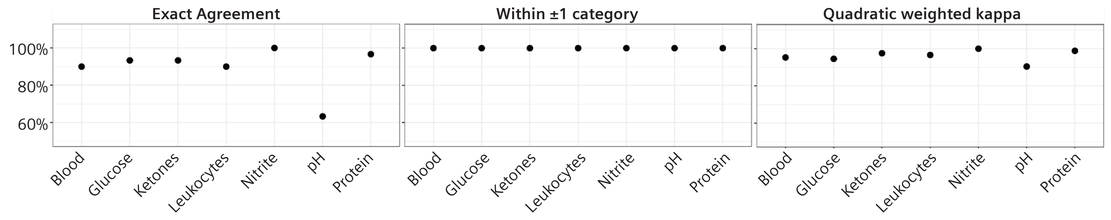


Figure 2. Agreement Metrics for Controlled Rollout Validation at Waikato Hospital. Multistix 8SG parameters (blood, glucose, ketones, leukocytes, nitrite, pH, and protein) testing using Atellica LumIQ Analzyer compared with CLINITEK Status+ Analyzer, N=30 samples.

Table 1. Comprehensive characterization of agreement of Atellica LumIQ Analyzer vs. CLINITEK Status+ Analyzer for blood, glucose, ketones, leukocytes, nitrite, pH, and protein. The primary and directional agreement as well as the ordinal association of testing was determined for each analyte in question for the Independent Controlled Evaluation and the Real-World validation performed at Wakaito Hospital.

Waikato Hospital		Primary Agreement		Directional Agreement		Ordinal Association	
		Exact	Within ±1	Atellica LumIQ Analyzer higher	Atellica LumIQ Analyzer lower	Quadratic weighted κ	Polychoric ρ
Analyte	N	% (95th% CI)	% (95th% CI)	% (95th% CI)	% (95th% CI)	# (95th% CI)	# (95th% CI)
Blood	30	90.0% (73.5%, 97.9%)	100.0% (88.4%, 100.0%)	6.7% (0.8%, 22.1%)	3.3% (0.1%, 17.2%)	0.953 (0.896, 1.000)	0.991 (0.975, 1.000)
Glucose	30	93.3% (77.9%, 99.2%)	100.0% (88.4%, 100.0%)	6.7% (0.8%, 22.1%)	0.0% (0.0%, 11.6%)	0.946 (0.918, 0.961)	0.999 (0.997, 1.000)
Ketones	30	93.3% (77.9%, 99.2%)	100.0% (88.4%, 100.0%)	3.3% (0.1%, 17.2%)	3.3% (0.1%, 17.2%)	0.976 (0.872, 1.000)	0.992 (0.982, 1.000)
Leukocytes	30	90.0% (73.5%, 97.9%)	100.0% (88.4%, 100.0%)	0.0% (0.0%, 11.6%)	10.0% (2.1%, 26.5%)	0.966 (0.918, 0.988)	0.986 (0.973, 0.995)
Nitrite	30	100.0% (88.4%, 100.0%)	100.0% (88.4%, 100.0%)	0.0% (0.0%, 11.6%)	0.0% (0.0%, 11.6%)	1.000 (1.000, 1.000)	1.000 (1.000, 1.000)
pH	30	63.3% (43.9%, 80.1%)	100.0% (88.4%, 100.0%)	0.0% (0.0%, 11.6%)	36.7% (19.9%, 56.1%)	0.904 (0.827, 0.953)	0.978 (0.966, 0.993)
Protein	30	96.7% (82.8%, 99.9%)	100.0% (88.4%, 100.0%)	0.0% (0.0%, 11.6%)	3.3% (0.1%, 17.2%)	0.989 (0.932, 1.000)	0.987 (0.981, 1.000)
Independent Controlled Evaluation		Primary Agreement		Directional Agreement		Ordinal Association	
Analyte	N	Exact	Within ±1	Atellica LumIQ Analyzer higher	Atellica LumIQ Analyzer lower	Quadratic weighted κ	Polychoric ρ
Blood	536	94.0%	100.0%	2.6%	3.4%	0.977	0.996
Glucose	522	95.4%	100.0%	2.9%	1.7%	0.983	0.996
Ketones	495	96.0%	100.0%	0.8%	3.2%	0.988	0.995
Leukocytes	538	92.8%	100.0%	2.8%	4.5%	0.973	0.996
Nitrite	486	99.8%	100.0%	0.0%	0.2%	0.993	1.00
pH	764	81.3%	99.6%	2.4%	16.4%	0.951	0.977
Protein	550	90.2%	100.0%	4.2%	5.6%	0.965	0.992

Findings were consistent with the **Independent Controlled Evaluation** (IFCC 2025).

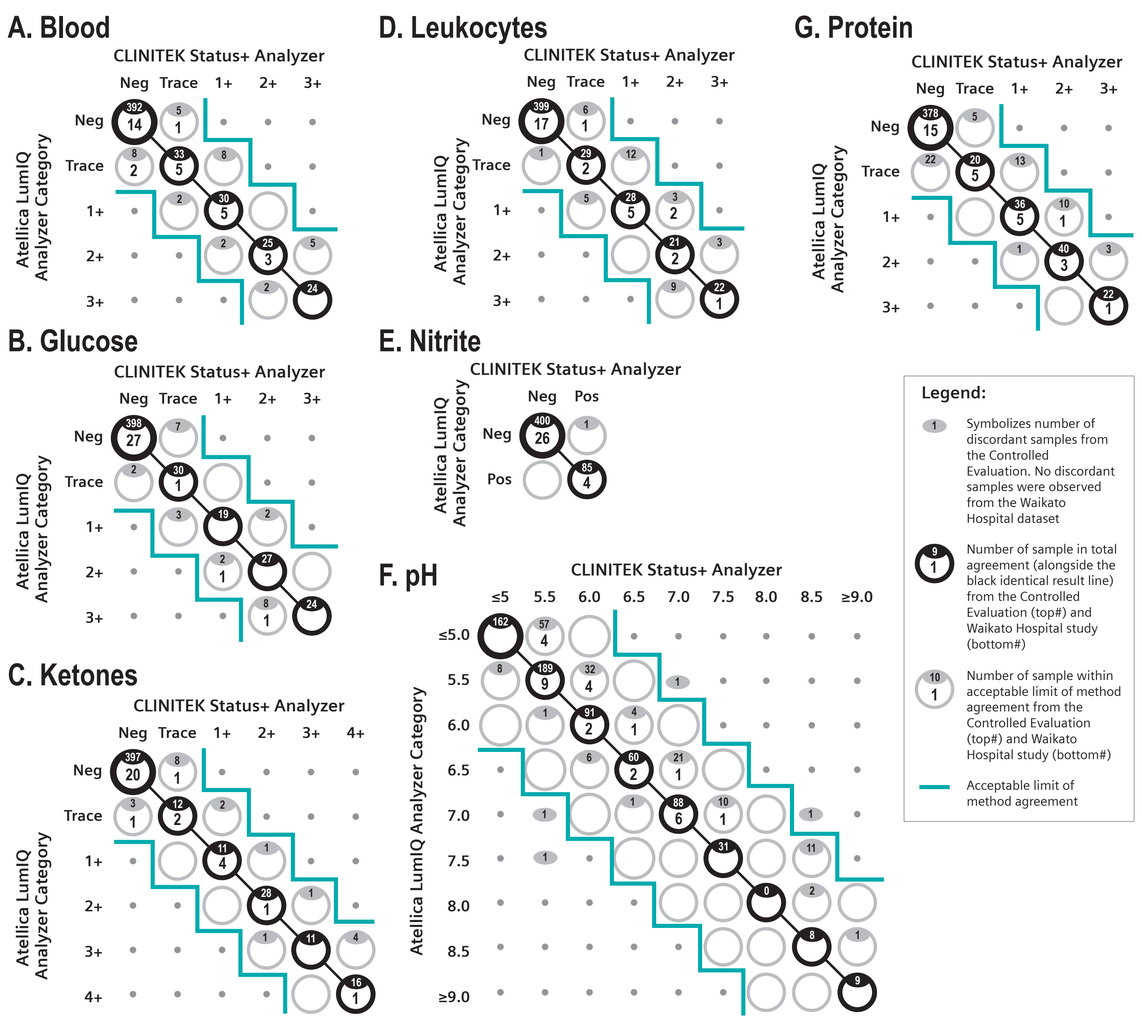


Figure 3. Multilayer Concordance plot showing Independent Controlled Evaluation (N=486-764) and Real-World Validation (N=30) Concordance between CLINITEK Status+ Analyzer and Atellica LumIQ Analyzer. Multistix 8SG strips parameters (blood, glucose, ketones, leukocytes, nitrite, pH, and protein) testing using Atellica LumIQ Analyzer compared with CLINITEK Status+ Analyzer . See legend.

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