

Atellica LumiQ Analyzer Performance Compared to CLINITEK Status+ Analyzer for Twelve Routine Urine Tests

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Background

Urinalysis is a key diagnostic tool for evaluating kidney function, urinary tract infections, carbohydrate metabolism, and liver function¹⁻⁴. This study compares the analytical performance of Siemens Multistix 10 SG, Multistix PRO 10LS, and CLINITEK Microalbumin 2 Reagent Strips on the new Atellica LumiQ Analyzer versus the CLINITEK Status+ Analyzer. The Atellica LumiQ Analyzer is a compact, semi-automated system for near-patient and central lab urinalysis testing. Reagent strip evaluations include test parameters for protein, creatinine, albumin, and associated ratios (P:C, A:C), as well as glucose, ketone, blood, leukocytes, nitrite, pH, specific gravity, bilirubin, and urobilinogen. Test results can be 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 10 SG, PRO 10LS, 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

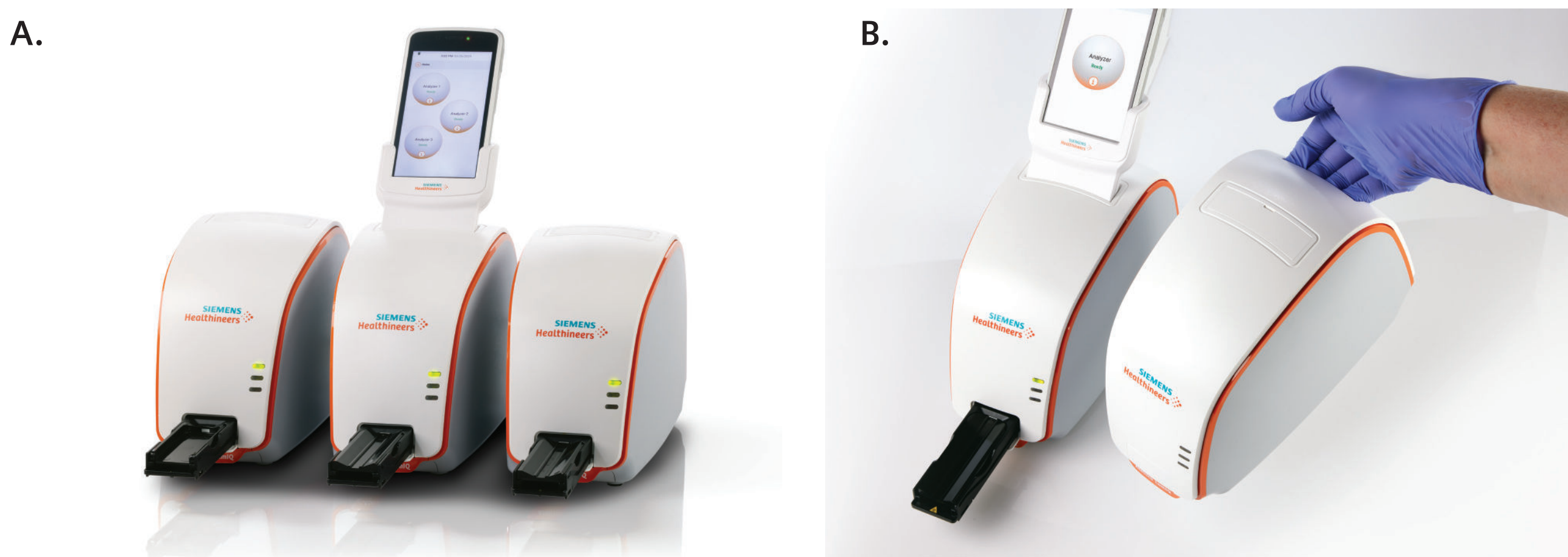


Figure 1. The Atellica LumiQ Analyzer. Panel A shows three interlocked systems, while Panel B is showing that one unit is easily carried by hand.

Principles of the Procedures *see package insert for details*

Material and Methods

The comparison of Multistix 10 SG 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 of clinical urine samples acquired through specimen acquisition or anonymous internal donation.

- Samples (n= 882 clinical urine samples, natural and contrived) were tested in singlicate and analyzed.
- Method comparison (MC) studies compared the testing results from the Atellica LumiQ Analyzers and CLINITEK Status+ Analyzers (one replicate each) using Multistix 10 SG, Multistix PRO 10LS, and CLINITEK Microalbumin 2 reagent strips, 12 reagents total and both A:C and P:C ratios were analyzed.
- Three 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.

Analysis

Each Atellica LumiQ Analyzer result was compared to the CLINITEK Status+ Analyzer result and the agreement was evaluated.

- Results from all enrolled samples and the 12 analytes and ratios were evaluated to determine the overall agreement.
- Negative and positive agreement was calculated to determine the specificity and sensitivity of each of the analytes or ratios using the Atellica LumiQ Analyzer as compared to the CLINITEK Status+ Analyzer.
- For reagents without positive and negative levels (Creatinine, pH, and Specific Gravity), exact agreement and ± 1 level, was evaluated.

Results

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

Negative and Positive Agreement

Negative and positive agreement were calculated as follows:	Percent Negative Agreement (specificity) = $TN \div (TN + FP)$ * 100 Percent Positive Agreement (sensitivity) = $TP \div (TP + FN)$ * 100
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Overall, the agreement of testing was substantial.

Table 2. Percent Agreement of Albumin. N = 486 samples total; Negative agreement, 95.1%; Positive agreement, 96.7%.

Atellica LumiQ Analyzer (Albumin, mg/L)	CLINITEK Status+ Analyzer (Albumin, mg/L)			
	10	30	80	150
10	95.1%	10.0%	0.0%	0.0%
30	4.9%	85.0%	28.3%	0.0%
80	0.0%	5.0%	70.0%	15.0%
150	0.0%	0.0%	1.7%	85.0%

Table 3. Percent Agreement of Bilirubin. N = 506 samples total; Negative agreement, 99.3%; Positive agreement, 98.1%.

Atellica LumiQ Analyzer (Bilirubin)	CLINITEK Status+ Analyzer (Bilirubin)			
	Negative	Small	Moderate	Large
Negative	99.3%	5.0%	0.0%	0.0%
Small	0.8%	85.0%	7.7%	0.0%
Moderate	0.0%	10.0%	87.2%	14.8%
Large	0.0%	0.0%	5.1%	85.2%

Table 4. Percent Agreement of Blood. N = 536 samples total; Negative agreement, 98.0%; Positive agreement, 96.3%.

Atellica LumiQ Analyzer (Blood)	CLINITEK Status+ Analyzer (Blood)				
	Negative	Trace	Small	Moderate	Large
Negative	98.0%	12.5%	0.0%	0.0%	0.0%
Trace	2.0%	82.5%	20.0%	0.0%	0.0%
Small	0.0%	5.0%	75.0%	0.0%	0.0%
Moderate	0.0%	0.0%	5.0%	92.6%	17.2%
Large	0.0%	0.0%	0.0%	7.4%	82.8%

Table 5. Percent Agreement of Creatinine. N = 614 samples total; exact agreement, 87.3%; ± 1 level, 100%.

Atellica LumiQ Analyzer (Creatinine, mg/dL)	CLINITEK Status+ Analyzer (Creatinine, mg/dL)				
	10	50	100	200	300
10	94.3%	2.3%	0.0%	0.0%	0.0%
50	5.7%	89.2%	7.8%	0.0%	0.0%
100	0.0%	8.5%	82.6%	4.2%	0.0%
200	0.0%	0.0%	9.6%	89.8%	20.6%
300	0.0%	0.0%	0.0%	5.9%	79.4%

Table 6. Percent Agreement of Glucose. N = 522 samples total; Negative agreement, 99.5%; Positive agreement, 94.3%.

Atellica LumiQ Analyzer (Glucose, mg/dL)	CLINITEK Status+ Analyzer (Glucose, mg/dL)			
	Negative	100	250	500
Negative	99.5%	17.5%	0.0%	0.0%
100	0.5%	75.0%	0.0%	0.0%
250	0.0%	7.5%	90.5%	5.4%
500	0.0%	0.0%	9.5%	73.0%
≥ 1000	0.0%	0.0%	0.0%	21.6%

Table 7. Percent Agreement of Ketones. N = 495 samples total; Negative agreement, 99.3%; Positive agreement, 91.6%.

Atellica LumiQ Analyzer (Ketones, mg/dL)	CLINITEK Status+ Analyzer (Ketones, mg/dL)				
	Negative	Trace	15 mg/dL	40 mg/dL	80 mg/dL
Negative	99.3%	40.0%	0.0%	0.0%	0.0%
Trace	0.8%	60.0%	15.4%	0.0%	0.0%
15 mg/dL	0.0%	0.0%	84.6%	3.3%	0.0%
40 mg/dL	0.0%	0.0%	0.0%	93.3%	8.3%
80 mg/dL	0.0%	0.0%	0.0%	3.3%	91.7%
≥ 160 mg/dL	0.0%	0.0%	0.0%	0.0%	80.0%

Table 8. Percent Agreement of Leukocytes. N = 538 samples total; Negative agreement, 99.8%; Positive agreement, 95.7%.

Atellica LumiQ Analyzer (Leukocytes)	CLINITEK Status+ Analyzer (Leukocytes)				
	Negative	Trace	Small	Moderate	Large
Negative	99.8%	15.0%	0.0%	0.0%	0.0%
Trace	0.3%	72.5%	30.0%	0.0%	0.0%
Small	0.0%	12.5%	70.0%	9.1%	0.0%
Moderate	0.0%	0.0%	0.0%	63.6%	12.0%
Large	0.0%	0.0%	0.0%	27.3%	88.0%

Table 9. Percent Agreement of Nitrite. N = 486 samples total; Negative agreement, 100.0%; Positive agreement, 98.8%.

Atellica LumiQ Analyzer (Nitrite)	CLINITEK Status+ Analyzer (Nitrite)	
	Negative	Positive
Negative	100.0%	1.2%
Positive	0.0%	98.8%

Table 10. Percent Agreement of pH. N = 796 samples total; exact agreement, 80.2% ± 1 level, 98.1%.

Atellica LumiQ Analyzer (pH)	CLINITEK Status+ Analyzer (pH)							
	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5
5.0	95.3%	22.9%	0.0%	0.0%	0.0%	0.0%	N/A	0.0%
5.5	4.7%	75.9%	24.8%	0.0%	0.9%	0.0%	N/A	0.0%
6.0	0.0%	0.4%	70.5%	6.2%	0.0%	0.0%	N/A	0.0%
6.5	0.0%	0.0%	4.7%	92.3%	19.1%	0.0%	N/A	0.0%
7.0	0.0%	0.4%	0.0%	1.5%	80.0%	24.4%	N/A	4.5%
7.5	0.0%	0.4%	0.0%	0.0%	0.0%	75.6%	N/A	50.0%
8.0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	N/A	9.1%
8.5	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	N/A	36.4%
≥ 9.0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	N/A	10.0%

Table 11A. Percent Agreement of Protein with Multistix 10SG Strips. N = 550 samples total; Negative agreement, 94.5%; Positive agreement, 96.7%.

Atellica LumiQ Analyzer with Multistix 10 SG Strips (Protein,mg/dL)	CLINITEK Status+ Analyzer with Multistix 10 SG Strips (Protein,mg/dL)				
	Negative	Trace	30	100	≥ 300
Negative	94.5%	20.0%	0.0%	0.0%	0.0%
Trace	5.5%	80.0%	26.0%	0.0%	0.0%
30	0.0%	0.0%	72.0%	20.0%	0.0%
100	0.0%	0.0%	2.0%	80.0%	12.0%
≥ 300	0.0%	0.0%	0.0%	0.0%	88.0%

Table 11B. Percent Agreement of Protein with Multistix PRO 10LS Strips. N = 545 samples total; Negative agreement, 95.3%; Positive agreement, 98.6%.

Atellica LumiQ Analyzer with Multistix PRO 10LS Strips (Protein,mg/dL)	CLINITEK Status+ Analyzer with Multistix PRO 10LS Strips (Protein,mg/dL)				
	Negative	15	30	100	≥ 300
Negative	95.3%	7.4%	0.0%	0.0%	0.0%
15	4.8%	66.7%	36.0%	0.0%	0.0%
30	0.0%	25.9%	64.0%	16.3%	0.0%
100	0.0%	0.0%	0.0%	83.7%	4.0%
≥ 300	0.0%	0.0%	0.0%	0.0%	96.0%

Table 12. Percent Agreement of Specific Gravity. N = 625 samples total; exact agreement, 79.2%; ± 1 level, 99.5%.

Atellica LumiQ Analyzer (Specific Gravity)	CLINITEK Status+ Analyzer (Specific Gravity)					
	≤ 1.005	1.01	1.015	1.02	1.025	≥ 1.030
≤ 1.005	93.8%	8.3%	0.0%	0.0%	0.0%	0.0%
1.01	6.3%	73.3%	5.5%	0.4%	0.0%	0.0%
1.015	0.0%	18.3%	75.2%	9.5%	1.1%	0.0%
1.02	0.0%	0.0%	19.3%	80.2%	14.7%	1.5%
1.025	0.0%	0.0%	0.0%	9.9%	81.1%	15.2%
≥ 1.030	0.0%	0.0%	0.0%	0.0%	3.2%	83.3%

Table 13. Percent Agreement of Urobilinogen. N = 486 samples total; Negative agreement, 99.5%; Positive agreement, 100.0%.

Atellica LumiQ Analyzer (Urobilinogen, E.U./dL)	CLINITEK Status+ Analyzer (Urobilinogen, E.U./dL)			
	0.2	1	2	≥ 8.0
0.2	100.0%	3.3%	0.0%	0.0%
1	0.0%	90.0%	0.0%	0.0%
2	0.0%	6.7%	87.5%	5.0%
4	0.0%	0.0%	12.5%	90.0%
≥ 8.0	0.0%	0.0%	0.0%	5.0%

Table 14. Percent Agreement of Albumin:Creatinine (A:C Ratio). N = 774 samples total; Negative agreement, 85.3%; Positive agreement, 94.3%.

Atellica LumiQ Analyzer with Microalbumin 2 (A:C Ratio, mg/g)	CLINITEK Status+ Analyzer with Microalbumin 2 (A:C Ratio, mg/g)		
	<30 Normal	30–300 Abnormal	>300 High Abnormal
<30 Normal	85.3%	9.2%	0.0%
30–300 Abnormal	14.7%	88.7%	16.9%
>300 High Abnormal	0.0%	2.1%	83.1%

Table 15. Percent Agreement of Protein:Creatinine (P:C Ratio). N = 831 samples total; Negative agreement, 88.9%; Positive agreement, 93.5%.

Atellica LumiQ Analyzer with Multistix PRO 10LS Strips (P:C Ratio, mg/g)	CLINITEK Status+ Analyzer with Multistix PRO 10LS Strips (P:C Ratio, mg/g)				
	Normal Dilute	Normal	150 mg/g	300 mg/g	>500 mg/g
Normal Dilute	69.0%	0.2%	0.0%	0.6%	0.0%
Normal	15.5%	88.7%	18.6%	6.9%	0.0%
150 mg/g	3.4%	9.4%	78.0%	17.2%	0.0%
300 mg/g	5.2%	1.7%	3.4%	71.3%	28.5%
>500 mg/g	6.9%	0.0%	0.0%	4.0%	71.5%

Conclusions

Evaluation of the Multistix 10 SG 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, Creatinine, and P:C ratio) Urine Testing using the Atellica LumiQ Analyzer demonstrated acceptable performance compared to the CLINITEK Status+ Analyzer.

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