

CLINICAL COMPARISON BETWEEN CLARITY PLATINUM URINE ANALYZER AND SIEMENS CLINITEK STATUS+

As shown in the following table summary of results, the data is represented in concordance charts showing percent exact match agreement and percent agreement within ± 1 color block match between Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ at 3 POC sites.

Glucose		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		1000	500	250	100	Neg	Overall
Clarity Platinum Urine Analyzer	1000	16	4	0	0	0	20
	500	4	37	0	0	0	41
	250	0	0	10	0	0	10
	100	0	0	0	25	0	25
	Neg	0	0	0	0	413	413
Total		20	41	10	25	413	509
Agreement within same color block (Exact Match)		80.00% (16/20)	90.24% (37/41)	100.0% (10/10)	100.0% (25/25)	100.0% (413/413)	98.43% (501/509)
Agreement within ± 1 color block		100.0% (20/20)	100.0% (37/41)	100.0% (10/10)	100.0% (25/25)	100.0% (413/413)	100.0% (509/509)

Glucose concentration levels compared at a 98.43% overall exact match and a 100.0% overall agreement ± 1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

Bilirubin		Siemens Clinitek Status + Urine Analyzer				
3 Sites, N=509		3+	2+	1+	Neg	Overall
Clarity Platinum Urine Analyzer	3+	35	1	0	0	36
	2+	0	31	0	0	31
	1+	0	0	51	5	56
	Neg	0	0	0	386	386
Total		35	32	51	391	509
Agreement within same color block (Exact Match)		100.0% (35/35)	96.88% (31/32)	100.0% (51/51)	98.72% (386/391)	98.82% (503/509)
Agreement within ± 1 color block		100.0% (35/35)	100.0% (32/32)	100.0% (51/51)	100.0% (391/391)	100.0% (509/509)

Bilirubin concentration levels compared at a 98.82% overall exact match and a 100.0% overall agreement ± 1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

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Clarity Diagnostics - 1060 Holland Drive, Suite A, Boca Raton, Florida 33487

Phone: 877.722.6339 Fax: 561.288.3929 www.claritydiagnostics.com

Ketone		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		80	40	15	Trace	Neg	Overall
Clarity Platinum Urine Analyzer	80	13	1	0	0	0	14
	40	0	18	1	0	0	19
	15	0	0	24	1	0	25
	TRA	0	0	0	44	4	48
	Neg	0	0	0	1	402	403
Total		13	19	25	46	406	509
Agreement within same color block (Exact Match)		100.0% (13/13)	94.74% (18/19)	96.0% (24/25)	95.65% (44/46)	99.01% (402/406)	98.43% (501/509)
Agreement within ±1 color block		100.0% (13/13)	100.0% (19/19)	100.0% (25/25)	100.0% (46/46)	100.0% (406/406)	100.0% (509/509)

Ketone concentration levels compared at a 98.43% overall exact match and a 100.0% overall agreement ±1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

Specific Gravity		Siemens Clinitek Status + Urine Analyzer						
3 Sites, N=509		≥1.030	1.025	1.020	1.015	1.010	≤1.005	Overall
Clarity Platinum Urine Analyzer	>1.030	57	5	0	0	0	0	62
	1.025	6	55	5	0	0	0	66
	1.020	0	21	112	10	0	0	143
	1.015	0	0	16	135	6	0	157
	1.010	0	0	0	8	40	7	55
	<1.005	0	0	0	0	4	22	26
Total		63	81	133	153	50	29	509
Agreement within same color block (Exact Match)		90.48% (57/63)	67.90% (55/81)	84.21% (112/133)	88.24% (135/153)	80.0% (40/50)	75.86% (22/29)	82.71% (421/509)
Agreement within ±1 color block		100.0% (63/63)	100.0% (81/81)	100.0% (133/133)	100.0% (153/153)	100.0% (50/50)	100.0% (29/29)	100.0% (509/509)

Specific Gravity concentration levels compared at an 82.71% overall exact match and a 100.0% overall agreement ±1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

***The Acceptance Criteria for SG is +/- 0.005.**

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Blood		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		3+	2+	1+	Trace	Neg	Overall
Clarity Platinum Urine Analyzer	3+	32	3	0	0	0	35
	2+	0	55	0	0	0	55
	1+	0	0	21	0	0	21
	Trace	0	0	1	63	2	66
	Neg	0	0	0	4	328	332
	Total	32	58	22	67	330	509
Agreement within same color block (Exact Match)		100.0% (32/32)	94.83% (55/58)	95.45% (21/22)	94.03% (63/67)	99.39% (328/330)	98.04% (499/509)
Agreement within ± 1 color block		100.0% (32/32)	100.0% (58/58)	100.0% (22/22)	100.0% (67/67)	100.0% (330/330)	100.0% (509/509)

Blood concentration levels compared at a 98.04% overall exact match and a 100.0% overall agreement ± 1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

Protein		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		>300	100	30	Trace	Neg	Overall
Clarity Platinum Urine Analyzer	>300	26	0	0	0	0	26
	100	0	35	0	0	0	35
	30	0	3	34	0	0	37
	Trace	0	0	2	46	6	54
	Neg	0	0	0	3	354	357
	Total	26	38	36	49	360	509
Agreement within same color block (Exact Match)		100.0% (26/26)	92.11% (35/38)	94.44% (34/36)	93.88% (46/49)	98.33% (354/360)	97.25% (495/509)
Agreement within ± 1 color block		100.0% (26/26)	100.0% (38/38)	100.0% (36/36)	100.0% (49/49)	100.0% (360/360)	100.0% (509/509)

Protein concentration levels compared at a 97.25% overall exact match and a 100.0% overall agreement ± 1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

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Urobilinogen		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		>8.0	4	2	1	0.2	Overall
Clarity Platinum Urine Analyzer	>8.0	31	0	0	0	0	31
	4.0	0	26	0	0	0	26
	2.0	0	0	22	0	0	22
	1.0	0	0	0	14	0	14
	0.2	0	0	0	2	414	416
Total		31	26	22	16	414	509
Agreement within same color block (Exact Match)		100.0% (31/31)	100.0% (26/26)	100.0% (22/22)	87.5% (14/16)	100.0% (414/414)	99.61% (507/509)
Agreement within ± 1 color block		100.0% (31/31)	100.0% (26/26)	100.0% (22/22)	100.0% (16/16)	100.0% (414/414)	100.0% (509/509)

Urobilinogen concentration levels compared at a 99.61% overall exact match and a 100.0% overall agreement ± 1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

pH		Siemens Clinitek Status + Urine Analyzer							
3 Sites, N=509		8.5	8	7.5	7.0	6.5	6.0	5.0	Overall
Clarity Platinum Urine Analyzer	8.5	36	0	0	0	0	0	0	36
	8.0	2	15	5	0	0	0	0	22
	7.5	1	1	34	1	0	0	0	37
	7.0	0	0	0	100	0	0	0	100
	6.5	0	0	0	8	65	1	0	74
	6.0	0	0	0	0	11	89	8	108
	5.0	0	0	0	0	1	9	122	132
Total		39	16	39	109	77	99	130	509
Agreement within same color block (Exact Match)		92.31% (36/39)	93.75% (15/16)	87.18% (34/39)	91.74% (100/109)	84.42% (65/77)	89.90% (89/99)	93.85% (122/130)	90.57% (461/509)
Agreement within ± 1 color block		97.44% (38/39)	100.0% (16/16)	100.0% (39/39)	100.0% (109/109)	98.70% (76/77)	100.0% (99/99)	100.0% (130/130)	99.61% (507/509)

pH concentration levels compared at an 90.57% overall exact match and a 99.61% overall agreement ± 1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

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Nitrite		Siemens Clinitek Status + Urine Analyzer		
3 Sites, N=509		POS	NEG	Overall
Clarity Platinum Urine Analyzer	POS	80	2	82
	NEG	1	426	427
Total		81	428	509
Agreement within same color block (Exact Match)		98.77% (80/81)	99.53% (426/428)	99.41% (506/509)
Agreement within ± 1 color block		N/A	N/A	N/A

Nitrite concentration levels compared at a 99.41% overall exact match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

Leukocyte		Siemens Clinitek Status + Urine Analyzer					
3 Sites, N=509		3+	2+	1+	Trace	Neg	Overall
Clarity Platinum Urine Analyzer	3+	39	0	0	0	0	39
	2+	0	12	0	0	0	12
	1+	0	1	49	0	0	50
	Trace	0	0	1	27	7	35
	Neg	0	0	0	2	371	373
Total		39	13	50	29	378	509
Agreement within same color block (Exact Match)		100.0% (39/39)	92.31% (12/13)	98.00% (49/50)	93.10% (27/29)	98.15% (371/378)	97.84% (498/509)
Agreement within ± 1 color block		100.0% (39/39)	100.0% (12/13)	100.0% (50/50)	100.0% (29/29)	100.0% (378/378)	100.0% (509/509)

Leukocyte concentration levels compared at a 97.84% overall exact match and a 100% overall agreement ± 1 color block match between the Clarity Platinum Urine Analyzer and Siemens Clinitek Status+ Analyzer.

Conclusion: The Clarity Platinum Urine Analyzer has an 99.9% overall agreement when compared to the Siemens Clinitek Status+ Analyzer-This data was submitted and approved by the USFDA.



Ashish Parikh
Director of Product and Business Development
Clarity Diagnostics LLC
Email : ashish.parikh@claritydiagnostics.com

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