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Clinical Study

1. General

The evaluation followed “Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (2002) NCCLS, EP9A.

2. Test information

1) Site of study: One evaluation one was Samsung Hospital (Site A, sample number: 255samples), the other was Authoritative local university hospital (Hospital at national Univ.of Pusan) (Site B, sample number: 280samples) and another was Authoritative local university hospital (Hospital at national Univ.of Dong Ai) (Site C, sample number: 332samples) .

2) Date on Test: 2012/12/01

3) Date OFF Test: 2013/05/30

4) Study completion Test: 2013/06/10

5) Test Strip (CYBOW 10) Lot No: 120101, 120525, 120612

Test Instrument (CYBOW R-50S) Serial Number: S4113066, S2313012, S1113002

Predicative Device

- CLINITEK Status, a semi-automatic urine instrument (Simens) using Multistix® 10SG

3. Test procedure

3-1 Clinical analysis

1) Three independent laboratory evaluations of the New Device (CYBOW R-50S) and Predicative Device were conducted by Professional (trained medical technician).

2) Fresh urine sample (spontaneous urine was used and processed within 4 hours, not-centrifuged urine, free of detergent, not spiked) was reacted with the device and the results were read by CYBOW R-50S Display. Results of these reading compared to results measured by Professional (trained medical technician).

4. Acceptance Criteria

The comparison results of the new device versus predicate device should be over more than 80% concordance rate.

5. Clinical Analysis and Results

5-1 Table of results from the new device (y-axis) versus predicate device (x-axis), including all of the data points.

Data points were performed separately for each clinical site.

The blocks in the tabs, representing semi-quantitative results, were compared between the new device and predicate device. As the blocks can overlap at the border regions when using semi-quantitative methods, any results which

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over-lapped into neighboring within one blocks were combined and scored as being in concordance.

5.3

%Exact Agreement = sum of specimens where color block response for the test device agree exactly with the Color block response for the predicate device divided by the total number of specimens (X100).

% Within One Block Agreement=(sum of cases where color block response for the test device agrees exactly with the color block response for the predicate device)+(the sum of the cases where the color block response for the test condition are +/- 1 color block relative the predicate condition) divided by the total number of specimens(X100).

The results are listed in the table below.

Table 1.1 Comparative results with new device (CYBOW R-50S) and Predicate device of urinary Urobilinogen.

URO(Site A)		Predicate device(mg/dl)				
New device (mg/dl)	8				1	6
	4			2	11	1
	2		1	9	1	
	1		10			
	Norm	213				
		Norm	1	2	4	8
Total		213	11	11	13	7
Exact agreement		100%	91%	82%	85%	86%
Within One Block		100%	100%	100%	100%	100%

URO(Site B)		Predicate device(mg/dl)				
New device (mg/dl)	8				2	8
	4			1	12	
	2		2	12		
	1		18	1		
	Norm	224				
		Norm	1	2	4	8
Total		224	20	14	14	8
Exact agreement		100%	90%	86%	86%	100%
Within One Block		100%	100%	100%	100%	100%

URO(Site C)		Predicate device(mg/dl)				
New device (mg/dl)	8				2	21
	4			1	16	1
	2		1	22		
	1		17			
	Norm	251				
		Norm	1	2	4	8
Total		251	18	23	18	22
Exact agreement		100%	94%	96%	89%	95%
Within One Block		100%	100%	100%	100%	100%

Table1.2 Comparative results with new device(CYBOW R-50S) and Predicate device of urinary Glucose.

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GLU(Site A)		Predicate device(mg/dl)					
New device (mg/dl)	1000				2	10	12
	500			3	23	1	
	250		1	19	3		
	100		19				
	NEG	162					
		NEG	100	250	500	1000	2000
Total		162	20	22	28	11	12
Exact agreement		100%	95%	86%	82%	91%	100%
Within One Block		100%	100%	100%	100%	100%	100%


GLU (Site B)		Predicate device(mg/dl)					
New device (mg/dl)	1000					11	18
	500				10	1	1
	250		2	16	2		
	100		31	2			
	NEG	186					
		NEG	100	250	500	1000	2000
	Total		186	33	18	12	12
Exact agreement		100%	94%	89%	83%	92%	95%
Within One Block		100%	100%	100%	100%	100%	95%

GLU (Site C)		Predicate device(mg/dl)					
New device (mg/dl)	1000				4	8	8
	500			3	18	1	
	250			21			
	100		11				
	NEG	258					
		NEG	100	250	500	1000	2000
Total		258	11	24	22	9	8
Exact agreement		100%	100%	88%	82%	89%	100%
Within One Block		100%	100%	100%	100%	100%	100%

Table 1.3 Comparative results with new device (CYBOW R-50S) and Predicate device of urinary Bilirubin.

BIL(Site A)		Predicate device(mg/dl)			
New device (mg/dl)	4				5
	2		1	10	1
	1		7	1	
	NEG	230			
		NEG	1	2	4
Total		230	8	11	6
Exact agreement		100%	88%	91%	83%
Within One Block		100%	100%	100%	100%

BIL(Site B)		Predicate device(mg/dl)			
New device (mg/dl)	4				4
	2		3	17	1
	1		27	3	
	NEG	225			
		NEG	1	2	4
Total		225	30	20	5
Exact agreement		100%	90%	85%	80%
Within One Block		100%	100%	100%	100%

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BIL(Site C)		Predicate device(mg/dl)			
New device (mg/dl)	4				7
	2		2	6	
	1		15	1	
	NEG	301			
		NEG	1	2	4
Total		301	17	7	7
Exact agreement		100%	88%	86%	100%
Within One Block		100%	100%	100%	100%

Table 1.4 Comparative results with new device(CYBOW R-50S) and Predicate device of urinary Ketones.

KET(Site A)		Predicate device(mg/dl)					
New device (mg/dl)	100				2	15	4
	40				8	1	
	15		1	12			
	5		14	3			
	NEG	195					
		NEG	5	15	40	80	160
Total		195	15	15	10	16	4
Exact agreement		100%	93%	80%	80%	94%	100%
Within One Block		100%	100%	100%	100%	100%	100%

KET(Site B)		Predicate device(mg/dl)					
New device (mg/dl)	100				2	11	3
	40				13		
	15		1	10			
	5		7	3			
	NEG	230					
		NEG	5	15	40	80	160
Total		230	8	13	15	11	3
Exact agreement		100%	88%	77%	87%	100%	100%
Within One Block		100%	100%	100%	100%	100%	100%

KET(Site C)	Predicate device(mg/dl)

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New device (mg/dl)	100				5	8	1
	40				20	1	
	15			31			
	5		27	3			
	NEG	236					
		NEG	5	15	40	80	160
Total		236	27	34	25	9	1
Exact agreement		100%	100%	91%	80%	89%	100%
Within One Block		100%	100%	100%	100%	100%	100%

Table 1.5 Comparative results with new device (CYBOW R-50S) and Predicate device of urinary Blood.

BLD (Site A)		Predicate device(RBC/ul)				
New device (RBC/ul)	250				4	32
	50			6	60	
	10		28	48		
	NEG	77				
		NEG	10	25	80	250
Total		77	28	54	64	32
Exact agreement		100%	100%	89%	94%	100%
Within One Block		100%	100%	100%	100%	100%

BLD (Site B)		Predicate device(RBC/ul)				
New device (RBC/ul)	250				5	77
	50		1	2	35	
	10		41	21		
	NEG	98				
		NEG	10	25	80	250
Total		98	42	23	40	77
Exact agreement		100%	98%	91%	88%	100%
Within One Block		100%	100%	100%	100%	100%

BLD (Site C)		Predicate device(RBC/ul)				
New device (RBC/ul)	250				6	69
	50			5	51	3
	10		33	44		
	NEG	121				
		NEG	10	25	80	250
Total		121	33	49	57	72
Exact agreement		100%	100%	90%	89%	96%
Within One Block		100%	100%	100%	100%	100%

Table 1.6 Comparative results with new device (CYBOW R-50S) and Predicate device of urinary Protein.



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PRO(Site A)		Predicate device(mg/dl)					
New device (mg/dl)	1000						12
	300				3	18	1
	100			1	23	1	
	30		4	34			
	15		29	2			
	NEG	127					
		NEG	15	30	100	300	1000
Total		127	33	37	26	19	13
Exact agreement		100%	88%	92%	88%	95%	92%
Within One Block		100%	100%	100%	100%	100%	100%

PRO(Site B)		Predicate device(mg/dl)					
New device (mg/dl)	1000					1	1
	300				1	5	
	100			1	22		
	30		4	36	2		
	15		41				
	NEG	166					
		NEG	15	30	100	300	1000
Total		166	45	37	25	6	1
Exact agreement		100%	91%	97%	88%	83%	100%
Within One Block		100%	100%	100%	100%	100%	100%

PRO(Site C)		Predicate device(mg/dl)					
New device (mg/dl)	1000					1	3
	300					15	
	100			2	16		
	30		4	23			
	15		36				
	NEG	232					
		NEG	15	30	100	300	1000
Total		232	40	25	16	16	3
Exact agreement		100%	90%	92%	100%	94%	100%
Within One Block		100%	100%	100%	100%	100%	100%

Table 1.7 Comparative results with new device (CYBOW R-50S) and Predicate device of urinary Nitrite.

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NIT(Site A)		Predicate device			
New device (mg/dl)	10				98
	0.05	2			32
	NEG	123			
		NEG			Pos
Total		125			130
Exact agreement		98%			100%
Within One Block		98%			100%


NIT(Site B)		Predicate device			
New device (mg/dl)	10				134
	0.05				41
	NEG	105			
		NEG			Pos
Total		105			175
Exact agreement		100%			100%
Within One Block		100%			100%

NIT(Site C)		Predicate device			
New device (mg/dl)	10				74
	0.05				26
	NEG	232			
		NEG			Pos
Total		232			100
Exact agreement		100%			99%
Within One Block		100%			99%

Table 1.8 Comparative results with new device (CYBOW R-50S) and Predicate device of urinary Leukocytes.

LEU(Site A)		Predicate device(WBC/ul)				
New device (WBC/ul)	500					36
	75			44	29	3
	25		38	3		
	NEG	102				
		NEG	15	70	125	500
Total		102	38	47	29	39
Exact agreement		100%	100%	94%	100%	92%
Within One Block		100%	100%	100%	100%	100%

LEU(Site B)		Predicate device(WBC/ul)				
New device (WBC/ul)	500				3	32
	75			33	49	1
	25		28	2		
	NEG	132				
		NEG	15	70	125	500
Total		132	28	35	52	33
Exact agreement		100%	100%	94%	94%	97%
Within One Block		100%	100%	100%	100%	100%

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LEU(Site C)		Predicate device(WBC/ul)				
New device (WBC/ul)	500			2	7	45
	75			46	35	6
	25		34			
	NEG	157				
		NEG	15	70	125	500
Total		157	34	48	42	51
Exact agreement		100%	100%	96%	83%	88%
Within One Block		100%	100%	100%	100%	100%

Table1.9 Comparative results with new device (CYBOW R-50S) and Predicate device of urinary pH.

PH (SiteA)		Predicate device								
New device	9							1	22	10
	8						16	19	7	
	7					26	22			
	6.5			3	28	3				
	6		4	33						
	5	44	17							
		5	5.5	6	6.5	7	7.5	8	8.5	9
Total		44	21	36	28	29	38	20	29	10
Exact agreement		100%	100%	92%	100%	90%	100%	95%	100%	100%
Within One Block		100%	100%	100%	100%	100%	100%	100%	100%	100%


PH (Site B)		Predicate device								
New device	9								2	8
	8						16	29	13	
	7				2	32	14			
	6.5			1	46	1				
	6		9	37						
	5	42	28							
		5	5.5	6	6.5	7	7.5	8	8.5	9
Total		42	37	38	48	33	30	29	15	8
Exact agreement		100%	100%	97%	96%	97%	100%	100%	100%	100%
Within One Block		100%	100%	100%	100%	100%	100%	100%	100%	100%

PH(Site C)		Predicate device								
New device	9							1	6	8
	8						3	25	1	
	7				3	32	42	2		
	6.5			4	45	4	4			
	6		16	57	2					
	5	44	30	3						
		5	5.5	6	6.5	7	7.5	8	8.5	9
Total		44	46	64	50	36	49	28	7	8
Exact agreement		100%	100%	89%	90%	89%	92%	89%	100%	100%
Within One Block		100%	100%	100%	100%	100%	92%	100%	100%	100%

Table 1.10 Comparative results with new device (CYBOW R-50S) and Predicate device of urinary Specific Gravity.

SG(Site A)		Predicate device							
New device	1.030								23
	1.025						1	27	3
	1.020					2	59		
	1.015				3	37	2		
	1.010			4	41	3			
	1.005			26	4				
	1.000	18	2						
		1.000	1.005	1.010	1.015	1.020	1.025	1.030	
Total		18	32	48	42	62	27	26	
Exact Agreement		100%	81%	85%	88%	95%	100%	88%	
Within One Block		100%	100%	100%	100%	100%	100%	100%	

SG(Site B)		Predicate device							
New device	1.030							2	31
	1.025						2	23	1
	1.020					3	44	1	
	1.015				5	29	3		
	1.010			2	57	2			
	1.005	3	40	7					
	1.000	25							
		1.000	1.005	1.010	1.015	1.020	1.025	1.030	

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Total	28	42	69	34	49	26	32
Exact agreement	89%	95%	83%	85%	90%	88%	97%
Within One Block	100%	100%	100%	100%	100%	100%	100%

SG(Site C)		Predicate device						
New device	1.030						2	31
	1.025					2	39	1
	1.020				4	66	3	
	1.015			3	65	1		
	1.010		4	40	3			
	1.005	3	43	5				
	1.000	15	2					
		1.000	1.005	1.010	1.015	1.020	1.025	1.030
Total	18	49	48	72	69	44	32	
Exact agreement	83%	88%	83%	90%	96%	89%	97%	
Within One Block	100%	100%	100%	100%	100%	100%	100%	

7. Conclusion

A comparison results between CYBOW R-50S and predicative device revealed a very high concordance of between 80-100%.