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**APPROVED**

# Clinical Test Report


of

## **DUS10 (Urine Reagent Strips)**

Effective Date: April. 13. 2010

**DFI Lab**

Dong-Ai Hospital Medical Center: Clinical Pathology

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

Two independent laboratory evaluations of the New Device and Predicate Device were conducted. Clinical evaluation was performed at Dong-Ai Hospital (Site A, sample number: 198samples) for 20days.

The study consisted of performance of three manufactured lots of DUS 10 Strips compared with the marketed product Bayer Multistix 10SG.

New Device (DUS 10 Strip) Lot No: 100219(Exp date: 2012-01), 100225(Exp date: 2012-01), 100302(Exp date: 2012-02)

Predicate Device (Multistix 10SG) Lot No: 9A12D (Exp date: 2010-07), 9F18C (Exp date: 2010-12)

Fresh urine samples were obtained at the medical facility. Fresh urine sample (spontaneous urine was used and processed within 4 hours, not-centrifuged urine, free of detergent, not spiked) of patient’s population was reacted with **the DFI’s new device (DUS 10 Strips) and results of these each reading were compared to results measured with predicate device (Multistix 10SG Strips) by the same analyzer (CLINITEK Status) and (CLINITEK 500).**

***Analysis and Results:*** Table of results from the new device (y-axis) versus predicate device (x-axis), including all of the data points. The analytical method used the **Concordant Result (%) between Predicate device(Multistix 10SG Strips) and new device(DUS 10 Strips) by CLINITEK Urine Analyzers(CLINITEK Status, CLINITEK 500).**

***The results are listed in the table below.***


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Table 1 Comparative results with new device and Predicate device of urinary Urobilinogen.

8				
4				
2				
0.1-1	198			
	0.1-1	2	4	8
predicate device				

#### CLINITEK Status

##### DUS 10 vs MultiStix 10SG

Results on	100%
Concordant line	
Specificity	100%
Sensitivity	100%

8				
4	1			
2				
0.1-1	197			
	0.1-1	2	4	8
predicate device				

#### CLINITEK 500

##### DUS 10 vs MultiStix 10SG

Results on	99%
Concordant line	
Specificity	100%
Sensitivity	100%

Table 2 Comparative results with new device and Predicate device of urinary Glucose.

2000						
1000				1	2	
500				6		
250			2	1		
100		6				
NEG	180					
	NEG	100	250	500	1000	2000
predicate device						

#### CLINITEK Status

##### DUS 10 vs MultiStix 10SG

Results on	98.9%
Concordant line	
Specificity	100%
Sensitivity	100%


2000						
1000					3	
500				3		
250			4	2		
100		5				
NEG	181					
	NEG	100	250	500	1000	2000
predicate device						

#### CLINITEK 500

##### DUS 10 vs MultiStix 10SG

Results on	98.9%
Concordant line	
Specificity	100%
Sensitivity	100%

Table3 Comparative results with new device and Predicate device of urinary Bilirubin.

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3+				
2+				
1+	1	5	1	
NEG	190	1		
	NEG	1+	2+	3+
predicate device				

#### CLINITEK Status

##### DUS 10 vs MultiStix 10SG

Results on	
Concordant line	98%
Specificity	99%
Sensitivity	86%

3+				
2+		1		
1+		4	1	
NEG	191	1		
	NEG	1+	2+	3+
predicate device				

#### CLINITEK 500

##### DUS 10 vs MultiStix 10SG

Results on	
Concordant line	98%
Specificity	100%
Sensitivity	86%

Table 4 Comparative results with new device and Predicate device of urinary Ketones.

160						
80						
40					1	
15			1			
5		9	1			
NEG	184	2				
	NEG	5	15	40	80	160
predicate device						

#### CLINITEK Status

##### DUS 10 vs MultiStix 10SG

Results on	
Concordant line	98%
Specificity	100%
Sensitivity	86%


160						
80						
40					1	
15			2			
5		9				
NEG	184	2				
	NEG	5	15	40	80	160
predicate device						

#### CLINITEK 500

##### DUS 10 vs MultiStix 10SG

Results on	
Concordant line	98%
Specificity	98%
Sensitivity	86%

Table 5 Comparative results with new device and Predicate device of urinary Specific Gravity.

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1.030					5	13	24
1.025				1	25	32	1
1.020				21	27	1	1
1.015			7	26	3		
1.010			5	2			
1.005		2	2				
1.000							
	1.000	1.005	1.010	1.015	1.020	1.025	1.030
predicate device							

**CLINITEK Status**  
DUS 10 vs MultiStix 10SG  
  
±1 degree  
included 90%  
concordant


1.030						13	42
1.025					16	27	2
1.020			7	11	19	1	
1.015			11	26			
1.010		4	12	4			
1.005		3					
1.000							
	1.000	1.005	1.010	1.015	1.020	1.025	1.030
predicate device							

**CLINITEK 500**  
DUS 10 vs MultiStix 10SG  
  
±1 degree  
included 90%  
concordant

Table 6 Comparative results with new device and Predicate device of urinary Blood.

250				2	3	
80			3	2		
25	1	1	2			
trace	8	16				
NEG	155	5				
	NEG	10	25	80	200	
predicate device						

**CLINITEK Status**  
DUS 10 vs MultiStix 10SG  
  
Results on 90%  
Concordant line  
Specificity 95%  
Sensitivity 85%

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250				1	3	
80				2		
25		2	5	1		
trace	4	6				
NEG	174					
	NEG	10	25	80	200	
predicate device						

### CLINITEK 500

DUS 10 vs MultiStix 10SG

Results on  
Concordant line 96%

Specificity 98%

Sensitivity 100%

Table 7 Comparative results with new device and Predicate device of urinary pH.

9								1	
8.5								5	
8						2			
7.5					4	8	1	1	
7		1		5	33	3			
6.5		1	9	12	3				
6	1	24	25	6	1				
5.5	15	33	3	1					
5									
	5	5.5	6	6.5	7	7.5	8	8.5	9
predicate device									

### CLINITEK Status

DUS 10 vs MultiStix 10SG

±1 degree  
included 97%

concordant

9								1	
8.5								1	
8						3	3	1	
7.5					5	12	3		
7			2	3	19	3			
6.5			5	25	3				
6		19	80	4	3				
5.5		2	1						
5									
	5	5.5	6	6.5	7	7.5	8	8.5	9
predicate device									


### CLINITEK 500

DUS 10 vs MultiStix 10SG

±1 degree  
included 97%

concordant

Table 8 Comparative results with new device and Predicate device of urinary Protein.

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4+						
3+					2	
2+			1	2	1	
1+		6	6	2		
trace	5	12	1			
NEG	158	3				
	NEG	+/-	1+	2+	3+	4+
predicate device						

### CLINITEK Status

#### DUS 10 vs MultiStix 10SG

Results on	90%
Concordant line	
Specificity	97%
Sensitivity	92%

4+						
3+						
2+				2	1	
1+			1	2		
trace	8	5	1			
NEG	176	2				
	NEG	+/-	1+	2+	3+	4+
predicate device						

### CLINITEK 500

#### DUS 10 vs MultiStix 10SG

Results on	93%
Concordant line	
Specificity	96%
Sensitivity	86%

Table 9 Comparative results with new device and Predicate device of urinary Nitrite.

Pos			10	
+/-				
NEG	187		1	
	NEG	+/-	Pos	
predicate device				

### CLINITEK Status

#### DUS 10 vs MultiStix 10SG

Results on	99%
Concordant line	
Specificity	100%
Sensitivity	91%


Pos			13	
+/-				
NEG	184		1	
	NEG	+/-	Pos	
predicate device				

### CLINITEK 500

#### DUS 10 vs MultiStix 10SG

Results on	99%
Concordant line	
Specificity	100%
Sensitivity	93%

Table 10 Comparative results with new device and Predicate device of urinary Leukocytes.

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500						
125						
70				1	1	
trace	1	8	1			
NEG	184	2				
	NEG	15	70	125	500	
predicate device						

### CLINITEK Status

#### DUS 10 vs MultiStix 10SG

Results on  
Concordant line 97%

Specificity 99%

Sensitivity 85%

500						
125						
70			5	2		
trace	1	25	2			
NEG	158	5				
	NEG	15	70	125	500	
predicate device						

### CLINITEK 500

#### DUS 10 vs MultiStix 10SG

Results on  
Concordant line 95%

Specificity 99%

Sensitivity 87%

### Conclusion:

The numbers in the shaded areas of the diagonals represent identical results, i.e. direct concordance within the blocks. The majority of analysis display 90-100 % concordance over all blocks on comparing the results of primary diagnosis (except PH, SG). When the results, which fall between neighbouring blocks, are taken into account, concordance increases to around 90-100%.

The DUS 10 Strips enables in the hospital laboratory, hospital ward, or medical practice to make use the advantages of instrumental urinalysis.