

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: The evaluation was performed at a University Hospital (Sample number: 180 samples).
- 2) Start date: 2013/12/01
- 3) Completion date: 2013/12/27
- 4) Test Strip (INSIGHT MS2) Lot No: 131101, 130930, 131115
 Predicative Device
 Microalbustix (SIEMENS/Lot No: 304097/ Exp Date: 2014-10)
 MICRAL TEST (Roche /Lot No: 30314501/Exp Date: 2015-02)

3. Test procedure

- 1) Independent clinical evaluations of the INSIGHT MS2 were conducted. Sample number: 180 samples.
- 2) Testing was performed by professionals at clinical site.
- 3) Fresh urine samples (spontaneous urine was processed within 4 hours, no centrifugation, free of detergent, not spiked) of patient's population were analysed with the Test Strips and results were read visually.
- 4) Reagent areas on the strips were compared with corresponding colour charts on the containers. Colours falling between two colour pads were read as lower of the two values as per hospital procedures.

4. Interpretation of Test Results

Microalbumin Concentration

Conc. (mg/L)	10	30	80	150
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Creatinine Concentration

Conc. (mg/dL)	10	50	100	200	300
Conc. (g/L)	0.1	0.5	1.0	2.0	3.0
Conc. (mmol/L)	0.9	4.4	8.8	17.7	26.5

Microalbumin/Creatinine ratio

	Normal	Abnormal	High Abnormal
Conc. (mg/g)	<30	30-300	>300
Conc. (mg/mmol)	<3.4	3.4 –33.9	>33.9

CALCULATIONS:

Determine Microalbumin / Creatinine Ratio as follows:

Microalbumin/Creatinine Ratio

= Microalbumin Result (mg/L) / Creatinine Result (g/L)

= mg Albumin / g Creatinine

(Example)

Microalbumin Result = 30 mg/L

Creatinine result = 200 mg/dL = 2 g/L

Microalbumin /Creatinine Ratio = 30(mg/L)/2(g/L). Result < 30 mg/g (Normal)

Microalbumin testing (mg/L)	Creatinine testing(g/L)				
	0.1	0.5	1.0	2.0	3.0
10	Re-analysis	Normal	Normal	Normal	Normal
30	High abnormal	Abnormal	Abnormal	Normal	Normal
80	High Abnormal	Abnormal	Abnormal	Abnormal	Normal
150	High Abnormal	High abnormal	Abnormal	Abnormal	Abnormal

5. Acceptance Criteria

The comparison results should be over more than 90% concordance rate.

6. Result

1) The comparison result of Microalbumin strips by Visual analysis

1-1) The comparison result of Microalbumin strips (INSIGHT MS2 VS MICRAL TEST)

INSIGHT MS2 - mg/L	150mg/L			5	24	% concordance 93.9%
	80mg/L		4	46	4	
	30mg/L		49	10		
	10mg/L	36	2			
		NEG	20mg/L	50mg/L	100mg/L	
	MICRAL TEST(Roche) – mg/L					

1-2) The comparison result of Microalbumin strips (Microalbustix VS MICRAL TEST)

Microalbustix (SIEMENS) -mg/L	150mg/L			4	21	% concordance 95.5%
	80mg/L		2	48	7	
	30mg/L		51	9		
	10mg/L	36	2			
		NEG	20mg/L	50mg/L	100mg/L	
	MICRAL TEST(Roche) –mg/L					

1-3) The comparison result of Microalbumin strips (INSIGHT MS2 VS Microalbustix)

INSIGHT MS2 - mg/L	150mg/L			6	23	% concordance 90.5%
	80mg/L		4	48	2	
	30mg/L	1	55	3		
	10mg/L	37	1			
		10mg/L	20mg/L	50mg/L	100mg/L	
	Microalbustix (SIEMENS)–mg/L					

2) The comparison result of Creatinine strips (INSIGHT MS2 VS Microalbustix)

INSIGHT MS2 - mg/dL	>300				3	35	% concordance 92.2%
	200			2	52	2	
	100		2	31	1		
	50	1	32	3			
	10	16					
		10	50	100	200	300	
	Microalbustix (SIEMENS)-mg/dL						

3) The Comparison result of Microalbumin/Creatinine Ratio(INSIGHT MS2 VS Microalbustix)

INSIGHT MS2 (Microalbumin /Creatinine Ratio - mg/g)	>300		5	42	% concordance 94.4%
	30-300	2	80	3	
	<30	48			
		<30	30-300	>300	
		Normal	Abnormal	High Abnormal	
Microalbustix (SIEMENS)- Microalbumin/Creatinine Ratio - mg/g					

7. Conclusion

Comparison results between INSIGHT MS2 and Microalbustix (SIEMENS) revealed a very high concordance (90-95%). The evaluation was performed with 180 urine samples over 20 days. The comparison results between INSIGHT MS2 and Microalbustix (SIEMENS) show agreement above 90%.

	% concordance rate
Microalbumin Comparison (INSIGHT MS2 VS MICRAL TEST (Roche))	93.9%
Microalbumin Comparison (INSIGHT MS2 VS Microalbustix)	90.5%
Creatinine Comparison (INSIGHT MS2 VS Microalbustix)	92.2%
Microalbumin/Creatinine Ratio Comparison (INSIGHT MS2 VS Microalbustix)	94.4%