Comparative Evaluation of SURESIGN ® Professional Urine Analyser at Point of Care

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Introduction:

Point of Care urinalysis needs to be reliable, accurate and rapid to enable clinical results to be appropriately utilised in patient care. Semi-quantitative analysis of urines using dipstick technology can reduce the number of urines sent for central laboratory testing by screening but positive results on a single sample are not diagnostic and should be confirmed in the laboratory. Variability in specimen quality and interferents that may affect colour production or readability must be considered in interpretation.

Existing Siemens/Bayer Clinitek Status+® analysers using Multistix 10SG® strips were compared to the SURESIGN® Professional urine analyser and SURESIGN® 10U strips. Siemens Multistix 10SG® strips are used extensively within the Trust both in low use areas (manual analyses) and higher throughput areas including the diabetic clinic where analysers are required to facilitate faster result production and to reduce manual process and colour perception errors. SURESIGN® Professional urine analyser and SURESIGN® 10U strips are new products for professional usage and offer the same parameter choice as the in-use method.

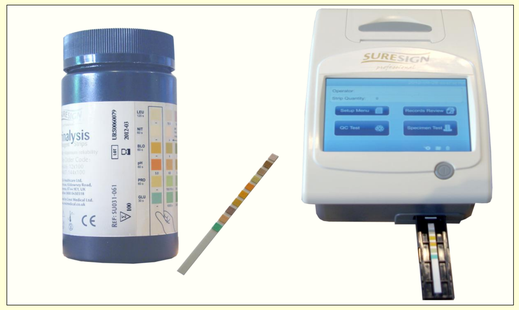
The main objective was to compare strip and analyser features, performance and user feedback.

Method:

Features of strips, equipment, processing/analysis, supportive documentation and strip packaging were compared to the existing (reference) methods and equipment.

42 redundant urine samples were analysed in clinic by clinic staff on day of clinic, within 2 hrs of voiding. 158 redundant random urine samples were analysed within 1 day of receipt into laboratory (usual requirement of testing with dipstick is within 2hrs of voiding). 2 EQA distribution samples were analysed alongside the other urines.

Feedback forms relating to ease of use, design, features and comparability were completed by clinic users.



Results:

Both manufacturers containers have clear user instructions, and labeling inclusive of lot number , expiration date, printed times for recording results and colour chart for result interpretation when manual testing. Users preferred vertical chart orientation on SURESIGN® container.

Documented system operating temperature of SURESIGN® wider than Siemens (0-40°C vs. 22-26°C). Overall preference varied between users but all preferred colour screens and flags present on SURESIGN® analyser. All perceived and preferred SURESIGN® quicker processing time (75s vs. 80s). Quality Controls analysed were all within documented acceptable limits.

All strip analyses were performed simultaneously once any sediment present had settled. SURESIGN® results were compared to the reference method (Siemens), and where discrepancies occurred assay cut off points and ranges were checked. Trust protocol states laboratory confirmation required if dipstick is positive for blood, protein, nitrites or leucocytes unless otherwise clinically indicated. 1 pH result was greater than one unit difference (pH5 vs. pH9). 23 urines using the SURESIGN® system would not have required laboratory confirmation in comparison to the reference. 11*** nitrite result discrepancies (neg vs. pos) may have been close to the limit of detection on both systems and would require investigation into clinical results for further comparison.

There were no significant discrepancies between EQA results obtained from either system.

Total Discrepancies (SURESIGN® vs. Siemens)			Between nominal values or range/sample** related		SURESIGN® vs. Siemens			
					Fewer samples for confirmation		Marked discrepancy/dependant upon clinical presentation	
N	%	Analyte	N	%	N	%	N	%
17	8.5	GLU	15	7.5	-	-	2	1
41	20.5	BIL	33	16.5	-	-	8	4
19	9.5	KET	13	6.5	-	-	6	3
81	40.5	SG	81	40.5	-	-	0	0
46	23	BLO/BLD*	19	9.5	5	2.5	22	11
98	49	pH	97	48.5	-	-	1 (pH5 vs pH9)	0.5
38	19	PRO*	14	7	4	2	20 [13 (+/- vs -) , 7 (- vs +/-)]	10
200	100	URO/UBG	200	100	-	-	0	0
11	5.5	NIT*	11***	5.5	11	5.5	11	5.5

* If positive result obtained should be sent for confirmation, ** colour, clarity/turbidity, *** close to limit of detection

Tests Codes and Availability		
SURESIGN® 10U	Siemens Multistix 10SG®	Test
GLU	GLU	Glucose
BIL	BIL	Bilirubin
KET	KET	Ketone
SG	SG	Specific Gravity
BLO	BLD	Blood (Occult)
pH	pH	pH
PRO	PRO	Protein
URO	UBG	Urobilinogen
NIT	NIT	Nitrite
LEU	LEU	Leukocytes
Other SURESIGN® sticks	Other Siemens sticks	Test
ALB	ALB	Albumin
CRE	CRE	Creatinine
A:C	A:C	Ratio-Albumin:Creatinine
P:C	P:C	Ratio-Protein:Creatinine

Conclusion:

The SURESIGN® analyser and 10U strips are suitable for use at the point of care and provide comparable results to the existing reference system. Feedback from users highlighted favourable additional features of the SURESIGN® analyser including colour screen and coloured results flags during analysis. Design of the test table was deemed by users to be more difficult to clean but the strip container was preferred due to vertical orientation of the interpretation chart.

With both systems, variability in specimen analyte concentrations that fall between nominal values of the strip may give results at either level. Where clinically indicated results would need confirming in the laboratory.

Users should be trained in differences between strips to ensure awareness of limits of detection.

The wider system operating temperature range of the SURESIGN® system may offer additional benefits in POC locations with more variable ambient temperatures.

Other additional strips available from SURESIGN® should be compared in further studies to determine specific performance characteristics in relation to other existing systems.