

Urine test strip CombiScreen 5SYS Plus and urine analyser CombiScan 100



Summary of an evaluation under the direction of SKUP Report SKUP/2010/79*

Background

Urine test strips are used as a screening method for early detection of possible diseases such as metabolic disorders, diseases of the kidneys and urogenital tract, and liver and haemolytic diseases. The urine test strip CombiScreen 5SYS Plus and the urine analyser CombiScan 100 are produced by Analyticon Biotechnologies AG and supplied in Scandinavia by Medinor. The system has not been launched onto the Scandinavian market yet. A pre-evaluation of CombiScreen 5SYS Plus and CombiScan 100 was carried out under the direction of SKUP from November 2009 to March 2010. The urine test strip contains test pads for glucose, protein, blood, nitrite and leukocytes.

The aim of the evaluation

The aim of the evaluation of CombiScreen and CombiScan is to

- reflect the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- compare the analytical quality between visual and mechanical reading of CombiScreen 5SYS Plus
- compare the analytical quality with two of the market leading products for urine analysis in Norway:
 - ✓ Clinitek Status+ Analyser (Siemens) with Multistix 8 SG urine test strip
 - ✓ Urisys 1100 Analyser (Roche) with Combur⁵ Test urine test strip
- evaluate the system regarding user-friendliness

Materials and methods

This evaluation is a rating agreement study performed between CombiScreen 5SYS Plus and two of the market leading products in Norway for analysing of urine samples with test strips. The evaluation took place at NOKLUS in Bergen. Urine samples were collected from the laboratory and the emergency care unit at Haralds plass Diaconale Hospital, the Laboratory of Clinical Biochemistry at Haukeland University Hospital and at Volvat Medical Centre in Bergen. The aim was to collect 100 positive urine samples for each of the components leukocytes, protein and nitrite. The samples were stored in the fridge until they were analysed at NOKLUS within 24 hours after sample collection. Two CombiScreen 5SYS Plus test strips, one Combur⁵ Test and one Multistix 8 SG test strip were immersed in each urine sample. Visual reading of CombiScreen 5SYS Plus was carried out before the mechanical reading of a new test strip on CombiScan 100. The three analysers read the urine samples in succession in the following reading order: CombiScan 100, Urisys 1100 and Clinitek Status+. Rating agreement analysis can never give true information about the analytical quality of the instrument. A reasonable use of the agreement data is to interpret the revealed agreement or disagreement as follows: If two raters disagree, at least one of them must be *incorrect*. If the raters agree, the next step should be to document if they are correct. Daily maintenance of the three analysers was carried out prior to starting the daily analysis. The user-friendliness of CombiScan 100 was assessed.

Results

The agreement was good between visual and mechanical reading of CombiScreen 5SYS Plus for the component nitrite with a kappa coefficient (κ) $>0,8$. The agreement was acceptable¹ for the components glucose, protein and blood with $\kappa \geq 0,6$. There was a disagreement between visual and mechanical reading for the component leukocytes. The κ_{\max} score for leukocytes of 0,64 verifies that there was an underlying bias between visual and mechanical reading for this component.

The agreement was good between CombiScan 100 and Clinitek Status+ for the components glucose, leukocytes and nitrite with $\kappa > 0,8$. The agreement was acceptable for the component blood.

When CombiScan 100 was compared to Urisys 1100, nitrite showed good agreement and glucose showed an acceptable agreement. For the components blood and leukocytes the κ_{\max} score was 0,68 and 0,76 respectively, and verifies that there was a discrepancy between CombiScan 100 and Urisys 1100 for these two components.

For the component protein a low κ and κ_{\max} score indicate a disagreement between all three urine analyzers. The results must be compared to a quantitative method for determination of protein in urine to find which method that lies closest to the true value.

The different agreement of CombiScan 100 and the two comparison methods is caused by a certain deviation between the two comparison methods.

The CombiScan system was regarded as user-friendly.

Conclusion

Visual and mechanical reading of CombiScreen 5SYS Plus: The agreement was good for the component nitrite, and acceptable for the components glucose, protein and blood. There was a disagreement for the component leukocytes.

A certain deviation between the two comparison methods was observed during the evaluation, most pronounced for the component protein. This explains a different agreement between CombiScan 100 and the two comparison methods in this evaluation.

Comparison with Clinitek Status+: The agreement was good for the components glucose, leukocytes and nitrite, and acceptable for the component blood. There was a disagreement for the component protein.

Comparison with Urisys 1100: The agreement was good for the component nitrite and acceptable for the component glucose. There was a disagreement for the components blood, leukocytes and protein.

User-friendliness: The CombiScan system was regarded as user-friendly.

Comments from Analyticon

A letter with comments from Analyticon Biotechnologies AG is attached to the report.

The complete report is found at www.skup.nu.

¹ Kappa coefficients between 0,60 and 0,80 were described as acceptable. Agreement in this intermediate category is neither good nor bad.