

# Urine test strip Medi-Test URYXXON Stick 10 and urine analyser URYXXON Relax



## Summary of an evaluation under the direction of SKUP Report SKUP/2010/82\*

### 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 Medi-Test Uryxxon Stick 10 and the urine analyser Uryxxon Relax are produced by Macherey-Nagel and supplied in Scandinavia by Medic24. The system has not been launched onto the Scandinavian market yet. A pre-evaluation of Medi-Test Uryxxon Stick 10 and Uryxxon Relax was carried out under the direction of SKUP from November 2009 to March 2010. The urine test strip contains test pads for blood, urobilinogen, bilirubin, protein, nitrite, ketons, glucose, pH, density and leukocytes. The five components glucose, protein, blood, nitrite and leukocytes are evaluated by SKUP.

### The aim of the evaluation

The aim of the evaluation of Medi-Test Uryxxon Stick 10 and Uryxxon Relax 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 Medi-Test Uryxxon Stick 10
- compare the analytical quality with two mechanical procedures for urine analysis:
  - ✓ Clinitek Status+ Analyser (Siemens) with Multistix 8 SG urine test strip
  - ✓ Urisys 1100 Analyser (Roche) with Combur<sup>5</sup> Test urine test strip
- evaluate the system regarding user-friendliness

### Materials and methods

This evaluation is a rating agreement study between Medi-Test Uryxxon Stick 10 and two similar methods for analysing 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 Medi-Test Uryxxon Stick 10 test strips, one Combur<sup>5</sup> Test and one Multistix 8 SG test strip were immersed in each urine sample. Visual reading of Medi-Test Uryxxon Stick 10 was carried out before the mechanical reading of a new test strip on Uryxxon Relax. The three analysers read the urine samples in succession in the following reading order: Uryxxon Relax, 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 Uryxxon Relax was assessed.

## Results

The agreement was good between visual and mechanical reading of Medi-Test Uryxxon Stick 10 for the component glucose and nitrite with a kappa coefficient ( $\kappa$ ) $>0,8$ . The agreement was acceptable<sup>1</sup> for the components protein, blood and leukocytes with  $\kappa \geq 0,6$ .

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

When Uryxxon Relax was compared to Urisys 1100 glucose, leukocytes and nitrite showed good agreement. For the components protein and blood the  $\kappa_{\max}$  score was 0,44 and 0,57 respectively, and verifies that there was a discrepancy between Uryxxon Relax and Urisys 1100 for these two components.

Regarding the component protein Uryxxon Relax gave an overestimation of positive readings in proportion to Urisys 1100, and an underestimation in proportion to Clinitek Status+. 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 Uryxxon Relax system was regarded as user-friendly.

## Conclusion

*Visual and mechanical reading of Medi-Test Uryxxon Stick 10:* The agreement was good for the components glucose and nitrite, and acceptable for the components protein, blood and leukocytes. *Comparison with Clinitek Status+:* The agreement was good for the components glucose, blood, leukocytes and nitrite, and acceptable for the component protein.

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

*User-friendliness:* The Uryxxon Relax system was regarded as user-friendly.

## Comments from Macherey-Nagel

A letter with comments from Macherey-Nagel is attached to the report.

The complete report is found at [www.skup.nu](http://www.skup.nu).

---

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