# Medi-Test URYXXON Stick 10 and URYXXON Relax

A urine test strip and urine analyser
from Macherey-Nagel GmBH & Co. KG

**Report from a premarketing evaluation**
**organised by SKUP**

The evaluation was ordered by Medic24, Norway

SKUP/2010/82*

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# The organisation of SKUP

*Scandinavian evaluation of laboratory equipment for primary health care, SKUP*, is a co-operative commitment of NOKLUS[1] in Norway, DAK-E[2] in Denmark, and EQUALIS[3] in Sweden. SKUP was established in 1997 at the initiative of laboratory medicine professionals in the three countries. SKUP is led by a Scandinavian *steering committee* and the secretariat is located at NOKLUS in Bergen, Norway.

*The purpose of* SKUP is to improve the quality of near patient testing in Scandinavia by providing objective and supplier-independent information on analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP *evaluations*.

SKUP offers manufacturers and suppliers evaluations of equipment for primary healthcare and also of devices for self-monitoring. Provided the equipment is not launched onto the Scandinavian market, it is possible to have a confidential pre-marketing evaluation. The company requesting the evaluation pays the actual testing costs and receives in return an impartial evaluation.

There are *general guidelines* for all SKUP evaluations and for each evaluation a specific *SKUP protocol* is worked out in co-operation with the manufacturer or their representatives. SKUP signs *contracts* with the requesting company and the evaluating laboratories. A *complete evaluation* requires one part performed by experienced laboratory personnel as well as one part performed by the intended users.

Each evaluation is presented in a *SKUP report* to which a unique *report code* is assigned. The code is composed of the acronym SKUP, the year and a serial number. A report code, followed by an asterisk (*), indicates a special evaluation, not complete according to the guidelines, e.g. the part performed by the intended users was not included in the protocol. If suppliers use the SKUP name in marketing, they have to refer to www.skup.nu and to the report code in question. For this purpose the company can use a logotype available from SKUP containing the report code.

SKUP reports are published at www.skup.nu

[1] NOKLUS (Norwegian Quality Improvement of Primary Care Laboratories) is an organisation founded by Kvalitetsforbedringsfond III (Quality Improvement Fund III), which is established by The Norwegian Medical Association and the Norwegian Government. NOKLUS is professionally linked to “Seksjon for Allmennmedisin” (Section for General Practice) at the University of Bergen, Norway.

[2] SKUP in Denmark is placed in Hillerød Hospital. SKUP in Denmark reports to DAK-E (Danish Quality Unit of General Practice), an organisation that is supported by KIF (Foundation for Quality and Informatics) and Faglig udvalg (Professional Committee), which both are supported by DR (The Danish Regions) and PLO (The Organisation of General Practitioners in Denmark).

[3] EQUALIS AB (External quality assurance in laboratory medicine in Sweden) is a limited company in Uppsala, Sweden, owned by “Sveriges Kommuner och Landsting” (Swedish Association of Local Authorities and Regions), “Svenska Läkaresällskapet” (Swedish Society of Medicine) and IBL (Swedish Institute of Biomedical Laboratory Science).

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A detailed list of previous SKUP evaluations is included in the attachments.

The report is written by
SKUP in Norway,
May 2010

# 1. Summary

**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$^{5}$ 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 Haraldsplass 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$^{5}$ 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[4] 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 Realx system was regarded as user-friendly.

**Comments from Macherey-Nagel**
A letter with comments from Macherey-Nagel is attached to the report. Please see attachment 9.

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

# 2. Analytical quality goals

Qualitative and semi-quantitative measurements are often expressed as categorical data and can be read on the ordinal scale; an example of this is the reading of urine test strips in arbitrary units. When comparing methods read on the ordinal scale, it is practical to use Concordance analysis with Kappa statistics [1] [2]. The aim of the model is to decide on the agreement between two or more ordinal scale categories based on contingency tables of two or more classes (e.g. 2 x 2, 3 x 3 tables, etc.). In the majority of cases, the diagonal in the tables will represent correlated/corresponding observations between the methods. For more details about Kappa statistics, se chapter 4 “Statistical expressions and calculations”.

Requirements set for the assessment of the Kappa value are based on the fact that semi-quantitative studies will classify more than half of the cases not due to chance as correct [1].

Analytical quality specifications expressed as Cohen’s Kappa coefficient (κ).

| | **Optimum** | **Minimum** |
|---|---|---|
| **Simple κ coefficient** | >0.8 | >0.6 |

The quality specifications are based on common sense: any clinical laboratory examination should classify more than half of the non-random cases correctly. Arbitrarily, this is equivalent to κ>0,6, although optimally the value should be >0,8 if achievable.

The Kappa coefficient will be provided with a 95% confidence interval, calculated using the standard error of κ.

# 3. Materials and methods

## 3.1. Medi-Test Uryxxon Stick 10 and Uryxxon Relax

### 3.1.1. Medi-Test Uryxxon Stick 10 urine test strip


The Medi-Test Uryxxon Stick 10 urine test strip used in this evaluation is produced by Macherey-Nagel, and contains test pads for blood, urobilinogen, bilirubin, protein, nitrite, ketons, glucose, pH, density and leukocytes. The components glucose, protein, blood, nitrite and leukocytes are evaluated by SKUP. The test pads for blood and glucose have a protection against interferences caused by ascorbic acid. The urine test strips should be stored in the test strip box at temperatures between 4 and 30°C and have a shelf life that equates to the expiry date specified on the box. The test strips can be used for visual readings or for mechanised reflectance-photometric evaluations. Immersion time in urine is approximately one second. The urine test strip should be read after 30 - 60 seconds for glucose, protein, blood and nitrite, and after 60 - 120 seconds for leukocytes.

<u>The principle for the test pads on the Medi-Test Uryxxon Stick test strip:</u>

*Glucose*

Detection of glucose in the urine is based on a glucose oxidase (GOD) - peroxidase (POD) - chromogen reaction (green to bluish green colour reaction). A yellow or greenish test pad should be considered negative or normal.

$$\text{Glucose} + O_2 \xrightarrow{\text{GOD}} \text{Gluconolactone} + H_2O_2$$

$$\text{Chromogen} + H_2O_2 \xrightarrow{\text{POD}} H_2O + \text{dye}$$

*Protein*

The test pad reacts particularly sensitively to albumin. The test is based on the "protein error" principle of the indicator that changes colour from yellow to greenish blue. The test strip detects values above 10 mg protein/dL urine.

$$\text{Indicator dye (yellow)} \xrightarrow[-H^+]{\text{Protein}} \text{Indicator dye anion (green)}$$

*Blood*

This test is based on the pseudoperoxidative activity of haemoglobin and myoglobin, which catalyzes the oxidation of an indicator by an organic hydroperoxide producing an green colour.

$$\text{Organic Hydroperoxide} + \text{Haemoglobin} + \text{Chromoge} \longrightarrow \text{Organic Hydroxy compound} + \text{dye}$$

*Leukocytes*

Detection of leukocytes is based on the activity of esterase from granulocytes which gives a violet colour reaction on the test pad.

$$\text{Indoxylester} \xrightarrow{\text{Esterase}} \text{Indoxyl}$$

$$\text{Indoxyl} + \text{diazonium salt} \longrightarrow \text{dye (violet)}$$

*Nitrite*
Nitrite detection is specific for detecting bacteriuria caused by microorganisms which are able to reduce nitrate to nitrite. The detection limit for nitrite at Medi-Test Uryxxon urine test strip is given at approximately 0,05 mg/dL. This test is based on the Griess reaction (pink colour reaction). Any degree of pink coloration indicates a bacterial infection of the urinary tract.

$$\text{Nitrate} \xrightarrow{\text{Bacterial reduction in urine}} \text{nitrite}$$

$$\text{Nitrite} + \text{aromatic amine} \xrightarrow{H^+} \text{diazonium salt}$$

$$\text{diazonium salt} + \text{coupling components} \longrightarrow \text{Azo dye (red)}$$

When checking for nitrite, the sample must be the first morning urine, or the urine should have been in the bladder for a minimum of four hours before taking the sample. We disregarded this guideline in the evaluation because we did not search for the "true" patient result, but assessed the agreement between the different types of urine test strips. The detection limit for nitrite is given at 0,05 mg/dL (11 µmol/L) for the comparison method Combur[5] Test (Roche) and 0,06 mg/dL for Multistix 8 SG (Siemens).

### 3.1.2. Uryxxon Relax Urine Analyser

The Uryxxon Relax Analyser is a semi-automated system and the measurement principle is reflectance photometry. The Uryxxon Relax can carry out 50 tests per hour as the test strip is incubated in the analyser before it is read. The analyser can store 200 test results including name or patient ID, and the last 20 QC measurements are stored in a separate memory. All user inputs are made via the touch screen display. When a test strip is placed on the strip holder, the instrument automatically detects the test strip and starts the measurement. The results can be transferred to a PC via the analyser's interface. The analyser can be operated with type AA batteries independent of the main supply.
More facts about the system are shown in attachment 1.

### 3.1.3. Product information

For manufacturer of the system and suppliers in the Scandinavian countries, see attachment 1.

*URYXXON Relax*
Serial no. UR2081-0609

*Medi-Test URYXXON Stick 10*
Lot A, lot no. 68940 Exp. 2011/10
Lot B, lot no. 689361 Exp. 2011/09
Lot C, lot no. 68924 Exp. 2011/07

*Medi-Test Control (level 1 & 2)*
Lot no. 400099 Exp. 2010/10

## 3.2. Designated comparison method

A designated comparison method is a fully specified method which, in the absence of a Reference method, serves as the common basis for the comparison of a field method.

### 3.2.1. The comparison methods in this evaluation

An agreement study is an indirect attempt to validate a new rating system or instrument. Because of the lack of a definitive criterion variable or "gold standard", and lack of an accessible designated comparison method, the accuracy of the new system is assessed by comparing its results with results from similar raters. In this evaluation it was decided to compare the Uryxxon Relax system with two established and approved methods for mechanical reading of urine samples in Norway.

*Multistix 8 SG urine test strip and Clinitek Status+ Analyser*
The urine test strip and the analyser are manufactured by Siemens. The test strip contains test pads for glucose, protein, blood, nitrite, leukocytes, pH, specific gravity and ketones. Specific gravity, pH and ketones are not part of the evaluation. The test principles for the test pads included in the evaluation, are the same as those for Medi-Test or similar. Maximum immersion time in urine is approximately one second. The measurement principle in Clinitek Status+ is reflectance photometry.

*Combur$^{5}$ Test urine test strip and Urisys 1100 Analyser*
The urine test strip and the analyser are manufactured by Roche. The test strip contains test pads for glucose, protein, blood, nitrite and leukocytes. The test principles are the same as those for Medi-Test or similar. Maximum immersion time in urine is approximately one second. The measurement principle in the Urisys 1100 is reflectance photometry.

### 3.2.2. Verification of the analytical quality of the comparison methods

Daily maintenance of Urisys 1100 and Clinitek Status+ was carried out prior to starting the daily analysis. At start-up, an automatic optical test is carried out on both analysers. Afterwards analysis of the manufacturers' urine control solutions at two levels was carried out. The results were entered on a separate form, see chapter 5.1.

### 3.2.3. Product information, the comparison methods

*Analyser*

| | | | |
|---|---|---|---|
| Roche: | Urisys 1100 | Serial no. UX09623814 | |
| Siemens: | Clinitek Status+ | Serial no. 200265 | |

*Urine test strip*

| | | | |
|---|---|---|---|
| Roche: | Combur$^{5}$ Test | Lot no. 23052245 | Exp. 2010/11 |
| Siemens: | Multistix 8 SG | Lot no. 9G25C | Exp. 2011/01 |
| | | Lot no. 9J11DC | Exp. 2011/02 |

*Internal quality control*
Quantimetrix the Dipper, Urine dipstick control 1&2 (used for the Roche system)
Lot no. 44490K Exp. 2010/08
Siemens Chek-Stix Combo Pak Control +/-
Lot no. C0071079E Exp. 2011/01

## 3.3. Planning of the evaluation

*Background for the evaluation*

Medi-Test URYXXON test strips are used as a screening method for the early detection of possible diseases such as metabolic disorders, diseases of the kidneys and urogenital tract, and liver and haemolytic diseases. The test strips can be used for mechanised reflectance-photometric evaluations. Urine test strips are routinely used in primary healthcare centres, in hospital laboratories and for bedside testing. The Medi-Test URYXXON Stick 10 and URYXXON Relax is produced by Macherey-Nagel and supplied in Scandinavia by Medic24. The system has not been launched onto the Scandinavian market yet. Medic24 in Norway turned to SKUP in November 2009 for an enquiry about a pre-evaluation of Medi-Test URYXXON urine test strip and the URYXXON Relax urine analyser. They wanted an assessment of the analytical quality of the urine test strip. Two approved mechanical methods for urine analysis, the systems from Roche and Siemens, were selected to be the comparison methods.

*Contract, protocol and arrangements*

SKUP made a proposal for an evaluation protocol in November 2009. The protocol was sent to Medic24 and to Niklas Rademacher in Macherey-Nagel for comments. The arrangement for an evaluation was agreed upon, and SKUP offered to start the evaluation in December 2009. The protocol was approved at the end of November and the evaluation contract was signed.

*Preparations and training program*

The preparations for the evaluation started in November 2009. Training in the use of the urine analyser was provided by Macherey-Nagel by means of an internet conference. Grete Monsen and Camilla Eide Jacobsen took part in this conference. SKUP received all the equipment for the evaluation from Macherey-Nagel in November.

*Collection of the urine samples*

The practical work with the evaluation was carried out from November 2009 to March 2010. Urine samples were collected from the laboratory and the emergency care unit at Haraldsplass Diakonale Hospital, the Laboratory of Clinical Biochemistry at Haukeland University Hospital and at Volvat Medical Centre in Bergen. Once the laboratories had analysed the urine samples according to their routine procedures, the samples were stored in the fridge until they were analysed within 24 hours at NOKLUS.

### 3.3.1. Evaluation sites and persons involved

The evaluation took place at NOKLUS in Bergen. Grete Monsen, SKUP, was the contact person and was responsible for the evaluation. Biomedical laboratory scientist, Camilla Eide Jacobsen, was responsible for the practical work. The Laboratory of Clinical Biochemistry and Volvat Medical Centre were contacted by advisory biomedical laboratory scientists Stein Binder and Hilde-Kristin Rondestveit, NOKLUS. Urine samples from these two laboratories were collected by Hilde-Kristin and Stein. Camilla had the responsibility to collect urine samples from the laboratory and the emergency care unit at Haraldsplass Diaconale Hospital. The statistical calculations are done by Camilla Eide Jacobsen, and the report is written by Camilla Eide Jacobsen and Grete Monsen.

## 3.4. The evaluation procedure

### 3.4.1. The model for the evaluation of Medi-test Uryxxon and Uryxxon Relax

*The SKUP evaluation*

The evaluation is carried out under the auspices of SKUP and follows to some extent the fundamental guidelines in the book "*Evaluation of analytical instruments. A guide particularly designed for evaluations of instruments in primary health care*" published by Alma Mater Forlag in autumn 1997 (ISBN 82-419-0230-1) [3].

This evaluation is a rating agreement study. The evaluation of Medi-Test Uryxxon Stick 10 and Uryxxon Relax comprises the assessment of the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a laboratory environment. This includes:

- a comparison between visual and mechanical reading of Medi-Test Uryxxon Stick 10
- a comparison with two mechanical procedures for urine analysis:
    - the Clinitek Status+ Analyser (Siemens) with the Multistix 8 SG urine test strip
    - the Urisys1100 Analyser (Roche) with the Combur$^{5}$ Test urine test strip
- evaluation of user-friendliness

*Training*

Training in the use of the Uryxxon Relax analyser was provided by Macherey-Nagel by means of an internet conference. The biomedical laboratory scientist spent sufficient time familiarising herself with the analyser before the start of the evaluation.

### 3.4.2. Handling of the urine samples and test strips

*Handling of the urine samples*

In the evaluation protocol it was suggested to aim at collecting 100 positive urine samples for each of the components leukocytes, protein and nitrite. To be counted as a positive sample it was enough with a positive reaction on one of the three systems. To achieve results throughout the whole glucose measuring range, it became necessary to produce some urine samples by adding glucose to "normal" urine samples. All urine samples were kept in the fridge at NOKLUS until they were analysed for the evaluation. Storage-time of the urine samples was not critical, since the reading of each sample with the different methods was done consecutively and within 2 minutes. The urine samples were analysed within 24 hours after sample collection, and the samples achieved room temperature and were mixed prior to analysis.

*Handling of the urine test strips*

The urine test strips were kept in the test strip box until they were used. The box was closed immediately after the test strip had been removed. The boxes were stored at room temperature between 20 and 25°C and were used within the expiry date. All instructions in the user's manual and in the package insert were followed closely.

*Immersion of urine test strips in urine*

The immersion time in urine was approximately one second for each of the test strips Medi-Test Uryxxon, Combur$^{5}$ Test and Multistix 8 SG. After the immersion of the test strip in the urine, the strip was held horizontally to avoid reagent contamination. Excess urine on the test strip was removed by touching the side edge of the test strip against a piece of absorbent paper. Some urine

samples were kept in the original containers, and some were transferred to a more practical container for dipping of the test strip. Two Medi-Test Uryxxon test strips, one Combur[5] Test and one Multistix 8 SG test strip were immersed in each urine sample. In addition, a test strip had already been immersed in the urine container at the laboratory where the urine sample was collected. In total, five urine test strips were immersed per urine sample.

*Restrictions on the number of immersions per urine sample*
Bayer states that 10–12 test strips may be immersed in the same urine control solution without this affecting the results and concludes that this also applies to urine samples. When the volume of urine is at least 10 mL, Macherey-Nagel and Roche states that up to ten test strips may be immersed in the sample.

### 3.4.3. Visual reading of urine test strips

Only the Medi-Test Uryxxon urine test strip was read visually. Visual reading was carried out before the mechanical reading with Uryxxon Relax, so that the result of the visual reading was not influenced by the result from the analyser. A stopwatch was used. The reaction time for Medi-Test Uryxxon is 30 - 60 seconds for glucose, protein, blood and nitrite and 60 - 120 seconds for leukocytes. Coloration after 120 seconds was not read. The urine test strip was compared with the colour codes on the test strip box and the results were read in the order shown on the box. The coloration of the test pad was read against the colour code on the test strip box that was closest to the colour in the reaction. The visual evaluation of Medi-Test Uryxxon was performed in a small laboratory with good lighting. The results were recorded on the result form prepared by SKUP.

### 3.4.4. Mechanical reading of urine test strips

The analysers used in the evaluation was the Uryxxon Relax Analyser with the Medi-Test Uryxxon Stick 10 test strip, the Urisys1100 analyser with the Combur[5] Test urine test strip and the Clinitek Status+ Analyser with the Multistix 8 SG urine test strip. All three analysers have built-in printers. The results were recorded on the result form prepared by SKUP and all original printouts were kept.

### 3.4.5. Analysing procedure

The urine sample was brought to room temperature and mixed prior to analysis. The colour of the urine was noted on the result form (clear, pale yellow, yellow, dark yellow or brown). The four urine test strips were read in succession mentioned below. The readings for each sample were carried out within 2 minutes.

- Urine test strip 1: Medi-Test Uryxxon Stick 10, visual reading
- Urine test strip 2: Medi-Test Uryxxon Stick 10, mechanical reading with Uryxxon Relax
- Urine test strip 3: Combur[5] Test, mechanical reading with Urisys 1100
- Urine test strip 4: Multistix 8 SG, mechanical reading with Clinitek Status+

For information about immersion of urine test strips in urine and mechanical reading of urine test strips, see section 3.4.2 and 3.4.4.

### 3.4.6. Maintenance and internal quality control of the analysers

Daily maintenance of all three analysers was carried out prior to starting the daily analysis. Before analysing the Medi-Test control (two levels), an optical test was carried out automatically on the Uryxxon Relax. The results were entered on a separate form. For the two comparison methods, the urine quality controls recommended by the manufacturers were analysed before starting the daily analysis, see section 3.2.2.

### 3.4.7. Registration of results

All results were registered consecutively by the biomedical laboratory scientist carrying out the practical work. A registration form adapted for this evaluation was used (prepared by SKUP). Raw data will be attached to the final report that is sent to Macherey-Nagel and Medic24, but will not be attached to the published report.

### 3.4.8. Evaluation of user-friendliness

Once the practical work was carried out, the user-friendliness of Uryxxon Relax was evaluated by the biomedical laboratory scientist. The evaluation form prepared by SKUP was used, see chapter 5.5.

# 4. Statistical expressions and calculations

## 4.1. Statistical terms and expressions

### 4.1.1. Concordance analysis with kappa statistics

Kappa statistics was used to calculate the degree of agreement. The kappa model takes into account the fact that two methods may agree by chance. The agreement that may occur by chance is calculated and deducted from the observed data. The calculated Cohen's Kappa coefficient ($\kappa$) is a measure of the degree of agreement between the methods that are being compared.

Simple kappa statistics are primarily used when there are only two or three categories to compare. Weighted kappa is used for contingency tables above a particular number of categories (4–5 classes) where the extent of the difference between the two methods being compared is taken into consideration. The categories are weighted according to where they are in relation to the category where it is expected that the methods agree. Weighted kappa penalizes disagreement in terms of their seriousness, whereas un-weighted kappa treats all disagreements equally [4]. In the evaluation the agreement between the methods for the components glucose, protein, blood and leukocytes will be calculated using weighted kappa, attaching greater emphasis to large differences between ratings than to small differences. Un-weighted kappa will be used for the calculation of agreement for nitrite.

It is suggested that the interpretation of kappa is assisted by also reporting the maximum value kappa can attain for the set of data concerned ($\kappa_{max}$) [4]. For a given reliability study, the difference between kappa and 1 indicates the total unachieved agreement beyond chance. The difference between $\kappa_{max}$ and 1 shows the effect on agreement of imbalance in the table totals, caused by pre-existing factors such as method bias. This provides useful information [4]. For the calculation of kappa and maximum kappa, see section 4.2.

Kappa statistics can only be used on symmetrical tables, e.g. 2 x 2, 5 x 5 etc. In this evaluation most of the tables have different numbers of columns and rows (e.g. 4 x 5 etc.). When calculating the kappa coefficient, these tables will have two rows or columns combined where one of the methods has an answer alternative more than the other method. The conversion from an asymmetrical table to a symmetrical table is illustrated in attachment 2.

### 4.1.2. Overall agreement

The calculation of overall agreement between the methods is performed to show accordance independent of the categorisation of the methods.

## 4.2. Statistical calculations

### 4.2.1. Number of samples

201 urine samples were collected for the analysis of glucose, protein, erythrocytes, leukocytes and nitrite. In addition 10 urine samples for analysis of glucose were made at NOKLUS by adding different concentrations of glucose to a "normal" urine sample. In addition, 44 urine samples were collected specially for the analysis of nitrite. There are no missing or excluded results in this evaluation.

### 4.2.2. Calculation of Cohen's Kappa coefficient

Calculation of the Kappa coefficient [1]: **$\kappa = (Po - Pe)/(1 - Pe)$**, where

Po = observed probability of agreement
Pe = expected probability of agreement by chance
(1 – Pe) = expected disagreement by chance

Kappa has the value of 1 when there is perfect agreement between the methods. A value of zero indicates that possible agreement of the two methods only occurs by chance. An un-weighted kappa value does not distinguish between the magnitudes of disagreement on samples.

### 4.2.3. Calculation of weighted kappa

The weights can be assigned by means of any judgement procedure set up to reflect the results on a ratio scale. The weights may be the result of a consensus of experts, or they can simply be the investigator's own judgement. The choice of weights will obviously affect the resulting kappa values, and can therefore be decisive for the assessments and conclusions.

In this evaluation it was decided to use the Fleiss-Cohen quadratic weights [4,5] in calculation of the weighted kappa coefficient. Fleiss-Cohen weights are based on agreement. In the evaluation the method of weighting is based on disagreement, where the magnitude of discrepancy is indicated in the weight given each pair of observations. This method of weighting will give a low value of kappa when methods have a large discrepancy between ratings. The magnitude of the weights used in this evaluation is quite moderate with a maximum weighting of 2,00. Illustration of the quadratic weights used in cross-tables 6x6 and 4x4 are presented in figure 1.

| Answer alternatives | Weights | | | | | |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 1 | 1,00 | 1,04 | 1,16 | 1,36 | 1,64 | 2,00 |
| 2 | 1,04 | 1,00 | 1,04 | 1,16 | 1,36 | 1,64 |
| 3 | 1,16 | 1,04 | 1,00 | 1,04 | 1,16 | 1,36 |
| 4 | 1,36 | 1,16 | 1,04 | 1,00 | 1,04 | 1,16 |
| 5 | 1,64 | 1,36 | 1,16 | 1,04 | 1,00 | 1,04 |
| 6 | 2,00 | 1,64 | 1,36 | 1,16 | 1,04 | 1,00 |

| Answer alternatives | Weights | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 1 | 1,00 | 1,11 | 1,44 | 2,00 |
| 2 | 1,11 | 1,00 | 1,11 | 1,44 |
| 3 | 1,44 | 1,11 | 1,00 | 1,11 |
| 4 | 2,00 | 1,44 | 1,11 | 1,00 |

**Figure 1**. Illustration of quadratic weights inn cross-tables 6x6 and 4x4

### 4.2.4. Calculation of maximum kappa ($\kappa_{max}$)

To calculate the maximum attainable kappa ($\kappa_{max}$), the proportions of judgments by each rater (i.e., the table totals) are taken as fixed. The distribution of paired ratings is then adjusted so as to represent the greatest possible agreement. $\kappa_{max}$ serves to gauge the strength of agreement while preserving the proportions of positive ratings demonstrated by each rater [4].

### 4.2.5. Assessment of the kappa coefficient

There is no general opinion on how to assess kappa coefficients for comparisons of urine test strips. In this evaluation a Kappa coefficient >0,80 was assessed as good agreement between the methods. A Kappa coefficient <0,60 was assessed as a disagreement. Kappa coefficients between 0,60 and 0,80 were described as acceptable. The agreement in this intermediate category is neither good nor bad. SKUP will probably use a more neutral term than acceptable for agreement according to this intermediate category in later evaluations of urine test strips.

### 4.2.6. Calculation of overall agreement

To calculate the overall agreement between the methods, the total number of concurrent results is divided with the overall number of results, and the answer is given in percent. The answer is provided with a 95% confidence interval based on binomial distribution.

# 5. Results and discussion

## 5.1. Internal quality control

The internal quality control measurements on Urisys 1100 were performed with Urine dipstick control Quantimetrix the Dipper 1&2 (negative and positive level). The internal quality control measurements on Clinitek Status+ were performed with Chek-Stik Combo Pak Control +/-. The internal quality control measurements on Uryxxon Relax were performed with Medi-Test Control (negative and positive level). All control measurements were performed daily by the biomedical laboratory scientist throughout the evaluation period. The control solutions were kept according to the instructions in the product inserts. The expiring time after opening was not exceeded. An optical test was performed at each system before analysing the controls. All of the optical tests passed during the whole evaluation period.

The results of the internal quality controls on the three systems were inside the limits stated by the producer of the control solutions. The raw data from the measurements with internal quality control solutions is shown in attachment 2 and 3.

## 5.2. Assessment of analytical quality

Rating agreement analysis can never give true information about the analytical quality of an 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.

Cross-tables are made to illustrate the agreement between visual and mechanical readings of Medi-Test Uryxxon, and between mechanical readings at Uryxxon Relax and the two comparison methods; Urisys 1100 and Clinitek Status+. The coloured areas in the tables (purple) represent the correlated/corresponding observations between the methods. For assessment of the agreement with the two comparison methods in section 5.4, the coloured areas in the tables (purple) are based on visual inspection of the transitional points (cut-offs) in figure 2 to 5. For the two comparison methods the theoretical cut-off between two subsequent answer alternatives is suggested as the mean of the given concentration for the two alternatives. For Uryxxon Relax the cut-offs are given by the manufacturer.
In some of the tables one of the methods has an answer alternative that covers two answer alternatives of the other method (illustrated by the figures). In the tables this is shown by more than one coloured area in the row or column. When calculating the kappa coefficient the correlated observations (coloured areas) are combined and counted together in the diagonal of the tables, and thereby weighted by a factor of 1,00. See attachment 2 for an illustration of how the cross-tables are combined before the calculation of kappa. Calculation of Cohen's Kappa coefficient ($\kappa$) reflects the degree of agreement between the methods compared, taking into the consideration the agreement arisen by chance.

The raw data from the visual and the mechanical readings of Medi-Test Uryxxon is shown in attachment 4. The raw data from mechanical readings of the comparison methods is shown in attachment 5.

## 5.3. Medi-Test Uryxxon Stick 10, visual versus mechanical reading

All readings were carried out in the laboratory at NOKLUS. The urine test strip was compared with the colour codes on the test strip box and the results were read in the order shown on the box. The coloration of the test pad was read against the colour code on the test strip box that was closest to the colour in the reaction. After finishing the visual reading, a new Medi-Test Uryxxon test strip was analysed mechanically at Uryxxon Relax. The results will be commented on in each section and discussed as a whole in the end of this chapter.

### 5.3.1. Glucose

The agreement between visual and mechanical reading of glucose with Medi-Test Uryxxon urine test strip is presented in table 1.

**Table 1.** Visual versus mechanical reading of glucose

| Medi-Test, visual | Glucose mmol/L | Medi-Test, mechanical: neg | norm | 2,8 (1+) | 8,3 (2+) | ≥27,8 (3+) | total |
|---|---|---|---|---|---|---|---|
| | neg | 70 | 60 | 0 | 0 | 0 | 130 |
| | norm | 0 | 18 | 1 | 0 | 0 | 19 |
| | 2,8 (1+) | 0 | 5 | 11 | 1 | 0 | 17 |
| | 8,3 (2+) | 0 | 0 | 2 | 12 | 0 | 14 |
| | 27,8 (3+) | 0 | 0 | 0 | 1 | 11 | 12 |
| | ≥55,5 (4+) | 0 | 0 | 0 | 0 | 19 | 19 |
| | **total** | 70 | 83 | 14 | 14 | 30 | **211** |

*Comments*

The visual reading of glucose has one answer alternative more than the mechanical reading (≥55,5 mmol/L). For the answer alternatives "neg" and "norm", table 1 shows that the mechanical reading is more sensitive to change in colour intensity than the visual reading. There is a minimal difference between these two answer alternatives, and the manufacturer Macherey-Nagel explains the two alternatives like this: "*Our glucose test pad can already detect glucose values of 20 mg/dL, while the threshold value given by the WHO for the pathological amount of glucose in urine is 50 mg/dL. Since a small concentration of glucose is often to be found in urine and can be considered normal, we added the additional "norm" test pad. That can be especially important for visual evaluation, since some people are capable of perceiving a slight color reaction with even a low amount of glucose present. With the "norm", we can then prevent false positive readings.*"

### 5.3.2. Protein

The agreement between visual and mechanical reading of protein with Medi-Test Uryxxon urine test strip is presented in table 2.

**Table 2.** Visual versus mechanical reading of protein

| Medi-Test, visual: Protein g/L | Medi-Test, mechanical: neg | 0,3 (1+) | 1 (2+) | 5 (3+) | total |
|---|---|---|---|---|---|
| neg | 88 | 8 | 0 | 0 | 96 |
| 0,3 (1+) | 8 | 76 | 0 | 0 | 84 |
| 1 (2+) | 0 | 7 | 9 | 0 | 16 |
| 5 (3+) | 0 | 0 | 5 | 0 | 5 |
| **total** | 96 | 91 | 14 | 0 | **201** |

*Comments*

In table 2 there are a few more readings lying below than above the diagonal. This indicates that the visual reading is slightly more sensitive to change in colour intensity than the mechanical reading.

### 5.3.3. Blood

The agreement between visual and mechanical reading of blood with Medi-Test Uryxxon urine test strip is presented in table 3.

**Table 3.** Visual versus mechanical reading of blood

| Medi-Test, visual: Blood Ery/µL | Medi-Test, mechanical: neg | 10 (1+) | 50 (2+) | 250 (3+) | total |
|---|---|---|---|---|---|
| neg | 90 | 2 | 0 | 0 | 92 |
| 5-10/10 (1+) | 17 | 27 | 5 | 0 | 49 |
| 50 (2+) | 0 | 5 | 36 | 2 | 43 |
| 250 (3+) | 0 | 0 | 7 | 10 | 17 |
| **total** | 107 | 34 | 48 | 12 | **201** |

*Comments*

In table 3 17 samples are registered as negative for mechanical readings while visual readings gave the answer alternatives “5-10” (intact erythrocytes) or “10” (lysed erythrocytes). This indicates that the visual reading is more sensitive to change in colour intensity in the low concentration area than the mechanical reading.

### 5.3.4. Leukocytes

The agreement between visual and mechanical reading of leukocytes with Medi-Test Uryxxon urine test strip is presented in table 4.

**Table 4.** Visual versus mechanical reading of leukocytes

| Medi-Test, visual: Leukocytes Leu/µL | Medi-Test, mechanical: neg | 25 (1+) | 75 (2+) | 500 (3+) | total |
|---|---|---|---|---|---|
| neg | 84 | 7 | 0 | 0 | 91 |
| 25 (1+) | 3 | 40 | 19 | 0 | 62 |
| 75 (2+) | 0 | 0 | 4 | 24 | 28 |
| 500 (3+) | 0 | 0 | 0 | 20 | 20 |
| **total** | 87 | 47 | 23 | 44 | **201** |

*Comments*

In table 4 nearly all readings are lying in or above the diagonal. Readings lying above the diagonal indicates that the mechanical reading is more sensitive to change in colour intensity than the eye.

### 5.3.5. Nitrite

The agreement between visual and mechanical reading of nitrite with Medi-Test Uryxxon urine test strip is presented in table 5.

**Table 5.** Visual versus mechanical reading of nitrite

| Medi-Test, visual: Nitrite µmol/L | Medi-Test, mechanical: neg (-) | pos (+) | total |
|---|---|---|---|
| neg (-) | 142 | 0 | 142 |
| pos (+) | 14 | 89 | 103 |
| **total** | 156 | 89 | **245** |

*Comments*

Table 5 shows that the eye registers 14 positive nitrite results that are not registered by the mechanical reading.

### 5.3.6. Calculation of agreement

The calculated agreement between visual and mechanical reading with Medi-Test Uryxxon urine test strip is presented in table 6.

**Table 6.** Overall agreement and Kappa coefficient

| Medi-Test Uryxxon$_{visual}$ vs Medi-Test Uryxxon$_{mechanical}$ | | | |
|---|---|---|---|
| **Urine test pad** | **Overall agreement (95% confidence interval)** | **Kappa coefficient κ (95% confidence interval)** | **Maximum kappa coefficient ($\kappa_{max}$)** |
| **Glucose** | 67% (60 – 73) | 0,53 (0,44 – 0,62)* | 0,57* |
| **Glucose**[1] | 95% (91 – 98) | 0,91 (0,87 – 0,96)* | 0,97* |
| **Protein** | 86% (80 – 91) | 0,74 (0,66 – 0,82)* | 0,93* |
| **Blood** | 81% (75 – 86) | 0,69 (0,61 – 0,77)* | 0,84* |
| **Leukocytes** | 74% (67 – 80) | 0,59 (0,52 – 0,67)* | 0,82* |
| **Nitrite** | 94% (91 – 97) | 0,88 (0,82 – 0,94) | 0,88 |

*Calculation based on weighted kappa

[1] The answer alternatives “neg” and “norm” are combined and calculated together as correlated/corresponding observations

*Discussion*

The Medi-Test Uryxxon Stick 10 package insert states that “Due to the fact that the human eye evaluates colour changes somewhat differently than a URYXXON 300 or a URYXXON Relax reflectormeter, there can also be differences between these two evaluations”.

The calculated agreement between visual and mechanical readings of glucose results in a kappa coefficient of 0,53 and $\kappa_{max}$ of 0,57. If the answer alternatives “neg” and “norm” are combined and registered as correlated/corresponding observations, the kappa coefficient increases to 0,91, representing good agreement.

For nitrite the agreement was good with κ score 0,88. For protein, blood and leukocytes the agreement between visual and mechanical reading was acceptable with $\kappa \geq 0,6$.

## 5.4. Uryxxon Relax versus the comparison methods

The accuracy of the new system is assessed by comparing its results with results from similar raters. The Uryxxon Relax system was compared with the Urisys 1100 and the Clinitek Status+. The mechanical readings of the urines were carried out in the following order: Uryxxon Relax with the Medi-Test Uryxxon test strip, Urisys 1100 with the Combur[5] test and Clinitek Status+ with the Multistix 8 SG test strip. Figure 2 to 5 were made to illustrate that the three urine test strips have unequal answer alternatives and cut-offs. The results will be commented on in each section and discussed as a whole in the end of this chapter.

### 5.4.1. Glucose

The answer alternatives and cut-offs for the glucose readings at the three different urine analysers are presented in figure 2. The comparison of the mechanical reading of glucose between Uryxxon Relax and Urisys 1100 is presented in table 7, and between Uryxxon Relax and Clinitek Status+ in table 8.

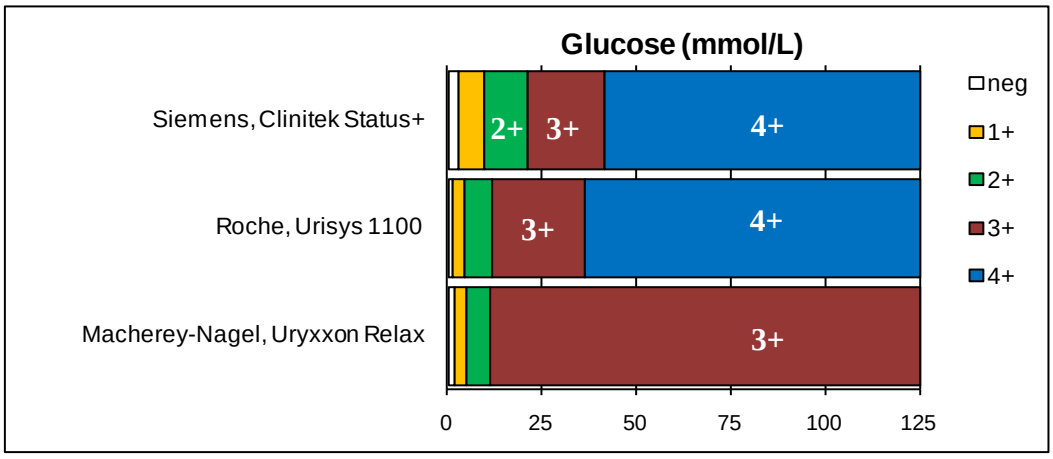


**Figure 2.** Illustration of transitional points (cut-offs) between the answer alternatives for glucose with the three urine test systems

**Table 7.** Mechanical reading of glucose, Uryxxon Relax versus Urisys 1100

| Uryxxon Relax: Glucose mmol/L | Urisys 1100: norm | 3 (1+) | 6 (2+) | 17 (3+) | 56 (4+) | total |
|---|---|---|---|---|---|---|
| neg | 65 | 5 | 0 | 0 | 0 | 70 |
| norm | 73 | 10 | 0 | 0 | 0 | 83 |
| 2,8 (1+) | 3 | 3 | 8 | 0 | 0 | 14 |
| 8,3 (2+) | 0 | 0 | 13 | 1 | 0 | 14 |
| ≥27,8 (3+) | 0 | 0 | 3 | 10 | 17 | 30 |
| **total** | 141 | 18 | 24 | 11 | 17 | **211** |

**Table 8.** Mechanical reading of glucose, Uryxxon Relax versus Clinitek Status+

| Uryxxon Relax: Glucose mmol/L | Clinitek Status+: neg | 5,5 (1+) | 14 (2+) | 28 (3+) | ≥55 (4+) | **total** |
|---|---|---|---|---|---|---|
| neg | 70 | 0 | 0 | 0 | 0 | 70 |
| norm | 83 | 0 | 0 | 0 | 0 | 83 |
| 2,8 (1+) | 5 | 9 | 0 | 0 | 0 | 14 |
| 8,3 (2+) | 0 | 14 | 0 | 0 | 0 | 14 |
| ≥27,8 (3+) | 0 | 3 | 11 | 13 | 3 | 30 |
| **total** | 158 | 26 | 11 | 13 | 3 | **211** |

*Comments*

The agreement in reporting glucose between Uryxxon Relax and the two comparison methods was good.

### 5.4.2. Protein

The answer alternatives and cut-offs for the protein readings at the three different urine analysers are presented in figure 3. The comparison of the mechanical reading of protein between Uryxxon Relax and Urisys 1100 is presented in table 9, and between Uryxxon Relax and Clinitek Status+ in table 10.

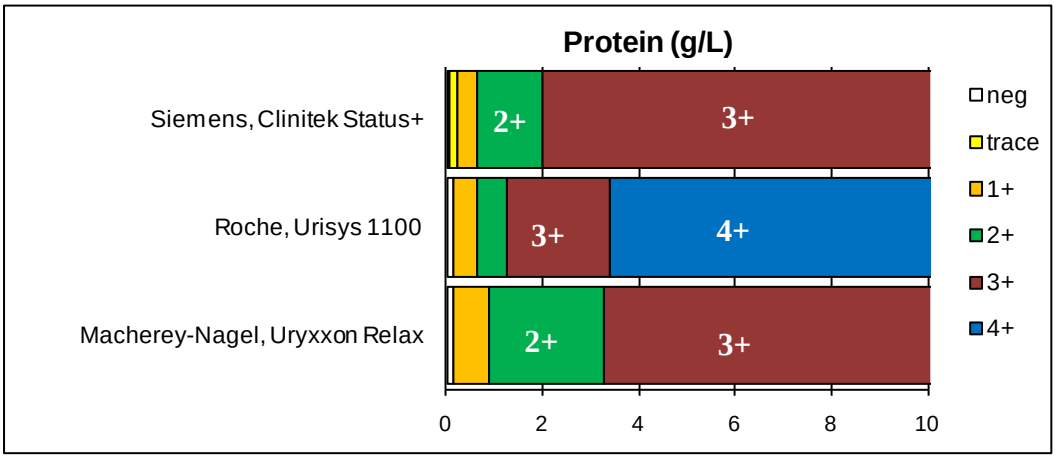


**Figure 3.** Illustration of transitional points (cut-offs) between the answer alternatives for protein with the three urine test systems

**Table 9.** Mechanical reading of protein, Uryxxon Relax versus Urisys 1100

| Uryxxon Relax: Protein g/L | Urisys 1100: neg | 0,25 (1+) | 0,75 (2+) | 1,5 (3+) | 5 (4+) | total |
|---|---|---|---|---|---|---|
| neg | 96 | 0 | 0 | 0 | 0 | 96 |
| 0,3 (1+) | 57 | 26 | 8 | 0 | 0 | 91 |
| 1 (2+) | 1 | 1 | 2 | 10 | 0 | 14 |
| 5 (3+) | 0 | 0 | 0 | 0 | 0 | 0 |
| **total** | 154 | 27 | 10 | 10 | 0 | **201** |

**Table 10.** Mechanical reading of protein, Uryxxon Relax versus Clinitek Status+

| Uryxxon Relax: Protein g/L | Clinitek Status+: neg | 0,15(trace) | 0,3 (1+) | 1 (2+) | ≥3,0 (3+) | total |
|---|---|---|---|---|---|---|
| neg | 44 | 30 | 21 | 1 | 0 | 96 |
| 0,3 (1+) | 0 | 3 | 31 | 47 | 10 | 91 |
| 1 (2+) | 0 | 0 | 0 | 1 | 13 | 14 |
| 5 (3+) | 0 | 0 | 0 | 0 | 0 | 0 |
| **total** | 44 | 33 | 52 | 49 | 23 | **201** |

*Comments*

There is a disagreement between Uryxxon Relax and Urisys 1100 regarding the answer alternatives “neg” and “1+” (0,3 g/L) for protein. Uryxxon Relax reads 57 samples as “1+” while Urisys 1100 reads the same samples as “neg”. The opposite is seen when Uryxxon Relax is compared to Clinitek Status+. Then there is 21 samples registered as “1+” at Clinitek Status+ while Uryxxon Relax reads these samples as “neg”. Clearly, there is a clear discrepancy between the two comparison methods Urisys 1100 and Clinitek Status+, for the component protein.

### 5.4.3. Blood

The answer alternatives and cut-offs for the erytrocytes readings at the three different urine analysers are presented in figure 4. The comparison of the mechanical reading of erytrocytes between Uryxxon Relax and Urisys 1100 is presented in table 11, and between Uryxxon Relax and Clinitek Status+ in table 12.

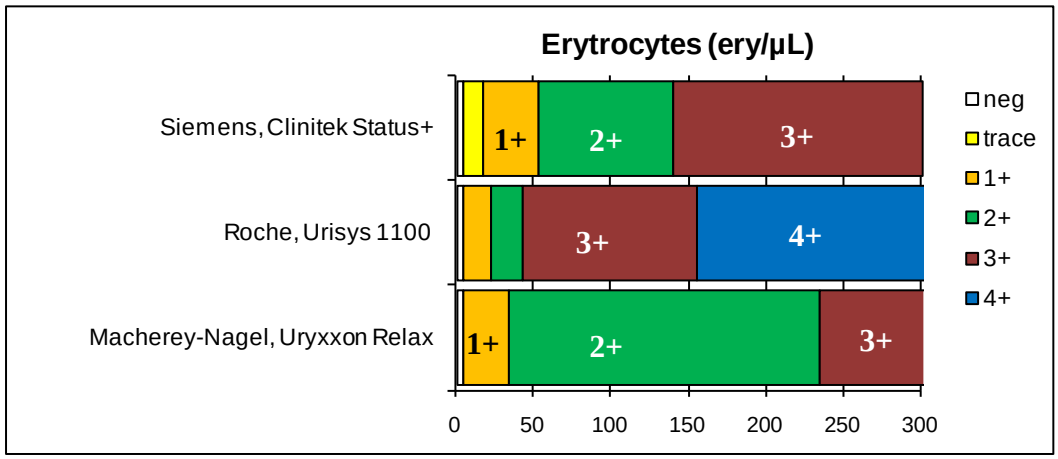


**Figure 4.** Illustration of transitional points (cut-offs) between the answer alternatives for blood with the three urine test systems

**Table 11.** Mechanical reading of blood, Uryxxon Relax versus Urisys 1100

| Uryxxon Relax: Blood Ery/µL | Urisys 1100: neg | 10 (1+) | 25 (2+) | 50 (3+) | 250 (4+) | total |
|---|---|---|---|---|---|---|
| neg | 47 | 38 | 22 | 0 | 0 | 107 |
| 10 (1+) | 7 | 5 | 19 | 3 | 0 | 34 |
| 50 (2+) | 0 | 0 | 2 | 16 | 30 | 48 |
| 250 (3+) | 0 | 0 | 0 | 0 | 12 | 12 |
| **total** | 54 | 43 | 43 | 19 | 42 | **201** |

**Table 12.** Mechanical reading of blood, Uryxxon Relax versus Clinitek Status+

| Uryxxon Relax: Blood Ery/µL | Clinitek Status+: neg | 10 (trace) | 25 (1+) | 80 (2+) | 200 (3+) | total |
|---|---|---|---|---|---|---|
| neg | 82 | 24 | 1 | 0 | 0 | 107 |
| 10 (1+) | 3 | 16 | 12 | 3 | 0 | 34 |
| 50 (2+) | 0 | 0 | 8 | 36 | 4 | 48 |
| 250 (3+) | 0 | 0 | 0 | 2 | 10 | 12 |
| **total** | 85 | 40 | 21 | 41 | 14 | **201** |

*Comments*

There is a clear discrepancy between Uryxxon Relax and Urisys 1100 regarding the component blood. Urisys 1100 gives several more positive test results for blood than Uryxxon Relax. The producer of the control material (Quantimetrix) states that the negative control may obtain false positive results for blood with Roche analyzers. Roche claims that this will not apply to patient samples. The agreement between Uryxxon Relax and Clinitek Status+ is good.

### 5.4.4. Leukocytes

The answer alternatives and cut-offs for the leukocytes readings at the three different urine analysers are presented in figure 5. The comparison of the mechanical reading of leucocytes between Uryxxon Relax and Urisys 1100 is presented in table 13, and between Uryxxon Relax and Clinitek Status+ in table 14.

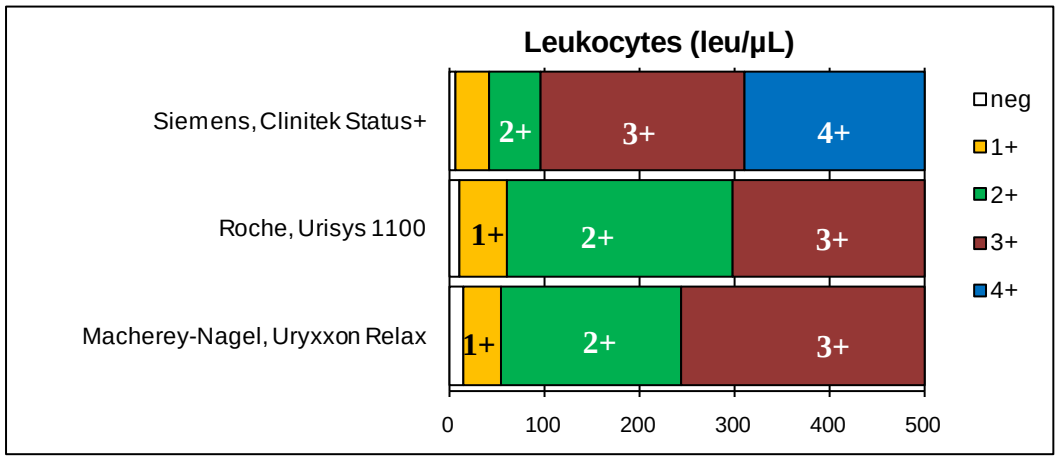


**Figure 5.** Illustration of transitional points (cut-offs) between the answer alternatives for leukocytes with the three urine test systems

**Table 13.** Mechanical reading of leukocytes, Uryxxon Relax versus Urisys 1100

| Uryxxon Relax \ Urisys 1100 | neg | 25 (1+) | 100 (2+) | 500 (3+) | total |
|---|---|---|---|---|---|
| neg | 56 | 28 | 3 | 0 | 87 |
| 25 (1+) | 16 | 22 | 9 | 0 | 47 |
| 75 (2+) | 0 | 1 | 20 | 2 | 23 |
| 500 (3+) | 0 | 0 | 6 | 38 | 44 |
| **total** | 72 | 51 | 38 | 40 | **201** |

**Table 14.** Mechanical reading of leukocytes, Uryxxon Relax versus Clinitek Status+

| Uryxxon Relax \ Clinitek Status+ | neg | 15 (1+) | 70 (2+) | 125 (3+) | 500 (4+) | total |
|---|---|---|---|---|---|---|
| neg | 86 | 1 | 0 | 0 | 0 | 87 |
| 25 (1+) | 11 | 18 | 18 | 0 | 0 | 47 |
| 75 (2+) | 1 | 4 | 17 | 1 | 0 | 23 |
| 500 (3+) | 0 | 0 | 6 | 22 | 16 | 44 |
| **total** | 98 | 23 | 41 | 23 | 16 | **201** |

*Comments*

Table 13 shows that a total of 30 leukocytes readings disagree when comparing Uryxxon Relax with Urisys 1100. When comparing Uryxxon Relax with Clinitek Status+ all of the readings for leukocytes lie in or below the coloured areas in table 14. Readings lying below the diagonal indicates that Uryxxon Relax is more sensitive to change in colour intensity than Clinitek Status+.

### 5.4.5. Nitrite

The comparison of the mechanical reading of nitrite between Uryxxon Relax and Urisys 1100 is presented in table 15, and between Uryxxon Relax and Clinitek Status+ in table 16.

**Table 15.** Mechanical reading of nitrite, Uryxxon Relax vs. Urisys 1100

| Uryxxon Relax | Nitrite | Urisys 1100 | | |
|---|---|---|---|---|
| | µmol/L | neg (-) | pos (+) | **total** |
| | neg (-) | 152 | 4 | 156 |
| | pos (+) | 2 | 87 | 89 |
| | **total** | 154 | 91 | **245** |

**Table 16.** Mechanical reading of nitrite, Uryxxon Relax vs. Clinitek Status+

| Uryxxon Relax | Nitrite | Clinitek Status+ | | |
|---|---|---|---|---|
| | | neg (-) | pos (+) | **total** |
| | neg (-) | 148 | 8 | 156 |
| | pos (+) | 0 | 89 | 89 |
| | **total** | 148 | 97 | **245** |

*Comments*

The cut-off value for nitrite is 0,05 mg/dL for Uryxxon Relax and Urisys 1100, and 0,06 mg/dL for Clinitek Status+. Both the comparison methods registered a few more positive nitrite results than Uryxxon Relax.

### 5.4.6. Calculation of agreement

The calculated agreement between mechanical reading of Uryxxon Relax and Urisys 1100 are presented in table 17, and between Uryxxon Relax and Clinitek Status+ in table 18.

**Table 17.** Overall agreement and Kappa coefficient

| Uryxxon Relax$_{mechanical}$ vs Urisys$_{mechanical}$ 1100 | | | |
|---|---|---|---|
| **Urine test pad** | **Overall agreement (95% confidence interval)** | **Kappa coefficient κ (95% confidence interval)** | **Maximum kappa coefficient ($\kappa_{max}$)** |
| **Glucose** | 98% (95 – 100) | 0,95 (0,91 – 1,00)* | 0,95* |
| **Protein** | 71% (64 – 77) | 0,43 (0,31 – 0,56)* | 0,44* |
| **Blood** | 65% (58 – 72) | 0,45 (0,36 – 0,55)* | 0,57* |
| **Leukocytes** | 85% (79 – 90) | 0,76 (0,69 – 0,83)* | 0,81* |
| **Nitrite** | 98% (95 – 99) | 0,95 (0,91 – 0,99) | 0,98 |

*Calculation based on weighted kappa

**Table 18.** Overall agreement and Kappa coefficient

| Uryxxon Relax$_{mechanical}$ vs Clinitek Status+$_{mechanical}$ | | | |
|---|---|---|---|
| **Urine test pad** | **Overall agreement (95% confidence interval)** | **Kappa coefficient κ (95% confidence interval)** | **Maximum kappa coefficient ($\kappa_{max}$)** |
| **Glucose** | 99% (96 – 100) | 0,96 (0,91 – 1,00)* | 0,96* |
| **Protein** | 84% (78 – 89) | 0,68 (0,60 – 0,77)* | 0,80* |
| **Blood** | 96% (92 – 98) | 0,92 (0,87 – 0,97)* | 0,93* |
| **Leukocytes** | 89% (84 – 93) | 0,82 (0,76 – 0,89)* | 0,90* |
| **Nitrite** | 97% (94 – 99) | 0,93 (0,88 – 0,98) | 0,93 |

*Calculation based on weighted kappa

*Discussion*

The agreement was good between Uryxxon Relax and Clinitek Status+ for the components glucose, blood, leukocytes and nitrite with $\kappa>0,8$. This was verified by high $\kappa_{max}$ scores. For protein there was an acceptable agreement between the two methods with $\kappa>0,6$.

The agreement between Uryxxon Relax and Urisys 1100 was slightly poorer than the agreement between Uryxxon Relax and Clinitek Status+. The components glucose, leukocytes and nitrite showed good agreement with $\kappa\geq0,8$. For the components protein and blood the $\kappa_{max}$ score (0,44 and 0,57 respectively) verifies that there was a discrepancy between Uryxxon Relax and Urisys 1100.

Protein was the component that showed the lowest $\kappa_{max}$ score when Uryxxon Relax was compared to either of the two comparison methods. Table 9 and table 10 show that Uryxxon Relax gives an overestimation of positive protein readings in proportion to Urisys 1100, and an underestimation in proportion to Clinitek Status+. To find out which of the three methods that lies closest to the true value, the results must be compared to a quantitative method for determination of protein in urine.

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.

## 5.5. Evaluation of user-friendliness

At the end of the evaluation period, the biomedical laboratory scientist filled in a questionnaire about the user-friendliness of Uryxxon Relax with Medi-Test Uryxxon Stick 10 test strip. The questionnaire and expressed opinions are presented in Table 19 to 22. The first column shows what is up for consideration. The second to fourth column show the rating options. The cell with the chosen rating is marked by coloured frame and bold text. The last row in each table summarises the ratings in the table.

The total rating of each table is not determined by the arithmetic mean of the individual ratings on the rows above. The total ratings are more an overall assessment of the property described on the row or in the headline of the table. A single poor rating can justify an overall poor rating if that property seriously influences on the user-friendliness of the system. Poor ratings are marked with an asterisk and will always be followed by an explanation below the table.

**Table 19.** Assessment of the information in the manual / insert

| **Information in the manual / insert about:** | 0 point | 1 point | 2 point |
|---|---|---|---|
| General impression | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Table of contents | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Preparations / Pre-analytic procedures | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Specimen collection[1] | Un-satisfactory | Less satisfactory | Satisfactory |
| Measurement / Reading | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Measurement principle | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Sources of error | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Fault-tracing / Troubleshooting | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Index | **Un-satisfactory*** | Less satisfactory | Satisfactory |
| Readability / Clarity of presentation | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Available in Danish, Norwegian and Swedish[2] | Un-satisfactory | Less satisfactory | **Satisfactory** |
| **Rating for information in the manual** | | | **Satisfactory** |

[1] Not a question when working with a urine analyzer.
[2]The manual will be translated when the system is launched onto the Scandinavian market.

*Negative comments: There is no index in the manual.

**Table 20.** Assessment of time factors

| **Time factors** | 0 point | 1 point | 2 point |
|---|---|---|---|
| Time for preparations / Pre-analytical time | >10 min. | 6 to 10 min. | **<6 min.** |
| Analytic time | >20 min. | 10 to 20 min. | **<10 min.** |
| Required training time | >8 hours | 2 to 8 hours | **<2 hours** |
| Stability of test, unopened package | <3 months | 3 to 5 months | **>5 months** |
| Stability of test, opened package | <14 days | 14 to 30 days | **>30 days** |
| **Rating of time factors** | | | **Satisfactory** |

**Table 21.** Assessment of quality control possibilities

| **Quality Control** | 0 point | 1 point | 2 point |
|---|---|---|---|
| Internal quality control | Un-satisfactory | Less satisfactory | **Satisfactory** |
| External quality control | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Stability of quality control material, unopened | <3 months | 3 to 5 months | **>5 months** |
| Stability of quality control material, opened | ≤1 days | 2 to 6 days | **>6 days or disposable** |
| Storage conditions of control material, unopened | –20°C | **+2 to +8°C** | +15 to +30°C |
| Storage conditions of control material, opened | –20°C | **+2 to +8°C** | +15 to +30°C |
| Usefulness of the Quality Control | Un-satisfactory | Less satisfactory | **Satisfactory** |
| **Rating of quality control** | | | **Satisfactory** |

Positive comments: -
Negative comments:-

**Table 22.** Assessment of the operation facilities

| **Operation facilities** | 0 point | 1 point | 2 point |
|---|---|---|---|
| To prepare the test / instrument | Un-satisfactory | Less satisfactory | **Satisfactory** |
| To prepare the sample | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Application of specimen | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Specimen volume | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Number of procedure step | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Instrument / test design | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Reading / Interpretation of the test result | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Sources of errors | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Cleaning / Maintenance | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Hygiene, when using the test | Un-satisfactory | Less satisfactory | **Satisfactory** |
| Storage conditions for tests, unopened package | –20°C | +2 to +8°C | **+15 to +30°C** |
| Storage conditions for tests, opened package | –20°C | +2 to +8°C | **+15 to +30°C** |
| Environmental aspects: waste handling | Special precautions | Sorted waste | **No precautions** |
| Intended users | Biomedical scientists | Laboratory experienced | **GP personnel or patients** |
| Size and weight of package | Un-satisfactory | Less satisfactory | **Satisfactory** |
| **Rating of the operation facilities** | | | **Satisfactory** |

Positive comments:-
Negative comments:-

### 5.5.1. Assessment of the user-friendliness

The information in the manual or insert was assessed as satisfactory. The biomedical laboratory scientist also thought that the time factors and quality control possibilities, as well as the operating facilities, were satisfactory. The Uryxxon Relax system was regarded as user-friendly.

# 6. References

1. ”European Urinanalysis Guidelines”; T. Kouri, G. Fogazzi, V. Gant, H. Hallander, W. Hofmann. W.G. Guder. Scand J clin Lab Invest – Vol. 60 – Supplement 231, 2000.

2. ”Practical Statistics for Medical Research”; D.G. Altman (403 – 409) 1997.

3. ”Utprøving av analyseinstrumenter”; N.G. Christensen, G. Monsen, S. Sandberg. Alma Mater Forlag, 1997.

4. ”The Kappa Statistic in Reliability Studies: Use, Interpretation, and Sample Size Requirements”; J. Sims, C.C. Wright. Physical Therapy – Vol 85 – no. 3, march 2005.

5. ”Statistical Methods for Rater and Diagnostic Agreement”. http://www.john-uebersax.com/stat/agree.htm

# Attachments

1. Facts about the system
2. Cross-tables used in the calculation of Cohen's Kappa coefficient
3. Raw data, internal quality control, Medi-Test Uryxxon Stick 10
4. Raw data, internal quality control, the comparison methods
5. Raw data, results from visual and mechanical readings of Medi-Test Uryxxon Stick 10
6. Raw data, results from mechanical readings of the comparison methods
7. "SKUP-info". Norwegian summary for primary healthcare
8. List of evaluations organised by SKUP
9. Comments from the manufacturer

Attachments with raw data are included only in the report to Macherey-Nagel and Medic24.

# Facts about the analyser

| **a) Name of the analyser** | ***URYXXON® Relax*** |
|---|---|

| | |
|---|---|
| Physical dimensions | *width: 16 cm*<br>*depth: 20 cm*<br>*height: 7,5 cm* |
| Manufacturer (with address) | MACHEREY-NAGEL GmbH & Co. KG<br>Neumann-Neander-Strasse 6-8<br>D-52355 Dueren<br>GERMANY |
| Distributor (with address) | *Denmark*<br>*Medic24 AS*<br>*Storgatatn 112, 6. etg.*<br>*n-3921 Porsgrunn* |
| | *Norway*<br>*Medic24 AS*<br>*Storgatatn 112, 6. etg.*<br>*n-3921 Porsgrunn* |
| | *Sweden*<br>*Medic24 AB*<br>*Solvarvsgatan 4*<br>*S-507 40 Borås* |

**b) Analysis menu, sample materials and volume of the analysis**

| Component | Sample materials | Volume of the analysis |
|---|---|---|
| *All tests on strip* | *Urine* | *approx. 10 ml* |

**c) Analysis principles** (reference to the instruction manual)

| Parameter | Principle |
|---|---|
| Glucose | The detection is based on the glucoseoxidase-peroxidase-chromogen reaction. Apart from glucose, no other compound in urine is known to give a positive reaction. |
| Protein | The test is based on the „protein error“ principle of indicators. The test zone is buffered to a constant pH value and changes colour from yellow to greenish blue in the presence of albumin. Other proteins are indicated with less sensitivity. |
| Blood | The detection is based on the pseudoperoxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide producing a green colour. |
| Nitrites | Microorganisms, which are able to reduce nitrate to nitrite, are indicated indirectly by this test. The principle of Griess reagent is the basis of this test. The test paper contains an amine and a coupling component. A red coloured azo compound is formed by diazotisation and subsequent coupling. |
| Leucocytes | The test is based on the esterase activity of granulocytes. This enzyme splits carboxylic acid esters. The alcohol constituent released reacts with a diazo salt producing a violet colour. |

**d) Area of analysis**

| Component | Area of analysis | Designation |
|---|---|---|
| *Test strips* | *Screening test* | Test strips for visual evaluation and instrumental reading with URYXXON® Relax. For determination of Blood, Protein, Nitrite, Glucose and Leukocytes in urine. |
| *URYXXON® Relax reader* | *reflection photometer to evaluate MN test strips for urine analysis* | The instrument is a reflection photometer for the analysis of urine test strips. The measurements are performed under standardized conditions, measured values may be displayed, printed and transferred to a computer. The instrument is designed for in-vitro diagnostic use (IVD) and should be used by healthcare professionals only. |

**e) Time for analysis per component** (precisely stated)

| Component | Pre-analysis time (with an explanation) | Analysis time |
|---|---|---|
| **Glucose** | *None, place strip on device immediately* | *Ca. 60 s* |
| **Protein** | *None, place strip on device immediately* | *Ca. 60 s* |
| **Blood** | *None, place strip on device immediately* | *Ca. 60 s* |
| **Nitrites** | *None, place strip on device immediately* | *Ca. 60 s* |
| **Leucocytes** | *None, place strip on device immediately* | *Ca. 60 s* |

**f) Calibration**

| | |
|---|---|
| Is calibration possible? | *No, not necessary, automatic internal calibration* |
| How often is calibration recommended? | - |
| Number of standards | - |
| Who should carry out calibration? | - |

**g) Recommended maintenance**

| Maintenance | How often? |
|---|---|
| *Cleaning of strip holder and slide* | *Every day* |
| *Cleaning of housing and touch screen* | *At least once a week* |

**h) Control materials**

| | |
|---|---|
| Is control material available (from the producer or other companies)? | *MACHEREY-NAGEL produces and supplies control solution, which is ideal to use with the URYXXON® Relax. (Medi-Test Control, REF 93038)* |

| **a) Name of the analyser** | ***URYXXON® Relax*** |
|---|---|

**i) Marketing**

| | |
|---|---|
| In which country is the analyser marketed? | *World-wide* |
| When did the analyser first appear on the Scandinavian market? | *Not on the market yet* |
| When did the analyser receive CE approval? | *May 2006* |

**j) Language**

| | |
|---|---|
| In which Scandinavian language is the manual? | *The manual will be available in all 4 Scandinavien languages (NOR, SWE, FIN, DEN)* |

**k) Memory**

| | |
|---|---|
| What is the storage capacity of the analyser and what is stored? | *200 patient test results including name or patient ID.* |
| Is it possible to identify patients? | *Yes* |
| If yes, describe this: | *Every patient can receive an optional patient ID, which can be entered manually via the touch screen or with a keyboard / barcode scanner. You can search the memory for specific IDs.* |

**l) Power supply**

| | |
|---|---|
| Electric network connection | *110-240 V AC, automatic* |
| Battery | *Yes (optional)* |
| If yes, which type and how many batteries | *6 AA batteries* |

**m) Electronic communication**

| | |
|---|---|
| Can a printer be connected to the analyser? | *Yes* |
| Can a barcode reader be connected to the analyser? | *Yes* |
| Interface | *RS 232 or USB* |
| If yes, which port is required? | *RS 232 or USB* |
| Communication method | *Serial* |
| Transfer mode | *Unidirectional* |
| Transfer protocol | *Plain ASCII* |

**n) Standards and controls**

| | Standard | Control |
|---|---|---|
| Name | - | *Medi-Test Control* |
| Volume | - | *2 vials, negative and positive control solution, 15ml solution in each vial* |
| Shelf life unopened | - | *12 months after production* |
| Shelf life opened | - | *3 months* |
| Any comments: | No standards necessary | *Max. 20 tests per pack* |

**o) Reagents**

| Component | Time and temperature, unopened | Time and temperature, opened |
|---|---|---|
| *urine test strip (up to 11 parameters)* | *4-30°C, 24 months after production* | *4-30°C, 24 months after production* |
| Any comments: | | ***Provided the box is closed quickly after a test strip has been taken out.*** |

**p) Additional information**

| |
|---|
| |

**Raw data, internal quality control; Medi-Test Control Negative and Positive.**

| Date | Blood | Protein | Nitrite | Glucose | Leukocytes | Lot no. strip | Comments |
|---|---|---|---|---|---|---|---|
| 24.nov | neg | neg | neg | neg | neg | a | |
| 26.nov | neg | neg | neg | neg | neg | a | |
| 27.nov | neg | neg | neg | neg | neg | b | |
| 30.nov | neg | neg | neg | neg | neg | b | |
| 01.des | neg | neg | neg | neg | neg | b | |
| 02.des | neg | neg | neg | neg | neg | b | |
| 08.des | 10 | neg | neg | neg/norm | neg | b / c | |
| 09.des | neg | neg | neg | neg | neg | c | New bottle |
| 10.des | neg | neg | neg | neg | neg | c | |
| 11.des | neg | neg | neg | neg | neg | c | |
| 14.des | neg | neg | neg | neg | neg | a | |
| 15.des | neg | neg | neg | neg | neg | a | |
| 16.des | neg | neg | neg | neg | neg | a | |
| 17.des | neg | neg | neg | neg | neg | b | |
| 18.des | neg | neg | neg | neg | neg | c | |
| 21.des | neg | neg | neg | neg | neg | c | |
| 05.jan | neg | neg | neg | neg | neg | c | New bottle |
| 07.jan | neg | neg | neg | neg | neg | b | |
| 08.jan | neg | neg | neg | neg | neg | c | |
| 13.jan | neg | neg | neg | neg | neg | b | |
| 14.jan | neg | neg | neg | norm | neg | c | |
| 18.jan | neg | neg | neg | neg | neg | c | |
| 19.jan | neg | neg | neg | neg | neg | b | |
| 01.feb | neg | neg | neg | norm | neg | c | New bottle |
| 08.feb | neg | neg | neg | neg | neg | a | |
| 09.feb | neg | neg | neg | neg | neg | b | |
| 23.feb | neg | neg | neg | neg | neg | a | |
| 24.feb | neg | neg | neg | neg | neg | a | |

| Date | Blood | Protein | Nitrite | Glucose | Leukocytes | Lot no. strip | Comments |
|---|---|---|---|---|---|---|---|
| 24.nov | 250 | 5 | pos | ≥ 27,8 | 500 | a | |
| 26.nov | 250 | 5 | pos | ≥ 27,8 | 500 | a | |
| 27.nov | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 30.nov | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 01.des | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 02.des | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 08.des | 250 | 5 | pos | ≥ 27,8 | 500 | b / c | |
| 09.des | 250 | 5 | pos | ≥ 27,8 | 500 | c | New bottle |
| 10.des | 250 | 5 | pos | ≥ 27,8 | 500 | c | |
| 11.des | 250 | 5 | pos | ≥ 27,8 | 500 | c | |
| 14.des | 250 | 5 | pos | ≥ 27,8 | 500 | a | |
| 15.des | 250 | 5 | pos | ≥ 27,8 | 500 | a | |
| 16.des | 250 | 5 | pos | ≥ 27,8 | 500 | a | |
| 17.des | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 18.des | 250 | 5 | pos | ≥ 27,8 | 500 | c | |
| 21.des | 250 | 5 | pos | ≥ 27,8 | 500 | c | |
| 05.jan | 250 | 5 | pos | ≥ 27,8 | 500 | c | New bottle |
| 07.jan | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 08.jan | 250 | 5 | pos | ≥ 27,8 | 500 | c | |
| 13.jan | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 14.jan | 250 | 5 | pos | ≥ 27,8 | 500 | c | |
| 18.jan | 250 | 5 | pos | ≥ 27,8 | 500 | c | |
| 19.jan | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 01.feb | 250 | 5 | pos | ≥ 27,8 | 500 | c | New bottle |
| 08.feb | 250 | 5 | pos | ≥ 27,8 | 500 | a | |
| 09.feb | 250 | 5 | pos | ≥ 27,8 | 500 | b | |
| 23.feb | 250 | 5 | pos | ≥ 27,8 | 500 | a | |
| 24.feb | 250 | 5 | pos | ≥ 27,8 | 500 | a | |

**Raw data, internal quality control, the comparison method Urisys 1100 (Roche).**

**Quantimetrix the Dipper, Urine dipstick control 1 & 2.**

| Date | Glucose | Leukocytes | Nitrite | Protein | Blood* | Lot no. Strip | Comments |
|---|---|---|---|---|---|---|---|
| 24.nov | norm | neg | neg | neg | 10 | 23052245 | |
| 26.nov | norm | neg | neg | neg | 10 | 23052245 | |
| 27.nov | norm | neg | neg | neg | neg | 23052245 | |
| 30.nov | norm | neg | neg | neg | neg | 23052245 | |
| 01.des | norm | neg | neg | neg | 10 | 23052245 | |
| 02.des | norm | neg | neg | neg | 10 | 23052245 | |
| 08.des | norm | neg | neg | neg | neg | 23052245 | |
| 09.des | norm | neg | neg | neg | 10 | 23052245 | |
| 10.des | norm | neg | neg | neg | 10 | 23052245 | New bottle |
| 11.des | norm | neg | neg | neg | neg | 23052245 | |
| 14.des | norm | neg | neg | neg | neg | 23052245 | |
| 15.des | norm | neg | neg | neg | neg | 23052245 | |
| 16.des | norm | neg | neg | neg | neg | 23052245 | |
| 17.des | norm | neg | neg | neg | neg | 23052245 | |
| 18.des | norm | neg | neg | neg | neg | 23052245 | |
| 21.des | norm | neg | neg | neg | neg | 23052245 | |
| 05.jan | norm | neg | neg | neg | neg | 23052245 | New bottle |
| 07.jan | norm | neg | neg | neg | 10 | 23052245 | |
| 08.jan | norm | neg | neg | neg | neg | 23052245 | |
| 13.jan | norm | neg | neg | neg | 10 | 23052245 | |
| 14.jan | norm | neg | neg | neg | neg | 23052245 | |
| 18.jan | norm | neg | neg | neg | neg | 23052245 | |
| 19.jan | norm | neg | neg | neg | neg | 23052245 | New bottle |
| 01.feb | norm | neg | neg | neg | neg | 23052245 | |
| 08.feb | norm | neg | neg | neg | neg | 23052245 | |
| 09.feb | norm | neg | neg | neg | neg | 23052245 | |
| 23.feb | norm | neg | neg | neg | neg | 23052245 | |
| 24.feb | norm | neg | neg | neg | neg | 23052245 | |

*The producer of the control material states that some customers may obtain false positive results for blood.

| Date | Glucose | Leukocytes | Nitrite | Protein | Blood | Lot no. strip | Comments |
|---|---|---|---|---|---|---|---|
| 24.nov | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 26.nov | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 27.nov | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 30.nov | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 01.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 02.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 08.des | 56 | 500 | pos | 0,75 | 50 | 23052245 | |
| 09.des | 56 | 500 | pos | 0,75 | 50 | 23052245 | |
| 10.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | New bottle |
| 11.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 14.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 15.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 16.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 17.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 18.des | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 21.des | 56 | 500 | pos | 0,75 | 50 | 23052245 | |
| 05.jan | 56 | 500 | pos | 0,75 | 250 | 23052245 | New bottle |
| 07.jan | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 08.jan | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 13.jan | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 14.jan | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 18.jan | 56 | 500 | pos | 0,75 | 50 | 23052245 | |
| 19.jan | 56 | 500 | pos | 0,75 | 250 | 23052245 | New bottle |
| 01.feb | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 08.feb | 56 | 500 | pos | 0,75 | 250 | 23052245 | |
| 09.feb | 56 | 500 | pos | 0,75 | 50 | 23052245 | |
| 23.feb | 56 | 500 | pos | 0,75 | 25 | 23052245 | |
| 24.feb | 56 | 500 | pos | 0,75 | 250 | 23052245 | New bottle |

**Raw data, internal quality control, the comparison method Clinitek Status+ (Siemens).**

**Chek-Stix Combo Pak Control +/- .**

| Date | Glucose | Blood | Protein | Nitrite | Leukocytes | Lot no. strip | Comments |
|---|---|---|---|---|---|---|---|
| 24.nov | neg | neg | neg | neg | neg | 9G25C | |
| 26.nov | neg | neg | neg | neg | neg | 9G25C | |
| 27.nov | neg | neg | neg | neg | neg | 9G25C | |
| 30.nov | neg | neg | neg | neg | neg | 9G25C | |
| 01.des | neg | neg | neg | neg | neg | 9G25C | |
| 02.des | neg | neg | neg | neg | neg | 9G25C | |
| 08.des | neg | neg | neg | neg | neg | 9G25C | |
| 09.des | neg | neg | neg | neg | neg | 9G25C | |
| 10.des | neg | neg | neg | neg | neg | 9G25C | |
| 11.des | neg | neg | neg | neg | neg | 9G25C | |
| 14.des | neg | neg | neg | neg | neg | 9G25C | |
| 15.des | neg | neg | neg | neg | neg | 9G25C | |
| 16.des | neg | neg | neg | neg | neg | 9G25C | |
| 17.des | neg | neg | neg | neg | neg | 9G25C | |
| 18.des | neg | neg | neg | neg | neg | 9G25C | |
| 21.des | neg | neg | neg | neg | neg | 9G25C | |
| 05.jan | neg | neg | neg | neg | neg | 9G25C | |
| 07.jan | neg | neg | neg | neg | neg | 9G25C | |
| 08.jan | neg | neg | neg | neg | neg | 9G25C | |
| 13.jan | neg | neg | neg | neg | neg | 9G25C | |
| 14.jan | neg | neg | neg | neg | neg | 9G25C | |
| 18.jan | neg | neg | neg | neg | neg | 9G25C | |
| 19.jan | neg | neg | neg | neg | neg | 9G25C | |
| 01.feb | neg | neg | neg | neg | neg | 9G25C | |
| 08.feb | neg | neg | neg | neg | neg | 9J11DC | New lot |
| 24.feb | neg | neg | neg | neg | neg | 9J11DC | |

| Date | Glucose | Blood | Protein | Nitrite | Leukocytes | Lot no. strip | Comments |
|---|---|---|---|---|---|---|---|
| 24.nov | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 26.nov | 14,0 | 200 | 1,0 | pos | 70 | 9G25C | |
| 27.nov | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 30.nov | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 01.des | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 02.des | 5,5 | 200 | 1,0 | pos | 125 | 9G25C | |
| 08.des | 5,5 | 200 | 1,0 | pos | 125 | 9G25C | |
| 09.des | 5,5 | 200 | 1,0 | pos | 125 | 9G25C | |
| 10.des | 5,5 | 200 | 1,0 | pos | 125 | 9G25C | |
| 11.des | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 14.des | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 15.des | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 16.des | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 17.des | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 18.des | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 21.des | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 05.jan | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 07.jan | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 08.jan | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 13.jan | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 14.jan | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 18.jan | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 19.jan | 5,5 | 200 | 1,0 | pos | 125 | 9G25C | |
| 01.feb | 5,5 | 200 | 1,0 | pos | 70 | 9G25C | |
| 08.feb | 5,5 | 200 | 1,0 | pos | 70 | 9J11DC | New lot |
| 24.feb | 5,5 | 200 | 1,0 | pos | 70 | 9J11DC | |

# SKUP-info

**Medi-Test Uryxxon Stick 10 urinstrimmel og Uryxxon Relax urinstrimmel avleser fra Macherey-Nagel**

**Sammendrag fra en utprøving i regi av SKUP**


***Konklusjon***
***Visuell mot maskinell avlesning av Medi-Test Uryxxon Stick 10:*** **Godt samsvar for glukose og nitritt. Akseptabelt[1] samsvar for protein, blod og leukocytter.**
***Sammenligning med Clinitek Status+:*** **Godt samsvar for glukose, blod, leukocytter og nitritt. Akseptabelt samsvar for protein.**
***Sammenligning med Urisys 1100:*** **Godt samsvar for glukose, leukocytter og nitritt. Ikke tilfredsstillende samsvar mht blod og protein.**
**Utprøvingen gir ikke svar på hvilken av de tre metodene som ligger nærmest sann verdi.**


**Medi-Test Uryxxon Stick 10 urinstrimmel og Uryxxon Relax avleser** er produsert av Macherey-Nagel og forhandles i Skandinavia av Medic24. Urinstrimmelen har testfelt for blod, urobilinogen, bilirubin, protein, nitritt, ketoner, glukose, pH, leukocytter og tetthet. Fem av komponentene er evaluert av SKUP; glukose, protein, blod, nitritt og leukocytter.

**Utprøvingen** ble utført under optimale betingelser av laboratorieutdannet personale. Det ble samlet inn ca. 300 urinprøver fra pasienter på sykehus og i primærhelsetjenesten. Avlesning av Medi-Test Uryxxon Stick 10 på Uryxxon Relax ble sammenlignet med urinstrimmelen Combur[5] Test avlest på Urisys 1100 (Roche) og urinstrimmelen Multistix 8 SG avlest på Clinitek Status+ (Siemens). Visuell og maskinell avlesning av Medi-Test Uryxxon Stick 10 ble også sammenlignet.

**Resultater**
Det var godt samsvar mellom visuell og maskinell avlesning av Medi-Test Uryxxon Stick 10 for glukose og nitritt, og akseptabelt samsvar for protein, blod og leukocytter.
Det var godt samsvar mellom Uryxxon Relax og Clinitek Status+ for glukose, blod, leukocytter og nitritt, og akseptabelt samsvar for protein.
Samsvaret mellom Uryxxon Relax og Urisys 1100 var godt for glukose, leukocytter og nitritt.
Det var ikke tilfredsstillende samsvar mellom Uryxxon Relax og Urisys 1100 for avlesning av protein og blod.
Når det gjelder protein var det uenighet mellom de tre avlesningsmetodene. Uryxxon Relax gir flere positive avlesninger av protein enn Urisys 1100 og færre positive avlesninger enn Clinitek Status+.
Denne utprøvingen gir ikke svar på hvilken av de tre metodene som ligger nærmest sann verdi.

**Brukervennlighet**
Bioingeniøren vurderte Uryxxon-systemet til å være brukervennlig.

**Tilleggsinformasjon**
En fullstendig rapport fra utprøvingen av Medi-Test Uryxxon Stick 10 og Uryxxon Relax, SKUP/2010/82*, finnes på SKUPs nettside, www.skup.nu. Opplysninger om pris fås ved å kontakte leverandør. Laboratoriekonsulentene i NOKLUS kan gi nyttige råd om analysering av urinstrimmel på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

[1] Samsvaret i kategorien "Akseptabel" er verken god eller dårlig.

# List of previous SKUP evaluations

Summaries and complete reports from the evaluations are found at www.skup.nu

## SKUP evaluations from number 51 and further

| Evaluation no. | Component | Instrument/testkit | Producer |
|---|---|---|---|
| SKUP/2010/82* | Glucose, protein, blood, leukocytes, nitrite | Medi-Test URYXXON Stick 10 urine test strip and URYXXON Relax urine analyser | Macherey-Nagel GmBH & Co. KG |
| SKUP/2010/79* | Glucose, protein, blood, leukocytes, nitrite | CombiScreen 5SYS Plus urine test strip and CombiScan 100 urine analyser | Analyticon Biotechnologies AG |
| SKUP/2009/75 | Glucose | Contour | Bayer HealthCare |
| SKUP/2009/74 | Glucose[1] | Accu-Chec Mobile | Roche Diagnostics |
| SKUP/2010/73 | Leukocytes | HemoCue WBC | HemoCue AB |
| SKUP/2008/72 | Glucose[1] | *Confidential* | |
| SKUP/2009/71 | Glucose[1] | GlucoMen LX | A. Menarini Diagnostics |
| SKUP/2008/69* | Strep A | Diaquick Strep A test | Dialab GmbH |
| SKUP/2008/66 | Glucose[1] | DANA DiabeCare IISG | SOOIL Developement co. Ltd |
| SKUP/2008/65 | HbA1c | Afinion HbA1c | Axis-Shield PoC AS |
| SKUP/2007/64 | Glucose[1] | FreeStyle Lite | Abbott Laboratories |
| SKUP/2007/63 | Glucose[1] | *Confidential* | |
| SKUP/2007/62* | Strep A | QuikRead | Orion Diagnostica Oy |
| SKUP/2008/61 | CRP | i-CHROMA | BodiTech Med. Inc. |
| SKUP/2007/60 | Glucose[1] | *Confidential* | |
| SKUP/2007/59 | Glucose[1] | Ascensia BREEZE2 | Bayer HealthCare |
| SKUP/2006/58 | HbA1c | *Confidential* | |
| SKUP/2007/57* | PT (INR) | Simple Simon PT | Zafena AB |
| SKUP/2007/56* | PT (INR) | *Confidential* | |
| SKUP/2007/55 | PT (INR) | CoaguChek XS | Roche Diagnostics |
| SKUP/2007/54* | Mononucleosis | *Confidential* | |
| SKUP/2006/53* | Strep A | *Confidential* | |
| SKUP/2005/52* | Strep A | Clearview Exact Strep A Dipstick | Applied Biotech, Inc. |
| SKUP/2005/51* | Glucose[1] | FreeStyle | Abbott Laboratories |

*A report code followed by an asterisk, indicates that the evaluation for instance is a pre-marketing evaluation, and thereby confidential. A pre-marketing evaluation can result in a decision by the supplier not to launch the instrument onto the Scandinavian marked. If so, the evaluation remains confidential. The asterisk can also mark evaluations at special request from the supplier or evaluations that are not complete according to SKUP guidelines, e.g. the part performed by the intended users was not included in the protocol.

[1] Including a user-evaluation among diabetes patients.

Grey area – The instrument is not in the market any more.

## SKUP evaluations from number 1 — 50

| Evaluation no. | Component | Instrument/test kit | Producer |
|---|---|---|---|
| SKUP/2006/50 | Glucose[1] | Glucocard X-Meter | Arkray, Inc. |
| SKUP/2006/49 | Glucose[1] | Precision Xtra Plus | Abbott Laboratories |
| SKUP/2006/48 | Glucose[1] | Accu-Chek Sensor | Roche Diagnostic |
| SKUP/2006/47 | Haematology | Chempaq XBC | Chempaq |
| SKUP/2005/46* | PT (INR) | *Confidential* | |
| SKUP/2006/45 | Glucose[1] | HemoCue Monitor | HemoCue AB |
| SKUP/2005/44 | Glucose[1] | Accu-Chek Aviva | Roche Diagnostics |
| SKUP/2005/43 | Glucose[1] | Accu-Chek Compact Plus | Roche Diagnostics |
| SKUP/2005/42* | Strep A | Twister Quick-Check Strep A | ACON laboratories, Inc. |
| SKUP/2006/41* | HbA1c | *Confidential* | |
| SKUP/2005/40 | Glucose[1] | OneTouch GlucoTouch | LifeScan, Johnson & Johnson |
| SKUP/2005/39 | Glucose[1] | OneTouch Ultra | LifeScan, Johnson & Johnson |
| SKUP/2004/38* | Glucose | GlucoSure Plus | Apex Biotechnology Corp. |
| SKUP/2004/37* | u-hCG | Quick response u-hCG | Wondsfo Biotech |
| SKUP/2004/36* | Strep A | Dtec Strep A testcard | UltiMed |
| SKUP/2004/35* | u-hCG | QuickVue u-hCG | Quidel Corporation |
| SKUP/2004/34* | u-hCG | RapidVue u-hCG | Quidel Corporation |
| SKUP/2004/33 | PT (INR) | Hemochron Jr. Signature | ITC International Technidyne Corp |
| SKUP/2004/32* | Strep A | QuickVue In-Line Strep A test | Quidel Corporation |
| SKUP/2004/31* | PT (INR) | *Confidential* | |
| SKUP/2004/30 | Glucose[1] | Ascensia Contour | Bayer Healthcare |
| SKUP/2004/29 | Haemoglobin | Hemo_Control | EKF-diagnostic |
| SKUP/2003/28* | Strep A | QuickVue In-Line Strep A test | Quidel Corporation |
| SKUP/2003/27* | Strep A | QuickVue Dipstick Strep A test | Quidel Corporation |
| SKUP/2003/26* | HbA1c | *Confidential* | |
| SKUP/2003/25* | HbA1c | *Confidential* | |
| SKUP/2003/24* | Strep A | OSOM Strep A test | GenZyme, General Diag. |
| SKUP/2002/23* | Haematology with CRP | ABX Micros CRP | ABX Diagnostics |
| SKUP/2002/22 | Glucose[1] | GlucoMen Glycó | Menarini Diagnostics |
| SKUP/2002/21 | Glucose[1] | FreeStyle | TheraSense Inc. |
| SKUP/2002/20 | Glucose | HemoCue 201 | HemoCue AB |
| SKUP/2002/19* | PT(INR) | Reagents and calibrators | |
| SKUP/2002/18 | Urine–Albumin | HemoCue | HemoCue AB |
| SKUP/2001/17 | Haemoglobin | Biotest Hb | Biotest Medizin-technik GmbH |
| SKUP/2001/16* | Urine test strip | Aution Sticks and PocketChem UA | Arkray Factory Inc. |
| SKUP/2001/15* | Glucose | GlucoSure | Apex Biotechnology Corp. |
| SKUP/2001/14 | Glucose | Precision Xtra | Medisense |
| SKUP/2001/13 | SR | Microsed SR-system | ELECTA-LAB |
| SKUP/2001/12 | CRP | QuikRead CRP | Orion |
| SKUP/2000/11 | PT(INR) | ProTime | ITC International Technidyne Corp |
| SKUP/2000/10 | PT(INR) | AvoSure PT | Avocet Medical Inc. |
| SKUP/2000/9 | PT(INR) | Rapidpoint Coag | |
| SKUP/2000/8* | PT(INR) | Thrombotest/Thrombotrack | Axis-Shield |
| SKUP/2000/7 | PT(INR) | CoaguChek S | Roche Diagnostics |
| SKUP/2000/6 | Haematology | Sysmex KX-21 | Sysmex Medical Electronics Co |
| SKUP/2000/5 | Glucose | Accu-Chek Plus | Roche Diagnostics |
| SKUP/1999/4 | HbA1c | DCA 2000 | Bayer |
| SKUP/1999/3 | HbA1c | NycoCard HbA1c | Axis-Shield PoC AS |
| SKUP/1999/2* | Glucose | Precision QID/Precision Plus Electrode, whole blood calibration | Medisense |
| SKUP/1999/1 | Glucose | Precision G/Precision Plus Electrode, plasma calibration | Medisense |

**For comments regarding the evaluations, please see the indications on the first page**

# SKUP Report

## Comments of Macherey-Nagel

For almost all parameters, the *URYXXON® Relax* test results correlate in a good or acceptable way with the results derived from the two competitor instruments, *Clinitek Status+* and *Urysis 1100*.

For the parameters blood and protein, the report reveals a significant difference between the competitor systems *Clinitek Status+* and *Urysis 1100*. The greatest difference between the two can be found in the protein test results. For this particular parameter, the *URYXXON® Relax* lies in the middle with a slight tendency towards the *Clinitek Status+* results, yielding more positive results than the *Urysis 1100* and more negative results than the *Urysis 1100*.

The correlation of measurements for the parameter blood is very good for the *URYXXON® Relax* and the *Clinitek Status+*. Both systems are less sensitive than the *Urysis 1100*, which yields more positive results. However, measurements with control solution indicate, that the *Urysis 1100* system might be too sensitive.

Due to the differences between the two market leaders, it is impossible to have a good correlation with both systems for all parameters. However, there is no case, in which both the competitors correlate well and MACHEREY-NAGEL shows different test results. Therefore, the test results provided in the report are satisfying for MACHEREY-NAGEL and show the competitiveness of the *URYXXON® Relax* system in comparison with the *Clinitek Status+* and *Urysis 1100*.

In terms of user friendliness, MACHEREY-NAGEL will add an index to the next edition of the manual. Overall, the report confirms that the *URYXXON® Relax* system is highly user friendly.

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