Automated Urine Sediment Analyzer

UriSed 3 PRO

New PHASE with CONTRAST

- Revolutionary particle visualization and recognition utilizing both bright-field and phase contrast microscopy
- Zoomable HPF-like images
- Dual-view for both bright-field and phase contrast images
- Throughput: up to 130 tests/hour
- Fully automated sample preparation requiring only low sample volume
- Manual microscopy mode: Real-time view of any viewfield of the cuvette to see moving microorganisms as well
- No need for liquid reagents or calibrators
- Automated QC analysis and maintenance procedures
- UriSed 3 PRO and LabUMat 2 together make a Complete Urine Laboratory System
- Streamlined documentation by LIS connectivity

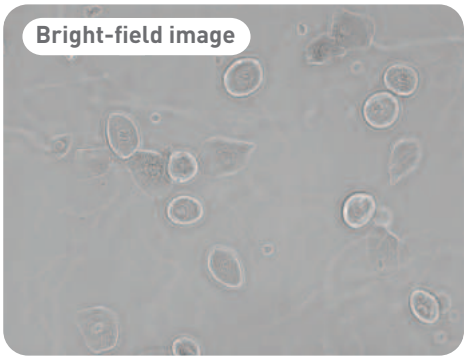
UriSed 3 PRO provides a uniquely advanced visualization and recognition of formed elements in urine sample using a special combination of bright-field and phase contrast microscopy by automating the gold standard method of sediment analysis.
It improves differentiation of hyaline casts, red blood cells, crystals, yeast and overall diagnostic performance in central screening laboratories as well as in specialist laboratories.

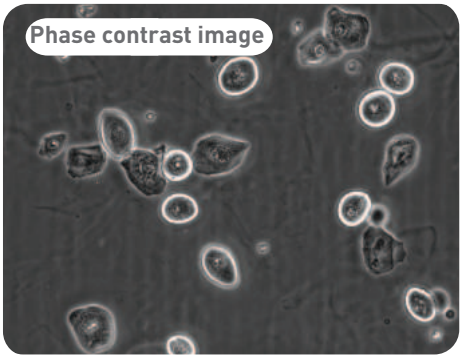
CE For professional Use
IVD

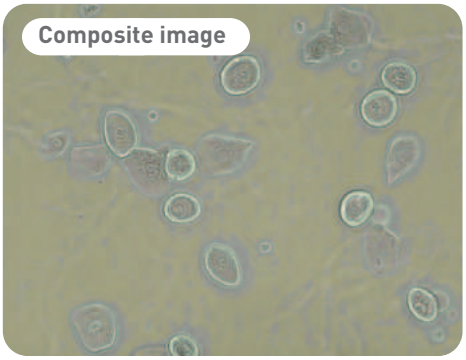
77 Elektronika Kft.

www.tuv.com
TÜVRheinland
ID 9105013356
- Certified Management System
- DIN EN ISO 14001
- EN ISO 13485
- EN ISO 9001

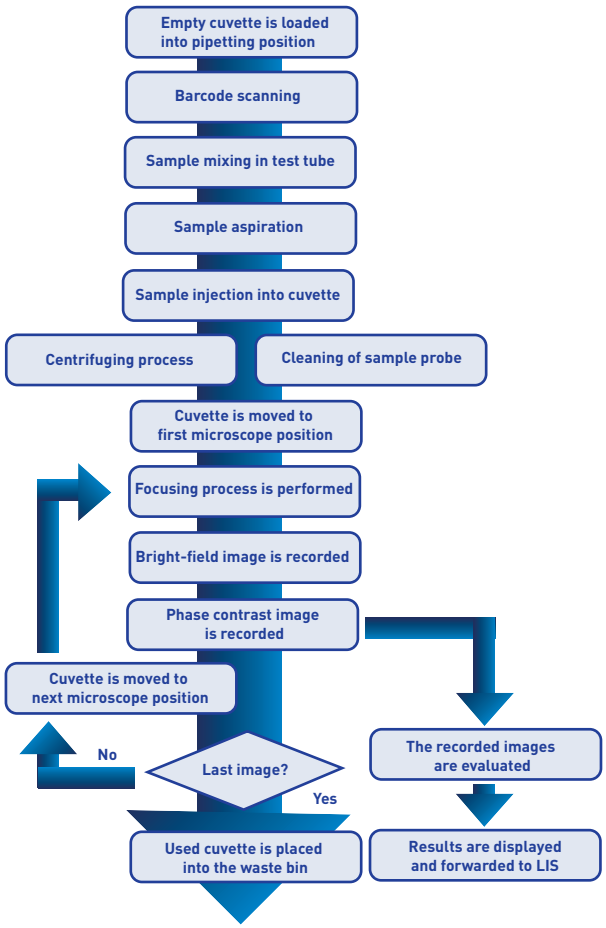
Urine particles with never-seen-before definition and clarity







Patented measurement process



Technical Specifications

Auto-detected particle classes:	Red Blood Cells (RBC); White Blood Cells (WBC); WBC Clumps (WBCc); Hyaline Casts (HYA); Pathological Casts (PAT); Squamous Epithelial Cells (EPI); Non-Squamous Epithelial Cells (NEC); Bacteria Cocci (BACc); Bacteria Rods (BACr); Yeast (YEA); Mucus (MUC); Sperm (SPRM); Crystals (CRY): Calcium-oxalate monohydrate (CaOxm), Calcium-oxalate dihydrate (CaOxd), Uric acid (URI), Triple phosphate (TRI).
Further classes for manual sub-classification are also available!	
Technology:	Cuvette based automated microscopy and image processing
Memory capacity:	10,000 results (including all images)
Throughput:	Up to 130 tests/hour
Magnification:	Zoomable HPF-like images
Displayed images:	Phase contrast, bright-field and composite
Min. sample volume:	2.0 ml (checked by liquid level sensor)
Batch size:	100 test tubes
Barcode reader:	Built-in
Printer:	Optional, external (connected to operating PC)
Interfaces:	USB, LAN, RS232 serial port
LIS connectivity:	LIS2-A2 or HL7
Size:	600 x 640 x 635 mm (W x D x H, without PC)
Weight:	63 kg (without operating PC)
Power (measuring unit):	100-240V AC / 50-60 Hz / max. 200 W
Power (operating PC):	100-127V AC / 47-63 Hz / max. 400 W
	220-240V AC / 47-63 Hz / max. 400 W

The operation of the instrument is based on the patented UriSed Technology. Working without any special liquid reagents, UriSed 3 PRO performs sample preparation, produces whole viewfield microscopic images and evaluates them using the Auto Image Evaluation Module (AIEM), a high-quality image processing software.

Using the phase contrast technology UriSed 3 PRO provides improved performance. It has outstanding visualization and recognition capabilities for every particle type even the ones that conventional bright-field microscopy cannot easily detect (such as casts and ghost red blood cells).

LabUMat 2 & UriSed 3 PRO

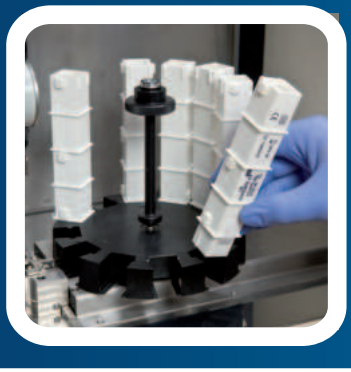
Complete Urine Laboratory System

Chemistry and sediment analysis in one system

The efficiency of LabUMat 2 test strip analyzer and UriSed 3 PRO microscopic sediment analyzer – both manufactured by 77 Elektronika – can be maximized by using the two instruments together as one system.
Common operation is enabled with physical and software connections between LabUMat 2 and UriSed 3 PRO. The results of both measurements are stored in a common database and reported as a common report.
Since all necessary measurements which have to be done on urine samples are completed by this integrated system in one process, the combination of LabUMat 2 and UriSed 3 PRO accelerates laboratory throughput and provides the most effective and reliable solution for complete and professional urine analysis.

All you need for complete urine analysis

LabStripU11 Plus GL test strips for LabUMat 2 (closed system)



Cuvettes for UriSed 3 PRO (closed system)

Normal distilled water

Standard test tubes

Automated Urine Chemistry Analyzer

- Up to 240 tests/hour throughput
- Spotting method: sample dosage by pipetting unit
- Cost-effective operation without any special liquid reagents
- Low sample volume; liquid level detection
- Advanced, patented detection technique
- Separate PMC module for measuring physical parameters
- User friendly and flexible software; easy operation via color touch screen
- Streamlined documentation by LIS connectivity
- Automated QC analysis and self-check
- Software and language upgrades via USB stick

LabUMat 2

Proficiency and efficiency in urinalysis

The LabUMat 2 is a fully automated urine chemistry analyzer evaluating 10 chemical parameters of LabStrip U11 Plus GL test strips and 3 physical parameters. Besides preserving all its former attractive features, the new version of LabUMat has been significantly improved for an even better performance. Continuing its predecessor's mission, LabUMat 2 is a high quality and reliable instrument meeting the requirements of modern automated laboratories and providing walk-away operation. Easy operation via touch screen, automatic handling of test strips and test tubes – including sample mixing and precise dosing for each test pad by the pipetting unit – advanced detection technique and intelligent data management provide maximum efficiency while making urinalysis simple.

About 77 Elektronika

77 Elektronika Kft. is a major global developer, manufacturer and supplier of in vitro diagnostic medical devices, mainly urine analyzers, rapid test readers, blood glucose meters and their consumables. The products are supplied throughout the world under the 77 Elektronika brand and as OEM products for market-leading multinational companies.

77 Elektronika was established in 1986 and is headquartered in Budapest, Hungary (EU). The company is committed to providing superior products and services to the complete satisfaction of its customers.

Technical features

Methodology:	reflectance photometer, 4 discrete wavelengths
Evaluated parameters:	Bilirubin, Urobilinogen, Ketones, Ascorbic acid, Glucose, Protein, Blood, pH, Nitrite, Leucocytes via LabStrip U11 Plus (GL) urine test strip Specific gravity, Color, Turbidity via PMC (Physical Measurement Cell) module
Max. throughput:	up to 240 tests / hour
Batch size:	100 test tubes
Min. sample volume:	2.0 ml (checked by liquid level sensor)
Memory:	max 10,000 results
Display:	800x600 TFT
Size:	600x650x635 mm (LxDxH)
Weight:	55 kg
Input:	100-250V AC / 50-60 Hz
Power consumption:	max 200 W
Interfaces:	USB, RS232 serial port, PS2, VGA
Printer:	built-in thermal printer
Barcode reader:	built-in barcode reader

URP-9303-1
77 Elektronika Kft.
Fehérvári út 98. H-1116 Budapest, Hungary
Sales Hotline: +36-1-481-0139
Phone: +36-1-206-1480 Fax: +36-1-206-1481
E-mail: sales@e77.hu Web: www.e77.hu

77 Elektronika Kft.

EC CERTIFICATE

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV excluding (4, 6)

No. 7-029-400-2002

The **NEOEMKI National Medical Device Conformity Assessment and Certification LLC.** certifies that the manufacturer:

77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

for the products / product categories:

Self-diagnosis systems for the measurement of blood sugar
(blood glucose meters and test strips)

applies a quality system which meets the requirements of Directive 98/79/EC on in vitro diagnostic medical devices, Annex IV.

Registry number of the related audit report: **NE/1006/2020**

This certificate is valid until **2025-02-12** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC. as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 3

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 13 February 2020.

Budapest, 2022-05-03

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI 2832

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate No. 7-029-400-2002

The certificate is valid for the following manufacturing sites / facilities:

77 Elektronika Műszeripari Kft.

H-1116 Budapest, Fehérvári út 98.
H-1116 Budapest, Sztregova utca 1.

The certificate is valid for the following products / models:

Self-diagnosis systems for the measurement of blood sugar (blood glucose meters and test strips)

dc61 **AutoSense** blood glucose meter

dc62 **AutoSense Voice** blood glucose meter

dc68 **AutoSense Plus** blood glucose meter

dc66 **Dcont NEMERE** blood glucose meter

dc67 **Dcont MONDA** blood glucose meter

dc71 **Dcont ETALON** blood glucose meter

dc72 **Dcont NOVUM** blood glucose meter

dc73 **Dcont ETALON B** blood glucose meter

ITB **Ideál Teszt** test strips
for Dcont Ideál, Dcont Ideál +, Dcont TREND, Dcont HUNOR, Dcont MAGOR, Dcont NEMERE and Dcont MONDA blood glucose meters

AST **AutoSense Test** test strips
for AutoSense, AutoSense Voice and AutoSense Plus blood glucose meters

ETN **ETALON Teszt** test strips
for Dcont ETALON, Dcont NOVUM and Dcont ETALON B blood glucose meters

Issue: 3 Date: 2022-05-03 First issued: 2020-02-13

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

Scope: Design and development, production, distribution, installation and servicing of blood glucose measuring systems, urine analyzers and rapid test readers, including related consumables.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design and development, production, distribution, installation and servicing.
/02	77 Elektronika Műszeripari Kft. Telephely Sztregova utca 1 1116 Budapest Hungary	Manufacture and warehouse of blood glucose measuring systems, urine analyzers, related consumables and parts. Manufacturing of SMT technology.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

This Certificate recognizes

Buza Grigorii

as a UriSed 3 PRO, LabUMat 2 and
UriSed mini
Specialist

after having successfully completed the

Service Training Program between

06th - 10th March, 2023.

Máté Tóth
Instructor

77 Elektronika Kft.
Budapest, Hungary

Zsolt Eszes
Service Manager

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1006099-1

Manufacturer: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

Products: In-vitro Diagnostic Medical Devices for self-testing and for professional use:

- SensoCard blood glucose meter
- SensoCard Plus blood glucose meter
- SensoCard Test Strips
- CareSens control solutions

- SensoLite Nova blood glucose meter
- SensoLite Nova Plus blood glucose meter
- SensoLite Nova Test Strips
- CareSens control solutions

- GlucoTalk blood glucose meter
- GlucoTalk Test Strips
- GlucoTalk control solutions

Replaces EC Certificate Registration No. HL 60147430 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 93387425-40

Effective date: 2022-05-24

Expiry date: 2025-03-02

Issue date: 2022-05-24

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1006099-1

Manufacturer: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

The scope of certification includes the following additional sites:

No.	Location	Product groups manufactured
/01	77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Activity: Design and development, distribution, installation and servicing of In-vitro diagnostic medical devices for self-testing and for professional use (blood glucose monitoring systems, urine analyzers).
/02	77 Elektronika Műszeripari Kft. Sztregova út 7. 1116 Budapest Hungary	Activity: Activities related to manufacture of IVDs.
/03	77 Elektronika Műszeripari Kft. Sztregova út 1. 1116 Budapest Hungary	Activity: Activities related to inspection, warehousing and final packaging of IVDs.

Report No.: 93387425-40

Effective date: 2022-05-24

Expiry date: 2025-03-02

Issue date: 2022-05-24

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

Quantimetrix®
Dip&Spin®

Urinalysis Dipstick & Microscopics Control
Level 1&2

Insert Revision 12/2024

LOT 240921 240922 | REF 1470-01 1470-02 | 2026-04-30

IVD | 2°C–8°C | Rx only

English

Intended Use
The Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control is intended as a control for urinalysis reagent strips, microalbumin, and creatinine by the listed test methods, and as a control for confirmatory tests such as **K-CHECK** and **Ictotest®** reagent tablets, and for **hCG** methods.

In addition, the Dip&Spin Control is intended as a means of validating the processing and centrifugation of patient urine samples prior to the microscopic evaluation of urine sediment. For professional use only.

Summary and Explanation
Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method.

Microscopic QC controls must be run each day the test is performed. Standardized microscopic evaluation or urine sediment is an important part of routine analysis or urine. Along with physical and chemical analysis, microscopic examination of urine can provide valuable information regarding not only renal and urinary tract disease, but also metabolic diseases unrelated to the kidney. Urinary sediment microscopy generally includes the detection and identification of red blood cells, leukocytes, epithelial cells, bacteria, casts, and crystals.

Product Description
The Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls are supplied liquid, ready-to-use in two levels. They do not require reconstitution or dilution. They are prepared from human urine to which stabilized human red and white blood cells, calcium oxalate crystals, and other compounds have been added to produce the desired reactions when tested by the methods indicated in the **Intended Use** section. Preservatives have been added to inhibit microbial growth.

Caution
Contains human urine, human blood cells and human Chorionic Gonadotropin (hCG) from pregnancy urine. The human hCG source material and all blood donor units comprising the human cell source material used in the manufacture of this product have been tested and found nonreactive for Hepatitis B Surface Antigen and Hepatitis C and HIV 1 & 2 antibody when tested by FDA accepted methods. No known test method can assure that a product derived from human material does not contain Hepatitis or HIV virus. Handle the QC material as you would a patient sample. QC materials should be used and disposed of in accordance with regulatory and accreditation requirements.

Warning ⚠ Hazard (H) and Precautionary (P) Statements
Contains Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, Level 1; 2,4-Pentanedione, Level 2.
H317 – May cause an allergic skin reaction.
P261 – Avoid breathing vapors, mist, or spray.
P272 – Contaminated work clothing should not be allowed out of the workplace.
P280 – Wear protective gloves, protective clothing, and eye protection.
P302+P352 – IF ON SKIN: Wash with plenty of water.
P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 – Take off contaminated clothing and wash it before reuse.
P501 – Dispose of contents/container in accordance with local, regional, national, and international regulations.
Safety Data Sheet (SDS) available for professional users at **quantimetrix.com.**

Storage and Stability
The Dip&Spin Control Kit should be at 2°C–8°C when not in use. **Do not freeze.** When stored at 2°C–8°C the controls are stable until the expiration date stated on the label. After opening, the controls will remain stable until the expiration date stated on the label when stored at 2°C–8°C between uses. Discard the control if it becomes more turbid or develops a stronger odor. Discard controls in the same manner as other biological specimens, according to local guidelines.

Procedure for Dipstick Urinalysis and Microscopic Evaluation of Urine Sediment
Remove the controls from the refrigerator and replace the cap on the control bottle with the spout cap included in the control box. Allow the control to come to room temperature (18°C–25°C) for approximately 15-90 minutes depending on the volume remaining in the bottle. Mix the controls thoroughly by inverting the bottle at least 20 times to assure homogeneity of the contents. Avoid foaming. Thorough mixing with each use is important in order to obtain reproducible results. Pour 12 mL of the controls into a standard 15 mL centrifuge tube.

For urinalysis, microalbumin and creatinine testing, immerse the reagent strip in the centrifuge tubes containing the control as if they were patient specimens. Read the urinalysis reagent strips, visually or with an instrumental reader, in accordance with the manufacturer's instructions.

For microscopic evaluation of urine sediment, treat the controls as you would patient samples in accordance with the manufacturer's instructions for the standardized microscopic urinalysis system you are using. The National Committee for Clinical Laboratory Standards (NCCLS) recommends the use of standardized systems in order to yield standardized, reproducible results and to enable the reporting of abnormal sediment elements per unit volume.[1]

Procedure for hCG Tests and Confirmatory Tests
Note: The bottles of Level 1 Control are to be used as negative controls for hCG methods. The bottles of Level 2 Control are to be used as positive controls for hCG methods.

Most manufacturers of pregnancy test kits specify the volume of sample to be used with their kits. Many kits include transfer pipets to be used to deliver a certain sample volume onto the test device. It is important that sufficient volume be used to produce the correct test result.

If dispensing the control for hCG tests and confirmatory tests directly from the control bottles, each user should validate that the volume (number of drops) dispensed by the included spout cap is sufficient to meet the pregnancy test kit's and confirmatory tests' requirement for sample volume.

Remove the controls from the refrigerator. Allow the controls to come to room temperature (18°C–25°C) for approximately 15-90 minutes depending on the volume remaining in the bottle. Mix the control thoroughly by inverting the bottle at least 20 times to assure homogeneity of the contents. Avoid foaming. Use the negative and positive controls as if they were patient specimens in accordance with the test kit manufacturer's instructions. If using the same bottle of control dispensed for urinalysis testing and microscopic evaluation, remove the volume of sample to be used for hCG tests and confirmatory tests after centrifugation, before discarding the supernatant and without disturbing the sediment. Immediately close the spout cap and store the controls at 2°C–8°C when not in use.

Expected Values
For visual readings, the expected ranges have been established from interlaboratory data by comparing the dipstick reaction that occurs with the controls to the color comparison chart with multiple lots of each manufacturers' dipsticks or reagent tablets. For expected values for urinalysis reagent strips not listed, please contact Quantimetrix Technical Services.

For instrument readings, the expected ranges have been established from interlaboratory data from multiple lots of each manufacturers' dipsticks. Each laboratory should establish its own precision parameters.

For specific gravity, the expected ranges by refractometer have been established from interlaboratory data.

For hCG, the positive and negative results were obtained by testing each lot number of the controls with multiple lot numbers of different hCG test kits with sensitivities of ≥ 25 mIU/mL.

For microscopic evaluation of urine sediment, the expected ranges for each type of formed element were determined by assay of multiple bottles of the indicated lot by the methods listed. A 12 mL sample volume of the samples were centrifuged at 400 RCF (relative centrifugal force) for 5 minutes. After centrifugation, urine sediment was resuspended in either ~0.5 or ~1.0 mL of remaining supernatant according to the plasticware manufacturer's directions. The ranges listed are based on the range of elements observed in 10 high power fields. Use of other systems or protocols may yield differing results. Each laboratory should establish its own precision parameters.

Limitations
Any future changes made by the manufacturer of a test method may give different values from the indicated range. Detailed information on the limitations of each test method is included in the limitations section of the manufacturers' package insert. Technical updates can be found on our website. The Quality Control Log can be downloaded from the Quantimetrix website at **quantimetrix.com** or contact Tech Support at (310) 536-0006, option 3.

Chemstrip/CombiScreen/Combur/Multistix/Urocheck Users
Colors produced by the **urobilinogen** and/or **bilirubin** reactions on these dipsticks with the Urinalysis Dipstick Control may not be characteristic of those shown on the manufacturer's label when reading the dipstick reactions visually. The urobilinogen reactions are consistent and intensify with the increase in the urobilinogen concentration but may not provide an exact color match to those displayed on the label.

Note: Siemens® CLINITEK 50 and Siemens® STATUS or CLINITEK STATUS PLUS may see an Albumin/Creatinine ratio result of "Abnormal" with the Level 1 control.

The appearance of a macroscopic crystalline precipitate in the product will not affect performance.

Deutsch

Verwendungszweck
Die Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control ist als Kontrolle für Urinanalyse-Reagenzstreifen, Mikroalbumin und Kreatinin gemäß den aufgeführten Testmethoden sowie als Kontrolle für Bestätigungstests wie z. B. **K-CHECK** und **Ictotest®** Reagenz-Tabletten und für **hCG**-Methoden bestimmt.

Darüber hinaus dient die Dip&Spin Control zur Bewertung der Verarbeitung und Zentrifugierung von Patienten-Urinproben vor der mikroskopischen Beurteilung des Urinsediments. Nur für den professionellen Gebrauch.

Zusammenfassung und Erklärung
Kontrollmaterialien mit bekannten Konzentrationen von Komponenten sind ein integraler Bestandteil diagnostischer Verfahren. Im Rahmen der täglichen Überwachung von Kontrollwerten werden laborinterne Parameter für die Genauigkeit und Präzision der Testmethode festgelegt.

An jedem Tag, an dem der Test durchgeführt wird, müssen mikroskopische Qualitätskontrollen (QC) laufen. Die standardisierte mikroskopische Beurteilung von Urinsediment ist ein wichtiger Bestandteil der routinemäßigen Urinanalyse. Zusammen mit der physikalischen und chemischen Analyse kann die mikroskopische Untersuchung des Urins wertvolle Informationen nicht nur über Erkrankungen von Nieren und Harnwegen, sondern auch über von der Niere unabhängige Stoffwechselerkrankungen liefern.Zur mikroskopischen Untersuchung von Urinsediment gehört grundsätzlich der Nachweis und die Identifizierung von roten Blutkörperchen, Leukozyten, Epithelzellen, Bakterien, Ausgüssen und Kristallen.

Produktbeschreibung
Die Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls werden gebrauchsfertig in zwei Stufen ausgeliefert. Es ist keine Rekonstitution oder Verdünnung erforderlich. Sie werden aus menschlichem Urin hergestellt, der mit stabilisierten roten und weißen Blutkörperchen, Kalziumoxalatkristallen und anderen Substanzen angereichert wurde, um die gewünschte Reaktion zu erzeugen, wenn das Produkt gemäß den unter **Verwendungszweck** beschrieben Verfahren eingesetzt wird. Das Produkt wurde mit Konservierungsstoffen angereichert, um mikrobiellem Keimwachstum entgegenzuwirken.

Warnhinweis
Enthält menschlichen Urin, menschliche Blutkörperchen und menschliches Choriongonadotropin (hCG) aus Urin bei Schwangerschaft. Das menschliche hCG-Quellenmaterial und alle bei der Produktherstellung verwendeten Blutspenden, die das menschliche Zellenquellenmaterial beinhalten, wurden unter Einhaltung anerkannter FDA-Methoden auf Hepatitis B-Oberflächenantigene, Hepatitis C und Antikörper gegen HIV 1 & 2 getestet. Die Testergebnisse waren nicht-reaktiv. Es sind keine Testmethoden bekannt, mit denen garantiert werden kann, dass die aus menschlichem Material gewonnenen Produkte frei von Hepatitis- oder HIV-Viren sind. Die Materialen für die Qualitätskontrolle sollten wie Patientenproben gehandhabt werden. Die Materialien müssen im Einklang mit den gesetzlichen Bestimmungen und Zulassungsvorschriften verwendet und entsorgt werden.

Achtung ⚠ Gefahrenhinweise (H) Sicherheitshinweise (P)
Gemisch, 3(2H)-isothiazolone, 5-chloro-2-methyl- mit 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, Stufe-1; 2,4-Pentanedione, Stufe-2.
H317 – Kann allergische Hautreaktionen verursachen.
P261 – Einatmen von Nebel, Dämpfen, Aerosol vermeiden.
P272 – Kontaminierte Arbeitskleidung nicht außerhalb des Arbeitsplatzes tragen.
P280 – Schutzhandschuhe, Schutzkleidung und Augenschutz tragen.
P302+P352 – BEI KONTAKT MIT DER HAUT: Mit viel Wasser waschen.
333+P313 – Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.
P362+P364 – Alle kontaminierten Kleidungsstücke sofort ausziehen und vor erneutem Tragen waschen.
P501 – Inhalt/Behälter entsprechend örtlichen, regionalen, nationalen und internationalen Richtlinien der Entsorgung zuführen.
Sicherheitsdatenblatt (SDB) steht ihnen im Internet unter **quantimetrix.com** zur Verfügung.

Lagerung und Stabilität
Das Dip&Spin Control Kit sollte bei Nichtgebrauch bei 2°C bis 8°C gelagert werden. **Nicht einfrieren**. Bei Lagerung bei 2°C bis 8°C sind die Kontrollen bis zum auf dem Etikett angegebenen Verfallsdatum stabil. Nach dem Öffnen bleiben die Kontrollen bis zum auf dem Etikett angegebenen Verfallsdatum stabil, wenn sie zwischen den Verwendungen bei 2°C bis 8°C gelagert werden. Falls die Kontrolle trüb wird oder einen starken Geruch ausströmt, sollte sie entsorgt werden. Kontrollen auf gleiche Weise wie andere biologische Proben gemäß den örtlichen Richtlinien entsorgen.

Verfahren für Dipstick Urinanalyse und mikroskopische Beurteilung von Urinsediment
Nehmen Sie die Kontrollen aus dem Kühlschrank, und tauschen Sie die Kappe des Kontrollfläschchens gegen den in der Kontrollbox enthaltenen Ausgießverschluss aus. Lassen Sie die Kontrollen je nach der noch im Fläschchen verbleibenden Menge ca. 15 bis 90 Minuten lang auf Raumtemperatur (18°C bis 25°C) aufwärmen. Mischen Sie die Kontrollen gründlich, indem Sie das Fläschchen mindestens 20 Mal umdrehen und so einen homogenen Inhalt sicherstellen. Nicht schäumen lassen. Ein gründliches Mischen vor jeder Verwendung ist unerlässlich, um reproduzierbare Resultate zu erhalten. Gießen Sie 12 ml der Kontrollen in ein standardmäßiges 15 ml Zentrifugenröhrchen.

Zur Urinanalyse, Mikroalbumin- und Creatinin-Testung tauchen Sie den Reagenzstreifen wie bei einer Patientenprobe in das Zentrifugenröhrchen mit der Kontrolle. Die Urinanalyse-Teststreifen visuell oder in einem Lesegerät gemäß den Herstelleranweisungen ablesen.

Zur mikroskopischen Beurteilung von Urinsediment behandeln Sie die Kontrollen wie Patientenproben entsprechend den Herstelleranweisungen für das von Ihnen verwendete, standardisierte, mikroskopische Urinanalysesystem. Das National Committee for Clinical Laboratory Standards (NCCLS) empfiehlt die Verwendung standardisierter Systeme, um standardisierte, reproduzierbare Ergebnisse zu erhalten und die Angabe abnormaler Sedimentbestandteile pro Volumeneinheit zu ermöglichen.[1]

Verfahren für hCG-Tests und Bestätigungstests

Hinweis: Die Fläschchen mit der Level-1-Kontrolle sind bei hCG-Methoden als negative Kontrollen vorgesehen. Die Fläschchen mit der Level-2-Kontrolle sind bei hCG-Methoden als positive Kontrollen vorgesehen.

Die meisten Hersteller von Schwangerschaftstests geben die für ihre Tests benötigte Probenmenge an. Viele Testkits enthalten Pipetten zum Übertragen einer bestimmten Probenmenge auf das Testgerät. Es ist wichtig, dass eine ausreichende Probenmenge verwendet wird, um das richtige Testergebnis zu erzielen.

Falls die Kontrolle für die hCG-Tests und die Bestätigungstests direkt von den Kontrollfläschchen aus verabreicht wird, muss der Benutzer bestätigen, dass die über den Tropfverschluss verabreichte Menge (Anzahl der Tropfen) ausreicht, damit sie die Anforderungen an die Probenmenge für den Schwangerschaftstest und für die Bestätigungstests erfüllt.

Die Kontrollen aus dem Kühlschrank nehmen. Die Kontrollen ca. 15 bis 90 Minuten lang auf Raumtemperatur (18°C bis 25°C) aufwärmen lassen, je nach der noch im Fläschchen verbliebenen Menge. Mischen Sie die Kontrollen gründlich, indem Sie das Fläschchen mindestens 20 Mal umdrehen und so einen homogenen Inhalt sicherstellen. Nicht schäumen lassen. Verwenden Sie die negativen und positiven Kontrollen entsprechend den Herstelleranweisungen des Testkits wie Patienten-Proben. Bei Verwendung der gleichen Flasche der Kontrolle für die Harnanalyse und die mikroskopische Auswertung sollte das für die hCG-Tests bzw. die Bestätigungstests verwendete Probenvolumen nach der Zentrifugierung entfernt werden, bevor der Überstand entsorgt wird. Die Sedimente dürfen dabei nicht aufgeschüttelt werden. Ausgießverschluss sofort verschließen und Kontrollen bei Nichtgebrauch bei 2°C bis 8°C lagern.

Erwartete Werte

Für **visuelle Messungen** wurden die erwarteten Bereiche aus den Daten verschiedener Labors bestimmt, indem die mit den Kontrollen erhaltene Teststäbchenreaktion mit der Farbvergleichstabelle verglichen wurde, die Farben für mehrere Chargen der Teststäbchen bzw. Reagenztabletten jedes Herstellers enthält. Erwartete Werte für nicht aufgeführte Urinanalyse-Reagenzstreifen sind von Quantimetrix Technical Services erhältlich.

Für **Gerätemessungen** wurden die erwarteten Werte anhand von Daten verschiedener Labors und mehreren Chargen von Teststäbchen jedes Herstellers bestimmt. Jedes Labor sollte seine eigenen Präzisionsparameter bestimmen.

Für die **relative Dichte** wurden die mit dem Refraktometer ermittelten, erwarteten Bereiche aus Daten von verschiedenen Labors bestimmt.

Für **hCG** wurden die positiven und negativen Ergebnisse durch Testen jeder Chargennummer der Kontrollen mit mehreren Chargennummern verschiedener hCG-Test-Kits mit Sensitivitäten von ≥ 25 mIE/ml erzielt.

Für die **mikroskopische Beurteilung** von Urinsediment wurden die erwarteten Werte für jede Art von geformten Elementen durch Nachweis mehrerer Fläschchen der angegebenen Charge durch die aufgeführten Methoden bestimmt. Ein Volumen von 12 ml der Probe wurde bei 400 RCF (relative Zentrifugalkraft) 5 Minuten lang zentrifugiert. Nach dem Zentrifugieren wurde das Urinsediment in entweder ~0,5 oder ~1,0 ml des verbleibenden Überstands entsprechend den Herstelleranweisungen resuspendiert. Die angegebenen Bereiche basieren auf dem Bereich von Elementen, die in 10 stark vergrößerten Feldern beobachtet wurden. Die Verwendung anderer Systeme oder Verfahren kann zu abweichenden Resultaten führen. Jedes Labor sollte seine eigenen Präzisionsparameter bestimmen.

Einschränkungen

Alle zu einem späteren Zeitpunkt vom Hersteller einer Testmethode vorgenommenen Änderungen können Abweichungen von dem angegebenen Bereich zur Folge haben. Detaillierte Informationen zu den Einschränkungen der einzelnen Testmethoden sind im Abschnitt Einschränkungen auf der Packungsbeilage des Herstellers aufgeführt. Technische Neuigkeiten entnehmen Sie bitte unserer Website. Sie erhalten das Qualitätskontrollprotokoll durch Herunterladen über die Website von Quantimetrix unter **quantimetrix.com**, oder indem Sie sich an den technischen Support unter der Rufnummer +1 (310) 536-0006, Option 3 wenden.

Chemstrip/CombiScreen/Combur/Multistix/Urocheck-Benutzer

Farben, die durch das **Urobilinogen** erzeugt werden, und/oder **Bilirubin**reaktionen auf diesen Teststäbchen mit der Urinteststäbchen-Kontrolle sind möglicherweise nicht charakteristisch für die auf dem Etikett des Herstellers aufgeführten Werte, wenn die Teststäbchen-Reaktionen visuell abgelesen werden. Die Urobilinogen-Reaktionen sind konsistent und nehmen bei Zunahme der Urobilinogenkonzentration an Intensität zu, stimmen farblich jedoch möglicherweise nicht exakt mit den auf dem Etikett angegebenen Farben überein.

Hinweis: Siemens® CLINITEK 50 und Siemens® STATUS oder CLINITEK STATUS PLUS können bei der Stufe-1-Kontrolle unter Umständen ein „anormales" Albumin/Kreatinin-Verhältnis anzeigen.

Das Auftreten eines makroskopischen kristallinen Niederschlags im Produkt beeinträchtigt die Leistung nicht.

Français

Utilisation prévue

Le Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control a pour fonction de vérifier les bandes de réactif d'analyse d'urine et le dosage de la micro-albumine et de la créatinine selon les méthodes de test indiquées et, de contrôler les tests de confirmation tels ceux des tablettes de réactif **K-CHECK** et **Ictotest®** ainsi que les méthodes **hCG**.

De plus, le contrôle Dip&Spin est conçu comme un moyen de valider le traitement et la centrifugation d'échantillons d'urine de patients avant l'évaluation microscopique du sédiment urinaire. Réservé à un usage professionnel.

Résumé et explication

Les contrôles dont les concentrations d'un composant sont connues font partie intégrante des procédures diagnostiques. Le relevé quotidien des valeurs du contrôle permet d'établir des paramètres de comparaison intralaboratoire garantissant la précision et l'exactitude de la méthode de test.

Les contrôles de qualité microscopiques doivent être effectués chaque jour qu'un test est réalisé. L'évaluation microscopique standardisée du sédiment urinaire représente une part importante de l'analyse d'urine de routine. De même que l'analyse physique et chimique, l'examen microscopique de l'urine peut fournir de précieuses informations concernant non seulement les pathologies rénales et urinaires, mais aussi les maladies métaboliques non liées aux reins. L'examen microscopique du sédiment urinaire comprend généralement la détection et l'identification de globules rouges, de leucocytes, de cellules épithéliales, de bactéries, de cylindres et de cristaux.

Description du produit

Les Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls sont disponibles en deux niveaux sous forme de liquides prêts à l'emploi. Ils ne nécessitent ni reconstitution, ni dilution. Ces contrôles sont élaborés à partir d'urine humaine à laquelle ont été ajoutés des globules rouges et des globules blancs humains stabilisés, des cristaux d'oxalate calcite et d'autres composés afin d'obtenir les réactions désirées lors de tests effectués avec les méthodes indiquées à la section **Utilisation prévue**. Des conservateurs ont également été ajoutés pour inhiber la prolifération microbienne.

Mise en garde

Contient de l'urine humaine, des cellules sanguines humaines et de l'hormone chorionique gonadotrope humaine (hCG) provenant d'urine de femmes enceintes. Les matériels humains de la source d'hCG ainsi que toutes les unités de donneurs de sang composant les matériels sanguins humains utilisés pour la fabrication de ce produit ont fait l'objet de tests conformes aux méthodes approuvées par la FDA. Ils se sont révélés non réactifs à l'antigène de surface de l'hépatite B, ainsi qu'aux anticorps de l'hépatite C et du VIH 1 et 2. Aucune méthode de test connue n'est en mesure de garantir qu'un produit dérivé de matérial humain ne contient pas le virus de l'hépatite ou du VIH. Manipuler les matériels du contrôle de qualité de la même façon que pour un échantillon de patient. Ces matériaux doivent être utilisés et éliminés conformément aux exigences réglementaires et critères d'accréditation.

Attention ⚠ Mentions de danger (H) Conseils de prudence (P)

Mélange , 3(2H)-isothiazolone, 5-chloro-2-methyl- avec 2-methyl-3(2H)-isothiazolone,
1,2-Propylene Glycol, niveau 1; 2,4-Pentanedione, niveau 2.
H317 – Peut causer une réaction allergique cutanée.
P261 – Éviter de respirer les vapeurs, les brouillards ou les aérosols.
P272 – Les vêtements de travail contaminés ne doivent pas quitter le lieu de travail.
P280 – Porter des gants de protection, des vêtements de protection et un dispositif de protection des yeux.
P302+P352 – EN CAS DE CONTACT AVEC LA PEAU : laver à grande eau.
P333+P313 – En cas d'irritation ou d'éruption cutanée : consulter un médecin.
P362+P364 – Enlever les vêtements contaminés et les laver avant réutilisation.
P501 – Éliminer le contenu/contenant conformément aux réglementations locales, régionales, nationales et internationales.
Une ficha de sécurité (SDS) est à disposition des vutilisateurs professionnels sur la site **quantimetrix.com**.

Stockage et stabilité

Le contrôle Dip&Spin doit être entreposé à une température de 2°C–8°C entre deux utilisations. **Ne pas congeler.** Stockés à la température indiquée, les contrôles sont stables jusqu'à la date de péremption figurant sur l'étiquette. Après ouverture, les contrôles resteront stables jusqu'à la date de péremption figurant sur l'étiquette s'ils sont conservés à une température de 2°C–8°C entre deux utilisations. eter le contrôle en cas de traces de turbidité ou d'apparition d'une odeur forte. Jetez les contrôles en procédant comme pour d'autres spécimens biologiques, conformément aux directives locales en vigueur.

Procédure pour analyse d'urine par bandelette réactive et examen microscopique du sédiment urinaire

Sortez les contrôles du réfrigérateur et remettez la capsule sur la bouteille de contrôle, le bouchon verseur étant rangé dans la boîte du contrôle. Patientez pendant 15-90 minutes, en fonction du volume restant dans la bouteille, que le contrôle soit à température ambiante (18°C–25°C). Mélangez bien les contrôles en retournant la bouteille au moins 20 fois pour assurer l'homogénéité de son contenu. Évitez de faire mousser. Il est important de bien mélanger le contrôle avant chaque utilisation pour obtenir des résultats reproductibles. Versez 12 ml de contrôle dans un tube de centrifugation standard de 15 ml.

Pour l'analyse d'urine, de microalbumine et de créatinine, immergez la bandelette réactive dans les tubes de centrifugation contenant le contrôle comme s'il s'agissait d'échantillons de patients. Interprétez les bandelettes réactives d'analyse d'urine, visuellement ou à l'aide d'un lecteur prévu à cet effet, conformément aux instructions du fabricant.

Pour l'évaluation du sédiment urinaire, procédez de la même manière qu'avec des échantillons de patients conformément aux instructions du fabricant pour le système standardisé d'analyse d'urine que vous utilisez. Le National Commitee for Clinical Laboratory Standards (NCCLS) recommande l'utilisation de systèmes standardisés afin de produire des résultats standardisés, reproductibles et de permettre de relever les éléments sédimentaires anormaux par volume unitaire.[1]

Procédure pour tests hCG et test de confirmation

Remarque: Les bouteilles de contrôle de niveau 1 peuvent servir de contrôles négatifs pour les méthodes hCG. Les flacons de contrôle de niveau 2 peuvent servir de contrôles positifs pour les méthodes hCG.

La plupart des fabricants de tests de grossesse précisent le volume d'échantillon à utiliser avec leurs kits. La plupart de ces tests contiennent des pipettes de transfert permettant de déposer un volume précis d'échantillon sur le dispositif de test. Il est important d'utiliser un volume suffisant pour obtenir des résultats de test adéquats.

Si le contrôle des tests hCG et des tests de confirmation est versé directement à partir des flacons de contrôle, chaque utilisateur doit s'assurer que la quantité (nombre de gouttes) distribuée par le bouchon verseur qui est fourni est suffisante pour répondre aux exigences du kit de test de grossesse et des tests de confirmation pour le volume de l'échantillon en question.

Sortez les contrôles du réfrigérateur. Patientez pendant 15-90 minutes, en fonction du volume restant dans la bouteille, jusqu'à ce que le contrôle soit à température ambiante (18°C–25°C). Mélangez bien le contrôle en retournant la bouteille au moins 20 fois pour assurer l'homogénéité de son contenu. Évitez de faire mousser. Traitez les contrôles positif et négatif comme s'il s'agissait d'échantillons prélevés sur des patients conformément aux instructions du fabricant du kit de test hCG. Si vous utilisez le même flacon de contrôle pour les tests d'analyse urinaire et l'évaluation microscopique, retirez le volume d'échantillon qui servira aux tests hCG et aux tests de confirmation après la centrifugation avant de jeter le supernageant et ce, sans troubler les sédiments. Refermez immédiatement le bouchon verseur et entreposez les contrôles à 2°C–8°C entre deux emplois.

Valeurs attendues

Pour les relevés visuels, les plages de valeurs attendues ont été établies à partir de données interlaboratoires en comparant la réaction de la bandelette utilisée pour le contrôle à l'échelle colorimétrique illustrant les lots de bandelettes et de tablettes réactives de chaque fabricant. Pour les valeurs attendues dans le cas des bandelettes réactives d'analyse d'urine non listées, veuillez contacter les services techniques de Quantimetrix.

Pour les relevés d'instruments, les plages de valeurs attendues ont été établies à partir de données interlaboratoires portant sur plusieurs lots de bandelettes réactives de chaque fabricant. Il incombe à chacun de ces laboratoires de déterminer ses propres paramètres de précision.

Pour la densité, les plages de valeurs attendues par réfractomètre ont été établies à partir de données interlaboratoires.

Pour le hCG, les résultats positifs et négatifs ont été obtenus en testant des lots de contrôles de tous types avec des lots de kits de divers test hCG ayant des sensibilités de ≥ 25mUI/ml.

Pour l'analyse microscopique du sédiment urinaire, les plages de valeurs attendues par Chaque type d'élément cellulaire figuré a été déterminé en testant plusieurs bouteilles des lots indiqués par la méthode indiquée. Un volume de 12 ml a été prélevé sur les échantillons et centrifugé à 400 RCF (relative centrifugal force) pendant 5 mn. Après centrifugation, le sédiment urinaire a été remis en suspension dans soit 0,5 soit 1,0 ml du surnageant restant les directives du fabricant de matériel plastique. Les plages de valeurs indiquées sont basées sur les éléments observés dans 10 champs
(hpf). Le recours à d'autres systèmes ou protocoles peut produire des résultats différents. Il incombe à chacun de ces laboratoires de déterminer ses propres paramètres de précision.

Limitations

Tout futur changement apporté par le fabricant d'une méthode de test peut donner lieu à des valeurs différentes de la plage indiquée. Le détail des limites inhérentes à chaque kit de test est décrit à la section Limites de la notice fournie par le fabricant du kit. Les mises à jour techniques sont disponibles sur notre site Web. Vous pouvez télécharger le journal de contrôle de la qualité sur le site Web de Quantimetrix (**quantimetrix.com**) ou contacter l'assistance technique au +1 (310) 536-0006, option 3.

Utilisateurs de bandes Chemstrip/CombiScreen/Combur/Multistix/Urocheck

Les colorations développées par les réactions de **l'urobilinogène** et/ou de la **bilirubine** sur ces bâtonnets avec le contrôle de bâtonnet d'analyse d'urine ne sont pas forcément caractéristiques de celles illustrées sur l'étiquette du fabricant lorsque les réactions des bâtonnets sont interprétées visuellement. Les réactions à l'urobilinogène sont homogènes et s'intensifient si la concentration en urobilinogène augmente, mais il se peut que la couleur ne soit pas exactement celle indiquée sur l'étiquette.

Remarque: les analyseurs CLINITEK 50 Siemens® et STATUS ou CLINITEK STATUS PLUS Siemens® peuvent indiquer un rapport albumine/créatinine « anormal » avec le témoin de niveau 1.

L'apparition d'un précipité cristallin macroscopique dans le produit n'affecte pas la performance.

Italiano

Finalità d'uso

Il Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control è pensato per essere impiegato come un controllo per strisce reattive per l'analisi delle urine, come un controllo per la microalbumina e la creatinina ottenute dai metodi di analisi elencati, e come un controllo per test di conferma a reagenti in compresse quali **K-CHECK** e **Ictotest®**, e per metodi **hCG**.

Inoltre Dip&Spin Control è inteso come mezzo di valutazione del trattamento e della centrifugazione dei campioni di urina del paziente prima dell'esame microscopico del sedimento urinario. Solo per uso professionale.

Riepilogo e spiegazione
Sostanze di controllo con concentrazioni note dei componenti sono parte integrante delle procedure diagnostiche. Il monitoraggio giornaliero dei valori di controllo stabilisce i parametri di accuratezza e di precisione del metodo di analisi del laboratorio.

I controlli microscopici QC devono essere effettuati ogni giorno in cui si esegue il test. La valutazione microscopica standardizzata del sedimento dell'urina è una fase importante dell'analisi di routine o delle urine. Insieme all'analisi fisica e chimica, l'esame microscopico delle urine può fornire un'informazione attendibile non solo sulle patologie renali e del tratto urinario, ma anche su quelle metaboliche non correlate ai reni. L'esame microscopico del sedimento urinario, in genere, comprende la ricerca dei globuli rossi, dei leucociti, delle cellule epiteliali, dei batteri, dei cilindri e dei cristalli.

Descrizione del prodotto
I Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls sono forniti in forma di controlli liquidi e pronti all'uso in due livelli. Non richiedono ricostituzione né diluizione. I controlli sono preparati partendo da urina umana, a cui vengono aggiunti globuli rossi e bianchi umani stabilizzati, cristalli di ossalato di calcio e altri composti, per produrre le reazioni desiderate all'analisi mediante i metodi indicati nella sezione **Finalità d'uso**. Sono stati aggiunti dei conservanti per inibire la crescita microbica.

Attenzione
Contiene urina umana, cellule ematiche umane e gonadotropina corionica umana (hCG) derivante da urina di donne gravide. Il materiale di origine della hCG umana e tutte le unità di sangue di donatore che compongono il materiale di origine a base di cellule umane utilizzato per preparare questo prodotto sono stati testati e trovati non reattivi per l'antigene di superficie dell'epatite B e gli anticorpi contro l'epatite C e l'HIV 1 e 2 quando analizzati con metodi approvati dalla FDA. Non si conoscono metodi di analisi che possano assicurare che un prodotto derivato da materiale umano non contenga i virus dell'epatite o dell'HIV. Trattare il material per CQ come si tratterebbero i campioni di pazienti, I materiali di CQ vanno usati e smaltiti attenendosi ai requisiti normativi e di accreditazione.

Attenzione ⚠ Indicazioni di pericolo (H) Indicazioni precauzionali (P)
Miscela, 3(2H)-isothiazolone, 5-chloro-2-methyl- con 2-methyl-3(2H)-isothiazolone,
1,2-Propylene Glycol, livello 1; 2,4-Pentanedione, livello 2.
H317 – Può provocare una reazione allergica cutanea.
P261 – Evitare di respirare i vapori, la nebbia o le particelle nebulizzate.
P272 – Gli indumenti di lavoro contaminati non devono essere portati fuori dal luogo di lavoro.
P280 – Indossare guanti protettivi, indumenti protettivi e protezioni per gli occhi.
P302+P352 – IN CASO DI CONTATTO CON LA PELLE: lavare abbondantemente con acqua.
P333+P313 – In caso di irritazione o eruzione della pelle: consultare/chiamare un medico.
P362+P364 – Togliere gli indumenti contaminati e lavarli prima del riutilizzo.
P501 – Smaltire i contenuti/il contenitore in conformità alle normative locali, regionali, nazionali e internazionali.
Scheda infomativa sulla sicurezza (SDB) ad uso professionale disponibile al sito **quantimetrix.com**.

Conservazione e stabilità
Il kit Dip&Spin Control deve essere conservato a una temperatura compresa tra 2°C–8°C se non utilizzato. **Non congelare.** Se conservati a temperature comprese fra 2°C e 8°C i controls rimangono stabili fino alla data di scadenza indicata sull'etichetta. Dopo l'apertura della confezione, i controls restano stabili fino alla data di scadenza indicata sull'etichetta, se conservati a temperature comprese tra 2°C–8°C. Smaltire il controllo se acquista ulteriore torbidità o un odore più forte. Eliminare i controlli allo stesso modo degli altri campioni biologici secondo le linee guida, locali.

Procedure di esame delle urine con dipstick e di valutazione microscopica del sedimento urinario
Togliere i controlli dal frigorifero e sostituire il tappo del flacone con il beccuccio in dotazione nella confezione. Lasciare scaldare il controllo a temperatura ambiente (18°C–25°C) per ca. 15-90 minuti in base al contenuto del flacone. Agitare capovolgendo delicatamente il flacone, per garantire l'omogeneità del contenuto. Evitare la formazione di schiuma. È importante miscelare bene il prodotto prima di ogni uso per ottenere risultati riproducibili. Inserire 12 ml di controllo in una provetta da centrifuga standard da 15 ml.

Per effettuare l'esame delle urine, il test della microalbumina e della creatinina, immergere la striscia di reagente nelle provette con il control come se si trattasse di campioni del paziente. Leggere le strisce di esame delle urine o utilizzare uno strumento di lettura in base alle istruzioni del fabbricante.

Per la valutazione microscopica del sedimento urinario trattare i controls come fossero campioni di paziente, in base alle istruzioni del fabbricante e in base al sistema di esame delle urine standardizzato utilizzato. Il National Committee for Clinical Laboratory Standards (NCCLS) consiglia l'uso di sistemi standardizzati al fine di ottenere risultati standardizzati riproducibili e per consentire il rilevamento di elementi di sedimentazione anomali per unità di volume.[1]

Procedure per test hCG e test di conferma
Nota: i flaconi di Control Level 1 devono essere utilizzati come controlli negativi nei metodi hCG. I flaconi di Control Level 2 devono essere utilizzati come controlli positivi nei metodi hCG.

La maggior parte dei fabbricanti di kit di test di gravidanza specifica il volume di campione da usare con i loro kit. Molti kit includono pipette di trasferimento da usare per erogare un determinato volume di campione sul dispositivo di analisi. È importante usare un volume sufficiente per produrre il corretto risultato del test.

Se si eroga il controllo per i test hCG e di conferma direttamente dalle flaconi del controllo, ogni utente dovrebbe convalidare che il volume (numero di gocce) erogato dal beccuccio incluso sia sufficiente per soddisfare il requisito di volume del campione per il kit di test di gravidanza e per i test di conferma.

Togliere i controlli dal frigorifero. Lasciare scaldare i controlli a temperatura ambiente (18°C–25°C) per ca. 15-90 minuti in base al contenuto del flacone. Agitare capovolgendo delicatamente il flacone per almeno 20 volte, al fine di garantire l'omogeneità del contenuto. Evitare la formazione di schiuma. Utilizzare i controlli negativi e positivi come se si trattasse del campione del paziente, in base alle istruzioni del fabbricante del kit di test. Se si usa lo stesso flacone del controllo erogato per le analisi delle urine e per la valutazione microscopica, rimuovere il volume del campione da usare per i test hCG e di conferma dopo la centrifugazione, prima di eliminare il supernatante e senza disturbare il sedimento. Chiudere immediatamente il beccuccio e conservare i controlli a temperature comprese tra 2°C–8°C fra i vari impieghi.

Valori previsti
Per le letture visive, i range previsti sono stati stabiliti attraverso dati di diversi laboratori, confrontando la reazione dei disticks con quelli della carta dei colori, utilizzando diversi lotti di ogni dipstick o di pastiglia reagente dei vari fabbricanti. Per conoscere i valori previsti delle strisce per l'esame delle urine non in elenco, contattare il servizio tecnico Quantimetrix.

In relazione alle letture con appositi strumenti i range previsti sono stati stabiliti da dati di vari laboratori su diversi lotti di ogni fabbricante di dipstick. Ogni laboratorio dovrà stabilire i propri parametri di precisione.

In relazione alla gravità specifica, gli ambiti previsti con l'uso del rifrattometro sono stati stabiliti attraverso i dati di diversi laboratori.

In relazione a hCG, i risultati positivi e negativi sono stati ottenuti testando ogni numero di lotto dei controlli con molteplici numeri di lotto di diversi kit di test hCG con sensibilità di ≥ 25 mIU/ml.

In relazione alla valutazione microscopica del sedimento urinario, gli ambiti previsti per ogni tipo di elemento formato è stato determinato mediante analisi di molteplici flaconi del lotto indicato, utilizzando il metodo elencato. 12 ml di campione sono stati centrifugati a 400 RCF (forza centrifuga relativa) per 5 minuti. Dopo la centrifugazione il sedimento urinario è stato risospeso in ~0,5 o ~1,0 ml del supernatante restante, in base alle istruzioni del fabbricante dell'articolo di plastica. Gli ambiti elencati fanno riferimento al range degli elementi osservati in 10 campi ad alto ingrandimento. L'impiego di altri sistemi o protocolli può portare a risultati differenti. Ogni laboratorio dovrà stabilire i suoi propri parametri di precisione.

Limiti
Eventuali futuri cambiamenti apportati dal fabbricante di un metodo di analisi potrebbero dare valori diversi dall'intervallo di valori indicato. Informazioni dettagliate sui limiti di ciascun metodo di analisi sono incluse nella sezione Limiti dell'inserto informativo del fabbricante. Aggiornamenti tecnici sono reperibili sul nostro sito web. Il registro del controllo della qualità si può ottenere scaricandolo dal sito web Quantimetrix all'indirizzo **quantimetrix.com** oppure contattando il team del Supporto tecnico al numero +1 (310) 536-0006, opzione 3.

Utilizzatori di Chemstrip/CombiScreen/Combur/Multistix/Urocheck
I colori prodotti dalle reazioni di **urobilinogeno** e/o **bilirubina** su questi dipstick con il Controllo dipstick urina potrebbero non rispecchiare quelli illustrati sull'etichetta del fabbricante quando le reazioni del dipstick vengono lette visivamente. Le reazioni dell'urobilinogeno sono costanti e aumentano di intensità all'aumentare della concentrazione di urobilinogeno ma è possibile che non vi sia un'esatta corrispondenza di colore con quelle mostrate sull'etichetta.

Nota: Siemens® CLINITEK 50 e Siemens® STATUS o CLINITEK STATUS PLUS potrebbero riscontrare risultati "Anomali" per il rapporto albumina/creatinina con il controllo di Livello 1.

La comparsa di precipitato cristallino macroscopico nel prodotto non ne pregiudica le prestazioni.

Español
Uso previsto
El Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control se utiliza como control para las tiras reactivas de análisis de orina, microalbúmina y creatinina por los métodos indicados, y como control de pruebas de confirmación como las tabletas reactivas **K-CHECK** e **Ictotest**® y para los métodos de detección de **hCG**.

Además, el Dip&Spin Control se utiliza para validar el procesado y centrifugado de muestras de orina de pacientes antes de la evaluación microscópica de la sedimentación presente en la orina. Solo para uso profesional.

Resumen y explicación
Los materiales de control que tienen concentraciones conocidas del componente forman parte integral de los procedimientos diagnósticos. La monitorización diaria de los valores de control establece los parámetros de exactitud y precisión del método de análisis en cada laboratorio.

Los controles microscópicos de control de calidad deben realizarse cada día que se lleva a cabo la prueba. La evaluación microscópica normalizada de la sedimentación presente en la orina es una parte importante del análisis rutinario de la orina. Junto con el análisis físico y químico, el estudio microscópico de la orina puede aportar valiosa información no sólo sobre enfermedades renales y del tracto urinario, sino también sobre enfermedades metabólicas que no tengan relación alguna con el riñon. El estudio microscópico de la sedimentación presente en la orina generalmente incluye la detección e identificación de hematíes, leucocitos, células epiteliales, bacterias, cilindros y cristales.

Descripción del producto
Los Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls se suministran líquidos, listos para usar en dos niveles. No requieren reconstitución o dilución. Están preparados a partir de orina humana a la que se han agregado glóbulos humanos rojos y blancos estabilizados, cristales de oxalato de calcio y otros compuestos para producir las reacciones deseadas cuando se prueban con los métodos indicados en la sección **Uso previsto**. Se han agregado conservantes para inhibir la proliferación microbiana.

Precaución
Contiene orina humana, células sanguíneas humanas y gonadotropina coriónica humana (hCG) de la orina del embarazo. El material fuente del hCG humano y de todas las unidades donantes de sangre que comprenden el material fuente de células humanas utilizado en la fabricación de este producto se ha probado y no se ha detectado ningún reactivo para el antígeno de superficie de la Hepatitis B ni anticuerpos de Hepatitis C y VIH 1 y 2 cuando las pruebas se realizan con métodos aceptados por la FDA. Ningún método de prueba conocido puede asegurar que un producto derivado de material humano no contenga hepatitis o virus VIH. Trabaje con el material QC como lo haría con una muestra de paciente. Los materiales QC deben usarse y eliminarse de acuerdo con los requisitos reglamentarios y de acreditación.

Atención ⚠ Indicaciones de peligro (H) Consejos de precaución (P)
Mezcla, 3(2H)-isothiazolone, 5-chloro-2-methyl- con 2-methyl-3(2H)-isothiazolone,
1,2-Propylene Glycol, nivel 1; 2,4-Pentanedione, nivel 2.
H317 – Puede causar una reacción alérgica cutánea.
P261 – Evite respirar vapores, niebla o aerosol.
P272 – La ropa de trabajo contaminada no debe sacarse del lugar de trabajo.
P280 – Lleve guantes, prendas y gafas de protección.
P302+P352 – EN CASO DE CONTACTO CON LA PIEL: lave con agua abundante.
P333+P313 – Si aparece irritación o erupción cutánea: consulte a un médico.
P362+P364 – Quítese la ropa contaminada y lávela antes de volver a utilizarla.
P501 – Elimine el contenido/contenedor conforme a la normativa local, regional, nacional e internacional vigente.
Le hoja de datos de seguridad (SDB) está disponible para los usarios profesionales en **quantimetrix.com**.

Almacenamiento y estabilidad
El Dip&Spin Control Kit deberá almacenarse a 2°C–8°C cuando no se utilice. **No congelar.** Cuando se almacenan a 2°C–8°C, los controles permanecen estables hasta la fecha de caducidad que figura en la etiqueta. Una vez abiertos, los controles permanecerán estables hasta la fecha de caducidad que figura en la etiqueta cuando se almacenen a 2°C–8°C después de cada uso. Deseche el control si se vuelve más turbio o si desarrolla un olor más fuerte. Desechar los controles de la misma forma que cualquier otra muestra biológica, conforme a las normativas locales.

Procedimiento para el análisis de orina con tira reactiva y la evaluación microscópica de la sedimentación presente en la orina
Extraiga los controles de la nevera y sustituya la tapa del frasco de control por la tapa del surtidor incluida en la caja de control. Deje que el control se estabilice a temperatura ambiente (18 °C–25 °C) durante aproximadamente 15-90 minutos, dependiendo del volumen que quede en el frasco. Mezcle bien los controles invirtiendo el frasco por lo menos 20 veces para garantizar la homogeneidad del contenido. Evite la formación de espuma. Para poder obtener resultados reproducibles, es importante mezclar bien los controles cada vez que se utilicen. Vierta 12 ml de los controles en un tubo de centrífuga estándar de 15 ml.

Para los análisis de orina, microalbuminuria y creatinina, sumerja la tira reactiva en los tubos de centrífuga que contienen el control, igual que si fueran muestras de pacientes. Lea las tiras reactivas de análisis de orina, visualmente o con un instrumento lector, de acuerdo con las instrucciones del fabricante.

Para la evaluación microscópica de la sedimentación presente en la orina, los controles deberán tratarse como si fueran muestras de pacientes, de acuerdo con las instrucciones del fabricante para el sistema microscópico normalizado de análisis de orina que esté utilizando. El National Committee for Clinical Laboratory Standards (NCCLS) recomienda el empleo de sistemas normalizados con el fin de obtener resultados reproducibles y normalizados, y poder detectar e informar acerca de la presencia de elementos anormales en la sedimentación en cada volumen unitario.[1]

Procedimiento para los ensayos de hCG y los ensayos de confirmación
Nota: Los frascos de control de concentración 1 se deben usar como controles negativos de los métodos de hCG. Los frascos de control de concentración 2 se deben usar como controles positivos de los métodos de hCG.

La mayoría de los fabricantes de kits de prueba de embarazo especifican el volumen de muestra a utilizar en sus kits. Muchos kits incluyen pipetas de transferencia que se utilizan para suministrar un determinado volumen de muestra en el dispositivo de prueba. Es importante que se use suficiente volumen para producir el resultado correcto de la prueba.

Si el control para pruebas hCG y pruebas confirmatorias se dispensa directamente desde de los frascos de los controles, cada usuario debe validar que el volumen (cantidad de gotas) dispensado por la tapa del surtidor sea suficiente para cumplir con los requisitos del kit de prueba de embarazo y las pruebas confirmatorias.

Extraiga los controles de la nevera. Deje que los controles se estabilicen a temperatura ambiente (18 °C–25 °C) durante aproximadamente 15-90 minutos, dependiendo del volumen que quede en el frasco. Mezcle bien los controles invirtiendo el frasco por lo menos 20 veces para garantizar la homogeneidad del contenido. Evite la formación de espuma. Use los controles positivo y negativo como si fueran muestras de paciente, de acuerdo con las instrucciones del fabricante del kit de análisis. Si el mismo frasco de control dispensado se utiliza para las pruebas de análisis de orina y la evaluación microscópica, retire el volumen de muestra a utilizar en las pruebas de hCG y las pruebas de confirmación después del centrifugado, antes de descartar el sobrenadante y sin perturbar el sedimento. Cierre inmediatamente la tapa del surtidor y almacene los controles a 2 °C–8 °C cuando no se utilicen.

Valores esperados

En el caso de lecturas visuales, los intervalos esperados se han establecido a partir de datos de varios laboratorios, comparando la reacción de la tira reactiva que se produce con los controles, con la carta de comparación de colores de varios lotes de tiras reactivas o tabletas de reactivo de cada fabricante. En cuanto a los valores esperados de las tiras de reactivo para análisis de orina que no figuren, póngase en contacto con el Servicio Técnico de Quantimetrix.

En el caso de lecturas con instrumento, los intervalos esperados se han establecido a partir de datos obtenidos en varios laboratorios con múltiples lotes de tiras reactivas de cada fabricante. Cada laboratorio deberá establecer sus propios parámetros de precisión.

En el caso del peso específico, los intervalos esperados con el refractómetro se han establecido a partir de datos obtenidos en varios laboratorios.

En el caso de hCG, los resultados positivo y negativo se obtuvieron analizando cada número de lote de los controles con múltiples números de lote de diferentes kits de análisis de hCG con sensibilidades de ≥ 25 mUI/ml.

En el caso de la evaluación microscópica de la sedimentación presente en la orina, los intervalos esperados para cada tipo de elemento formado se determinaron mediante valoración de varios frascos del lote indicado por medio de los métodos listados. Se centrifugó un volumen de las muestras de 12 ml a 400 RCF (fuerza centrífuga relativa) durante 5 minutos. Tras la centrifugación, la sedimentación presente en la orina se volvió a suspender en ~0,5 o ~1,0 ml del sobrenadante restante, de acuerdo con las instrucciones del fabricante de los plásticos. Los intervalos listados se basan en el intervalo de elementos observados en 10 campos de gran aumento. El uso de otros sistemas o protocolos puede arrojar resultados distintos. Cada laboratorio deberá establecer sus propios parámetros de precisión.

Limitaciones

Cualquier cambio futuro realizado por el fabricante de un método de prueba puede dar valores diferentes del rango indicado. En la sección de limitaciones del prospecto del fabricante se incluye información detallada sobre las limitaciones de cada método de prueba. En nuestro sitio web se pueden encontrar las actualizaciones técnicas. El registro de control de calidad se puede descargar en el sitio web de Quantimetrix en **quantimetrix.com** o poniéndose en contacto con el Soporte técnico en el +1 (310) 536-0006, opción 3.

Usuarios de Chemstrip/CombiScreen/Combur/Multistix/Urocheck

Los colores producidos por las reacciones al **urobilinógeno** y/o a la **bilirrubina** en esas tiras reactivas con el Control de tiras reactivas en orina podrían no ser características de las que se indican en la etiqueta del fabricante al leer visualmente las reacciones en la tira reactiva. Las reacciones de urobilinógeno son coherentes y se intensifican cuando aumenta la concentración de urobilinógeno, pero puede que no den colores exactamente iguales a los que se muestran en la etiqueta.

Nota: Siemens® CLINITEK 50 y Siemens® STATUS o CLINITEK STATUS PLUS pueden ver un resultado en la proporción de albúmina/creatinina calificado de "Anormal" con el control de Nivel 1.

La aparición de un precipitado cristalino macroscópico en el producto no afecta al rendimiento.

Polski

Przeznaczenie

Kontrole Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control są przeznaczone do stosowania jako kontrole dla pasków odczynnikowych do badania ogólnego moczu, oznaczania mikroalbuminy i kreatyniny za pomocą wymienionych metod testowych oraz jako kontrole do oznaczeń potwierdzających, takich jak **K-CHECK** i tabletki odczynnikowe **Ictotest®** oraz dla metod **hCG**.

Ponadto kontrola Dip&Spin Control może być także stosowana jako środek służący do walidacji przetwarzania i wirowania próbek moczu pacjenta przed mikroskopową oceną osadu moczu. Tylko do użytku profesjonalnego.

Podsumowanie i wyjaśnienie

Materiały kontrolne o znanych stężeniach składnika stanowią integralną część procedur diagnostycznych. Codzienne monitorowanie wartości kontrolnych pozwala ustalić wewnątrzlaboratoryjne parametry dokładności i precyzji dla metody testu.

Mikroskopowe kontrole KJ należy wykonywać każdego dnia, kiedy wykonywane są badania. Standaryzowana mikroskopowa ocena osadu moczu stanowi ważną część rutynowej analizy moczu. Obok analizy fizycznej i chemicznej badanie mikroskopowe moczu może dostarczyć cennych informacji nie tylko na temat chorób nerek i dróg moczowych, lecz także na temat chorób metabolicznych niezwiązanych z nerkami. Mikroskopowe badanie osadu moczu obejmuje zazwyczaj wykrywanie oraz identyfikację krwinek czerwonych, leukocytów, komórek nabłonka, bakterii, wałeczków i kryształów.

Opis produktu

Kontrole Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls są dostarczane w postaci płynnej, gotowej do użycia w dwóch poziomach. Nie wymagają one rekonstytucji ani rozcieńczania. Odczynniki te są przygotowywane z moczu ludzkiego, do którego dodano stabilizowane ludzkie krwinki czerwone i białe, kryształy szczawianu wapnia oraz inne substancje w celu uzyskania pożądanych reakcji po wykonaniu oznaczenia z użyciem metod opisanych w punkcie „Przeznaczenie". Do produktu dodano także środki konserwujące, aby zahamować wzrost drobnoustrojów.

Przestroga

Zawiera mocz ludzki, ludzkie krwinki oraz ludzką gonadotropinę kosmówkową (hCG) uzyskaną z próbek moczu kobiet w ciąży. Ludzki materiał źródłowy hCG oraz wszystkie jednostki krwi pobrane od dawców i tworzące materiał źródłowy komórek ludzkich stosowany do wytwarzania tego produktu został przetestowany z użyciem metod akceptowanych przez FDA i uznany za niereaktywny w przypadku antygenu powierzchniowego wirusa zapalenia wątroby typu B i C oraz przeciwciała przeciwko wirusowi HIV 1 i 2. Żadna znana metoda testowa nie daje pewności, że produkt uzyskiwany z materiału pochodzenia ludzkiego nie zawiera wirusów zapalenia wątroby lub HIV. Z materiałem KJ należy postępować tak samo jak z próbką pobraną od pacjenta. Materiały KJ należy stosować i usuwać zgodnie z wymaganiami przepisów i wymaganiami dotyczącymi akredytacji.

Ostrzeżenia ⚠ o zagrożeniach (H) i zwroty wskazujące środki ostrożności (P)

Zawiera mieszaninę, 3(2H)-izotiazolonu, 5-chloro-2-metylo- z 2-metylo-3(2H)-izotiazolonem, 1,2-propylenowy glikol, poziom 1; 2,4-pentanedion, poziom 2.
H317 – Może powodować reakcję alergiczną skóry.
P261 – Unikać wdychania gazu / mgły / rozpylonej cieczy.
P272 – Zanieczyszczonej odzieży ochronnej nie wynosić poza miejsce pracy.
P280 – Stosować rękawice ochronne / odzież ochronną / ochronę oczu.
P302+P352 – W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.
P333+P313 – W przypadku wystąpienia podrażnienia skóry lub wysypki: zasięgnąć porady / zgłosić się pod opiekę lekarza.
P362+P364 – Zdjąć zanieczyszczoną odzież i uprać ją przed ponownym użyciem.
P501 – Zawartość/pojemnik usuwać zgodnie z przepisami miejscowymi, regionalnymi, krajowymi i międzynarodowymi.
Karta charakterystyki substancji (SDS) jest dostępna dla użytkowników profesjonalnych na stronie **quantimetrix.com.**

Przechowywanie i stabilność

Nieużywany zestaw kontroli Dip&Spin powinien być przechowywany w temperaturze 2–8°C. **Nie zamrażać**. W przypadku przechowywania w temperaturze 2–8°C kontrole zachowują stabilność do daty ważności wskazanej na etykiecie. Po otwarciu kontrole zachowują stabilność do daty ważności podanej na etykiecie pod warunkiem ich przechowywania w temperaturze 2–8°C pomiędzy kolejnymi zastosowaniami. Kontrolę należy wyrzucić, jeśli dojdzie do jej zmętnienia lub pojawi się silniejszy zapach. Kontrole należy wyrzucać tak samo jak inne próbki biologiczne, zgodnie z lokalnymi wytycznymi.

Procedura paskowego badania ogólnego moczu i mikroskopowego badania osadu moczu

Należy wyjąć kontrole z lodówki, zdjąć zatyczkę z butelki i założyć na nią zatyczkę do wylewek dołączoną do opakowania kontroli. Pozostawić kontrolę do osiągnięcia temperatury pokojowej (18–25°C) przez mniej więcej 15-90 minut, w zależności od ilości odczynnika pozostającej w butelce. Dokładnie wymieszać kontrole, odwracając butelkę co najmniej 20 razy, aby zapewnić jednorodność jej zawartości. Unikać tworzenia piany. Dokładne wymieszanie przed każdym użyciem jest ważne dla zapewnienia powtarzalności wyników. Wlać 12 ml kontroli do standardowej probówki wirówkowej o pojemności 15 ml.
W przypadku badania ogólnego moczu, oznaczenia mikroalbuminy i kreatyniny zanurzyć pasek odczynnikowy w probówkach wirówkowych zawierających kontrolę tak, jakby były to próbki pobrane od pacjentów. Paski z odczynnikami do badania ogólnego moczu należy odczytać wzrokowo lub za pomocą czytnika, zgodnie z instrukcjami wydanymi przez producenta.
W przypadku mikroskopowej oceny osadu moczu kontrole należy traktować tak jak próbki pobrane od pacjenta, zgodnie z instrukcjami wydanymi przez producenta stosowanego standaryzowanego systemu mikroskopowego badania ogólnego moczu. Krajowa Komisja ds. Laboratoryjnych Norm Klinicznych (National Committee for Clinical Laboratory Standards, NCCLS) zaleca stosowanie standaryzowanych systemów w celu uzyskiwania standaryzowanych, powtarzalnych wyników oraz aby umożliwić podawanie nieprawidłowego składu osadu w przeliczeniu na jednostkę objętości[1].

Procedura badań w kierunku hCG i badań potwierdzających

Uwaga: Butelki z kontrolą poziomu 1 są przeznaczone do stosowania jako kontrole ujemne w przypadku metod oznaczania hCG. Butelki z kontrolą poziomu 2 są przeznaczone do stosowania jako kontrole dodatnie w przypadku metod oznaczania hCG.

Większość producentów testów ciążowych określa objętość próbki, jakiej należy użyć. Wiele zestawów zawiera pipety, których należy użyć do przeniesienia określonej objętości próbki na urządzenie testowe. Do uzyskania prawidłowego wyniku testu konieczne jest użycie wystarczającej objętości próbki.

W przypadku pobierania kontroli do testu w kierunku hCG i testów potwierdzających bezpośrednio z butelek z odczynnikiem kontrolnym każdy użytkownik powinien potwierdzić, że objętość (liczba kropli) pobrana za pomocą dołączonej zatyczki do wylewek jest wystarczająca, aby spełnić wymaganie w zakresie objętości próbki dla zestawów testów ciążowych i testów potwierdzających.

Wyjąć kontrole z lodówki. Pozostawić kontrole do osiągnięcia temperatury pokojowej (18–25°C) przez mniej więcej 15–90 minut, w zależności od ilości odczynnika pozostającej w butelce. Dokładnie wymieszać kontrolę, odwracając butelkę co najmniej 20 razy, aby zapewnić jednorodność jej zawartości. Unikać tworzenia piany. Kontroli ujemnej i dodatniej należy użyć tak jak próbek pobranych od pacjenta, zgodnie z instrukcjami dołączonymi przez producenta do zestawu testu. W przypadku korzystania z tej samej butelki z kontrolą do badania ogólnego moczu i badania mikroskopowego, należy usunąć objętość próbki, jaka ma zostać użyta do badań w kierunku hCG i badań potwierdzających po wirowaniu i przed wyrzuceniem supernatantu, uważając, aby nie poruszyć osadu. Natychmiast zamknąć zatyczkę do wylewek i przechowywać kontrole w temperaturze 2–8°C (kiedy nie są używane).

Wartości oczekiwane

W przypadku odczytów wizualnych oczekiwane zakresy ustalono na podstawie danych z różnych laboratoriów, porównując reakcję paskową, która występuje w przypadku kontroli z kartą porównawczą kolorów dla wielu partii pasków lub tabletek odczynnikowych każdego producenta. Aby uzyskać informacje na temat oczekiwanych wartości dla niewymienionych pasków odczynnikowych do badania ogólnego moczu, należy skontaktować się z serwisem technicznym firmy Quantimetrix.

W przypadku odczytów instrumentu oczekiwane zakresy ustalono na podstawie danych z różnych laboratoriów dla wielu partii pasków każdego producenta. Każde laboratorium powinno ustalić własne parametry precyzji.

W przypadku ciężaru właściwego oczekiwane zakresy według refraktometru ustalono na podstawie danych z różnych laboratoriów.

W przypadku hCG wyniki dodatnie i ujemne uzyskano, oznaczając każdą partię kontroli z wieloma partiami różnych zestawów w kierunku oznaczenia hCG o czułości ≥ 25 mIU/ml.

W przypadku mikroskopowej oceny osadu moczu oczekiwane zakresy dla każdego typu elementów morfotycznych ustalono na podstawie oznaczenia z użyciem wielu butelek wskazanej partii za pomocą wymienionych metod. Próbka o objętości 12 ml została odwirowana z prędkością 400 RCF (względna siła wirowania) przez 5 minut. Po wirowaniu osad moczu ponownie zawieszono w mniej więcej 0,5 lub 1,0 ml pozostałego supernatantu zgodnie ze wskazówkami producenta naczyń plastikowych. Wymienione zakresy są oparte na zakresach elementów obserwowanych pod 10-krotnym powiększeniem. Użycie innych systemów lub protokołów może dać odmienne wyniki. Każde laboratorium powinno ustalić własne parametry precyzji.

Ograniczenia

Wszelkie zmiany wprowadzone w przyszłości przez producenta metody testowej mogą doprowadzić do uzyskania wartości spoza wskazanego zakresu. Szczegółowe informacje na temat ograniczeń poszczególnych metod testowych można znaleźć w punkcie „Ograniczenia" w ulotce dołączonej do opakowania przez producenta. Informacje o aktualizacjach technicznych można znaleźć w naszej witrynie internetowej. Dziennik kontroli jakości można pobrać z witryny internetowej firmy Quantimetrix pod adresem **quantimetrix.com** lub kontaktując się z działem pomocy technicznej pod numerem telefonu (310) 536-0006, opcja 3.

Użytkownicy Chemstrip/CombiScreen/Combur/Multistix/Urocheck

Zabarwienie generowane przez reakcje **urobilinogenu** i/lub **bilirubiny** na tych paskach testowych po użyciu kontroli do paskowego badania ogólnego moczu mogą być niecharakterystyczne dla przedstawionych na etykiecie przez producenta w przypadku wzrokowego odczytywania wyniku reakcji na paskach testowych. Reakcje urobilinogenu są powtarzalne i ulegają intensyfikacji ze wzrostem stężenia urobilinogenu, ale mogą nie dać dokładnie takiego zabarwienia, jakie zostało wskazane na etykiecie.

Uwaga: W przypadku kontroli poziomu 1 urządzenia Siemens® CLINITEK 50 i Siemens® STATUS lub CLINITEK STATUS PLUS mogą wyświetlić wynik dla stosunku albumina/kreatynina jako „nieprawidłowy".

Obecność makroskopowego osadu krystalicznego nie ma wpływu na działanie produktu.

Analytes/Method	Level 1 - 240921	Level 2 - 240922	Units
Red Blood Cells (Erythrocytes)			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	0 - 25	5 - 145	p/µL
Teco UriScope 50 / COBIO Variants	2 - 16	54 - 123	p/µL
Mindray EU-5600, EU-5300, EU-3000	0 - 25	20 - 100	p/µL
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	0 - 25	33 - 95	p/µL
Mindray EU-5300 Pro, EU-5600 Pro	0 - 25	35 - 93	p/µL
YD Diagnostics URiSCAN PLUSCOPE	0 - 50	0 - 200	p/µL
ROCHE cobas 6500 (cobas u 701)	0 - 25	30 - 90	p/µL
KOVA® GLASSTIC® SLIDE 10 with GRIDS	1 - 12	29 - 140	p/µL
Non-grid slides (~0.5 mL)	0 - 8	6 - 45	p/hpf
Non-grid slides (~1.0 mL)	0 - 4	3 - 24	p/hpf
Slide & Coverslip (~0.5 mL)	0 - 5	2 - 23	p/hpf
Slide & Coverslip (~1.0 mL)	0 - 4	1 - 15	p/hpf
FisherBrand UriSystem DeciSlide	0 - 5	2 - 23	p/hpf
White Blood Cells (Leukocytes)			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	0 - 25	10 - 85	p/µL
Teco UriScope 50 / COBIO Variants	0 - 9	19 - 38	p/µL
Mindray EU-5600, EU-5300, EU-3000	0 - 25	0 - 60	p/µL
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	0 - 20	0 - 40	p/µL
Mindray EU-5300 Pro, EU-5600 Pro	0 - 20	0 - 40	p/µL
YD Diagnostics URiSCAN PLUSCOPE	0 - 50	0 - 200	p/µL
ROCHE cobas 6500 (cobas u 701)	0 - 25	23 - 71	p/µL
KOVA® GLASSTIC® SLIDE 10 with GRIDS	0 - 9	14 - 55	p/µL
Non-grid slides (~0.5 mL)	0 - 7	3 - 24	p/hpf
Non-grid slides (~1.0 mL)	0 - 4	2 - 11	p/hpf
Slide & Coverslip (~0.5 mL)	0 - 4	0 - 10	p/hpf
Slide & Coverslip (~1.0 mL)	0 - 4	0 - 9	p/hpf
FisherBrand UriSystem DeciSlide	0 - 4	1 - 9	p/hpf
Casts			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	may be present	
Teco UriScope 50 / COBIO Variants	Data not available		
ROCHE cobas 6500 (cobas u 701)	none	none	
Mindray EU-5600, EU-5300, EU-3000	none	none	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	none	none	
Mindray EU-5300 Pro, EU-5600 Pro	none	none	
YD Diagnostics URiSCAN PLUSCOPE	none	none	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	none	none	
Non-grid slides (~0.5 mL)	none	none	
Non-grid slides (~1.0 mL)	none	none	
Slide & Coverslip (~0.5 mL)	none	none	
Slide & Coverslip (~1.0 mL)	none	none	
FisherBrand UriSystem DeciSlide	none	none	
Crystals			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	present	
Teco UriScope 50 / COBIO Variants	Data not available		
Mindray EU-5600, EU-5300, EU-3000	none	present	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	may be present	present	
Mindray EU-5300 Pro, EU-5600 Pro	none	present	
YD Diagnostics URiSCAN PLUSCOPE	none	may be present	
ROCHE cobas 6500 (cobas u 701)	negative	positive	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	none	present	
Non-grid slides (~0.5 mL)	none	present	
Non-grid slides (~1.0 mL)	none	present	
Slide & Coverslip (~0.5 mL)	none	present	
Slide & Coverslip (~1.0 mL)	none	present	
FisherBrand UriSystem DeciSlide	none	present	
Bacteria			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	present	
Teco UriScope 50 / COBIO Variants	Data not available		
Mindray EU-5600, EU-5300, EU-3000	may be present	present	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	may be present	present	
Mindray EU-5300 Pro, EU-5600 Pro	may be present	present	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	may be present	present	
Non-grid slides (~0.5 mL)	may be present	present	
Non-grid slides (~1.0 mL)	may be present	present	
Slide & Coverslip (~0.5 mL)	may be present	present	
Slide & Coverslip (~1.0 mL)	may be present	present	
FisherBrand UriSystem DeciSlide	may be present	present	

Analytes	Level 1 - 240921	Level 2 - 240922
Accutest® URS 11 • URS 10 • URS 4 Urine Reagent Strips (VISUAL)		
Leukocytes	Negative	15 - 500 cells/µL (Tr - Lg)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 - 1 mg/dL)	1 - 8 mg/dL [7]
Protein	Negative	30 - 2000 mg/dL (1+ - 4+)
pH	5.0 - 7.0	7.5 - 8.5
Blood	Negative	25 - 200 cells/µL (Sm - Lg)
Specific Gravity	1.010 - 1.025	1.000 - 1.015
Ketones	Negative	5 - 160 mg/dL (Tr - Lg)
Bilirubin	Negative	Sm - Lg
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
Ascorbic Acid [12]	Negative	Negative
Accustrip® URS Reader/Visual		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L) [7]
Blood	Negative	10 - 250 Ery/µL
Glucose	Negative	20 - 1000 mg/dL (1.1 - 55.6 mmol/L)
Ketones	Negative	25 - 300 mg/dL (1+ - 3+) (2.5 - 30.0 mmol/L)
Leukocytes	Negative	25 - 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 - 6.5	7.0 - 9.0
Protein	Negative	30 - ≥300 mg/dL (0.3 - 5.0 g/L) (1+ - 3+)
Specific Gravity (Density)	1.010 - 1.025	1.000 - 1.020
Urobilinogen	Normal	2 - 8 mg/dL [7]
Beckman Coulter IRIS Diagnostics® iChem®VELOCITY™ Analyzer		
NOT AVAILABLE		
Confirmatory and Other Tests		
K-CHECK (Ketones)	Negative	Small - Large
Ictotest (Bilirubin)	Negative	Positive
Refractometer (Specific Gravity)	1.019 - 1.025	1.011 - 1.017
hCG	Negative	Positive
pH Paper	4.0 - 6.0	7.0 - 9.0
Sulfosalicylic Acid (Total Protein)	Negative (≤ 0.05) [10]	Positive (≥0.50) [10]
Germaine® Laboratories • AimStrip® and FisherBrand® 10-SG Urine Reagent Strips • Visual		
Leukocytes	Negative	70 - 500 Leu/µL (1+ - 3+)
Nitrite	Negative	Positive
Urobilinogen	0.2 mg/dL (Normal)	2 - 4 mg/dL [11]
Protein	Negative - Trace	30 - 300 g/dL (1+ - 3+)
pH	5.0 - 6.5	7.0 - 8.0
Blood	Negative	1+ - 3+
Specific Gravity	1.015 - 1.025	1.005 - 1.015
Ketones	Negative - Trace	5 - 160 mg/dL (Tr – 4+)
Bilirubin	Negative	1 - 4 mg/dL(1+ - 3+)
Glucose	Negative	100 - 500 mg/dL (± - 2+)
Germaine® Laboratories • AimStrip® and FisherBrand® 10-SG Urine Reagent Strips • AimStrip® Urine Analyzer II		
Leukocytes	Negative	70 - 500 Leu/µL (1+ - 3+)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	0.2- 2 mg/dL [11]
Protein	Negative	Tr - 300 g/dL (± - 3+)
pH	5.0 - 6.0	7.0 - 8.5
Blood	Negative	1+ - 3+
Specific Gravity	1.015 - 1.025	1.010 - 1.020
Ketones	Negative	5 - 80 mg/dL (Tr – 3+)
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+)
Glucose	Negative	250 - 1000 mg/dL (1+ - 3+)
Henry Schein One Step Plus/Urispec Plus Analyzer (Visual)		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L) [7]
Blood	Negative - 10 Ery/µL	10 - 250 Ery/µL
Glucose	Negative - Normal	50 - ≥500 mg/dL (8.3 - ≥27.8 mmol/L) [8]
Ketones	Negative	25 - 300 mg/dL (1+ - 3+) (2.5 - 30 mmol/L)
Leukocytes	Negative	25 - 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 - 7.0	7.0 - 9.0
Protein	Negative	30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+)
Specific Gravity (Density)	1.005 - 1.025	1.000 - 1.020
Urobilinogen	Normal	2 - 12 mg/dL (34 - 200 µmol/L) [7]
Ascorbic Acid [12]	Negative	Negative

Analytes	Level 1 - 240921	Level 2 - 240922
Henry Schein Urispec® 10SG (Visual)		
Leukocytes	Negative	70 - 500 Cells/µL (1+ - 3+)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	1 - 8 E.U./dL
Protein	Negative	30 - 2000 mg/dL (1+ - 4+)
pH	5.0 - 6.0	7.5 - 9.0
Blood	Negative - 10 Ery/µL	1+ - 3+
Specific Gravity (1.0~)	1.015 - 1.030	1.005 - 1.015
Ketones	Negative	5 - 160 mg/dL (Tr - Lg)
Bilirubin	Negative	Sm - Lg (1+ - 3+)
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
MACHEREY-NAGEL® URYXXON® Relax/300/500 Analyzer / VISUAL		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L)[7]
Blood	Negative	10 - 250 Ery/µL
Glucose	Negative - Normal	50 -≥500 mg/dL (8.3 - ≥27.8 mmol/L)[8]
Ketones	Negative	25 - 300 mg/dL (1+ - 3+) (2.5 - 30 mmol/L)
Leukocytes	Negative	25 - 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 - 7.0	7.0 - 9.0
Protein	Negative	30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+)
Specific Gravity	1.005 - 1.025	1.000 - 1.020
Urobilinogen	Normal	2 - 12 mg/dL (34 - 200 µmol/L)[7]
Ascorbic Acid[12]	Negative	Negative
McKesson® Consult Diagnostics 10SG Urine Reagent Strips Visual		
Glucose	Negative	100 - 1000 mg/dL (± - 3+)
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+)
Ketones	Negative	5 - 160 mg/dL (± - 4+)
Specific Gravity	1.015-1.025	1.000 - 1.015
Blood	Negative	1+ - 3+
pH	5.0-6.0	7.5 - 9.0
Protein	Negative	30 - 300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1 - 8 mg/dL
Nitrite	Negative	Positive
Leukocytes	Negative	15 - 500 Leu/µL (± - 3+)
McKesson® 120 Urine Analyzer •Consult Diagnostics® 10SG & M-ALB/CRE Strips		
Leukocytes	Negative	15 - 500 Leu/µL (± - 3+)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	0.2- 2.0 mg/dL[11]
Protein	Negative	Tr - 300 mg/dL (± -3+)
pH	5.0 - 6.5	7.5 - 9.0
Blood	Negative	25 - 200 Ery/µL (1+ - 3+)
Specific Gravity	1.015- 1.030	1.000 - 1.015
Ketones	Negative	5 - 80 mg/dL (Tr - 3+)
Bilirubin	Negative	1 -4 mg/dL (1+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (Tr - 3+)
Microalbumin	10 - 30 mg/L	30 - 300 mg/L
Creatinine	10 - 50 mg/dL	50 - 300 mg/dL
ROCHE VISUAL TESTING (Visual Test Strips Only)		
Specific Gravity	1.015 - 1.030	1.000 - 1.010
pH	5 - 6	7 - 9
Leukocytes	Negative	1+ - 2+
Nitrite	Negative	Positive
Protein	Negative	30 - 100 mg/dL (1+ - 2+)
Glucose	Normal	250 - 1000 mg/dL
Ketones	Negative	2+ - 3+
Urobilinogen[8]*	Normal	1 - 12 mg/dL (1+ - 4+)
Bilirubin[8]*	Negative	1+ - 3+
Blood	Negative	50 - 250 Ery/µL
Microalbumin[5]	Negative	50 - 100 mg/L
ROCHE Chemstrip 101 Urine Analyzer or ROCHE Urisys 1100 Urine Analyzer		
Blood	Negative	50 - 250 Ery/µL (1+ - 2+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (2+ - 3+)
Glucose	Normal	250 - 1000 mg/dL (2+ - 3+)
Protein	Negative[6]	30 - 100 mg/dL (1+ - 2+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	75 - 500 Leu/µL (1+ - 2+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.015
ROCHE Cobas 6500 (cobas u 601)		
Blood	Negative	150 - 250 Ery/µL
Leukocytes	Negative	100 - 500 Leu/µL
Nitrite	Negative	Positive
Ketones	Negative	50 - 150 mg/dL
Glucose	Normal	250 - 1000 mg/dL
Protein	Negative[6]	30 - 100 mg/dL[7]
Urobilinogen	Normal	1 - 8 mg/dL[7]*
Bilirubin	Negative	3 - 6 mg/dL*
pH	5 - 6.5	8 - 9
Specific Gravity	1.017 - 1.029	1.009 - 1.020
Color	Yellow - Pale Yellow	Brown
Clarity	Clear	Clear

Analytes	Level 1 - 240921	Level 2 - 240922
ROCHE cobas u 411		
Blood	Negative	150 - 250 Ery/µL (4+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (3+ - 4+)
Glucose	Normal	250 - 1000 mg/dL (3+ - 4+)
Protein	Negative[6]	30 - 100 mg/dL (2+ -3+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
ROCHE Urisys 1800		
Blood	Negative	150 - 250 Ery/µL (4+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (3+ - 4+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative[6]	75 - 150 mg/dL (2+ -4+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
SIEMENS VISUAL TESTING (Visual Test Strips Only)		
Glucose	Negative	100 - 1000 mg/dL
Bilirubin	Negative	Sm - Lg (1+ - 3+)
Ketones	Negative	5 - 160 mg/dL (Tr - Lg)
Specific Gravity	1.015 - 1.030	1.005 - 1.015
Blood	Negative	Sm - Lg (1+ - 3+)
pH	5.0 - 6.5	7.5 - 8.5
Protein	Negative	30 - 300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)[6]	2.0 - 8.0 E.U./dL*
Nitrite	Negative	Positive
Leukocytes	Negative	Tr - Lg (Tr - 3+)
Creatinine[2]	10 - 50 mg/dL	100 - 300 mg/dL
SIEMENS® CLINITEK 50		
Glucose	Negative	100 - ≥1000 mg/dL (Tr - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Trace - ≥80 mg/dL (Tr - 3+)
Specific Gravity	1.010 - ≥ 1.030	≤1.005 - 1.020
Blood	Negative	Trace - Large (Tr - 3+)
pH	5.0 - 6.5	7.0 - 8.5
Protein	Negative	Trace - ≥300 mg/dL (Tr - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1.0 - 4.0 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace - Large (Tr - 3+)
Microalbumin[1]	10 - 30 mg/L	30 - 300 mg/L
Creatinine[3]	10 - 100 mg/dL	50 - 300 mg/dL
SIEMENS® CLINITEK 500		
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Tr - ≥80 mg/dL (Tr - 3+)
Specific Gravity	1.015 - ≥1.030	≤1.005 - 1.020
Blood	Negative	Small - Large (1+ - 3+)
pH	5.0 - 6.5	7.5 - ≥9.0
Protein	Negative	30 - ≥300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	2.0 - ≥8.0 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Small - Large (1+ - 3+)
Creatinine[2]	10 - 50 mg/dL	50 - 300 mg/dL
SIEMENS® CLINITEK ADVANTUS		
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Trace - ≥80 mg/dL (Tr - 3+)
Specific Gravity	1.015 - ≥1.030	≤1.005 - 1.025
Blood	Negative	Small - Large (1+ - 3+)
pH	5.5 - 6.5	7.5 - ≥9.0
Protein	Negative	30 - ≥300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1.0 - ≥8.0 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace - Large (Tr - 3+)
Creatinine[2]	10 - 50 mg/dL	50 - 300 mg/dL
SIEMENS CLINITEK STATUS/ STATUS PLUS/STATUS CONNECT		
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Trace - ≥160 mg/dL (Tr - 4+)
Specific Gravity	1.010 -1.025	1.010 - 1.025
Blood	Negative	Small - Large (1+ - 3+)
pH	5.0- 6.0	6.5 - ≥9.0
Protein	Negative	30 - ≥300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	2.0 - ≥8.0 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace - Large (Tr - 3+)
Microalbumin[1]	10 - 30 mg/L	30 - 300 mg/L
Creatinine[3]	10 - 100 mg/dL	100 - 300 mg/dL
hCG	Negative	Positive

Analytes	Level 1 - 240921	Level 2 - 240922
Teco Diagnostics (Visual)		
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Trace - 80 mg/dL
Specific Gravity	1.010 - 1.020	≤1.005 - 1.020
Blood	Negative	Small - Large (1+ - 3+)
pH	5.5 - 7.0	6.5 - 8.0
Protein	Negative	30 - 300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	2 - ≥8 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace - Lg (Tr - 3+)
Albumin	10 - 30 mg/L	80 - 150 mg/L
Creatinine	10 - 50 mg/dL	50 - 200 mg/dL
Teco Diagnostics TC-101 • TC-201 • TC-720 Urine Analyzer		
Glucose	Negative	100 - 1000 mg/dL
Bilirubin	Negative	Sm - Lg (1+ - 3+)
Ketones	Negative	Trace - ≥80 mg/dL
Specific Gravity	1.010 - 1.025	≤1.005 - 1.015
Blood	Negative	Small - Large (1+ - 3+)
pH	5.0 - 6.5	7.0 - 8.5
Protein	Negative	Trace - ≥300 mg/dL (Tr - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	0.2 - ≥8 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Tr - Mod (Tr - 2+)
Albumin	10 - 30 mg/L	80-150 mg/L
Creatinine	10 - 50 mg/dL	50 - 200 mg/dL
Uriscan™ • 10 SGL Strips (Visual)		
Blood	Negative	10 - 250 RBC/µL (1+ - 3+)
Bilirubin	Negative	0.5 - 3.0 mg/dL (1+ - 3+)
Urobilinogen	Negative - Normal	1 - 12 mg/dL (1+ - 4+)
Ketones	Negative	5 - 100 mg/dL (± - 3+)
Protein	Negative	30 - 1000 mg/dL (1+ - 4+)[7]
Nitrite	Negative	Positive
Glucose	Negative	250 - 2000 mg/dL (1+ - 4+)
pH	5.0 - 6.5	7.5 - 8.5

INTERNATIONAL USE ONLY

This Section is for International Use only and contains data for methods that are not available or cleared for diagnostic use in the United States.

Method	Level 1 - 240921	Level 2 - 240922	Units
Red Blood Cells (Erythrocytes)			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	0 - 25	5 - 145	p/µL
Teco UriScope 50 / COBIO Variants	2 - 16	54 - 123	p/µL
Mindray EU-5600, EU-5300, EU-3000	0 - 25	20 - 100	p/µL
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	0 - 25	33 - 95	p/µL
Mindray EU-5300 Pro, EU-5600 Pro	0 - 25	35 - 93	p/µL
YD Diagnostics URiSCAN PLUSCOPE	0 - 50	0 - 200	p/µL
ROCHE cobas 6500 (cobas u 701)	0 - 25	30 - 90	p/µL
KOVA® GLASSTIC® SLIDE 10 with GRIDS	1 - 12	29 - 140	p/µL
Non-grid slides (~0.5 mL)	0 - 8	6 - 45	p/hpf
Non-grid slides (~1.0 mL)	0 - 4	3 - 24	p/hpf
Slide & Coverslip (~0.5 mL)	0 - 5	2 - 23	p/hpf
Slide & Coverslip (~1.0 mL)	0 - 4	1 - 15	p/hpf
FisherBrand UriSystem DeciSlide	0 - 5	2 - 23	p/hpf
White Blood Cells (Leukocytes)			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	0 - 25	10 - 85	p/µL
Teco UriScope 50 / COBIO Variants	0 - 9	19 - 38	p/µL
Mindray EU-5600, EU-5300, EU-3000	0 - 25	0 - 60	p/µL
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	0 - 20	0 - 40	p/µL
Mindray EU-5300 Pro, EU-5600 Pro	0 - 20	0 - 40	p/µL
YD Diagnostics URiSCAN PLUSCOPE	0 - 50	0 - 200	p/µL
ROCHE cobas 6500 (cobas u 701)	0 - 25	23 - 71	p/µL
KOVA® GLASSTIC® SLIDE 10 with GRIDS	0 - 9	14 - 55	p/µL
Non-grid slides (~0.5 mL)	0 - 7	3 - 24	p/hpf
Non-grid slides (~1.0 mL)	0 - 4	2 - 11	p/hpf
Slide & Coverslip (~0.5 mL)	0 - 4	0 - 10	p/hpf
Slide & Coverslip (~1.0 mL)	0 - 4	0 - 9	p/hpf
FisherBrand UriSystem DeciSlide	0 - 4	1 - 9	p/hpf
Casts			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	may be present	
Teco UriScope 50 / COBIO Variants	Data not available		
ROCHE cobas 6500 (cobas u 701)	none	none	
Mindray EU-5600, EU-5300, EU-3000	none	none	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	none	none	
Mindray EU-5300 Pro, EU-5600 Pro	none	none	
YD Diagnostics URiSCAN PLUSCOPE	none	none	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	none	none	
Non-grid slides (~0.5 mL)	none	none	
Non-grid slides (~1.0 mL)	none	none	
Slide & Coverslip (~0.5 mL)	none	none	
Slide & Coverslip (~1.0 mL)	none	none	
FisherBrand UriSystem DeciSlide	none	none	

Method	Level 1 - 240921	Level 2 - 240922	Units
Crystals			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	present	
Teco UriScope 50 / COBIO Variants	Data not available		
Mindray EU-5600, EU-5300, EU-3000	none	present	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	may be present	present	
Mindray EU-5300 Pro, EU-5600 Pro	none	present	
YD Diagnostics URiSCAN PLUSCOPE	none	may be present	
ROCHE cobas 6500 (cobas u 701)	negative	positive	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	none	present	
Non-grid slides (~0.5 mL)	none	present	
Non-grid slides (~1.0 mL)	none	present	
Slide & Coverslip (~0.5 mL)	none	present	
Slide & Coverslip (~1.0 mL)	none	present	
FisherBrand UriSystem DeciSlide	none	present	
Bacteria			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	present	
Teco UriScope 50 / COBIO Variants	Data not available		
Mindray EU-5600, EU-5300, EU-3000	may be present	present	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	may be present	present	
Mindray EU-5300 Pro, EU-5600 Pro	may be present	present	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	may be present	present	
Non-grid slides (~0.5 mL)	may be present	present	
Non-grid slides (~1.0 mL)	may be present	present	
Slide & Coverslip (~0.5 mL)	may be present	present	

Analytes	Level 1 - 240921	Level 2 - 240922
77 Elektronika (Visual / Analyzers)		
Bilirubin	Negative	1 - 6 mg/dL (17 - 100 µmol/L)[8]
Urobilinogen	Normal	2 - 12 mg/dL (35 - 200 µmol/L)[8]
Ketones	Negative	5 - 150 mg/dL (0.5 - 15 mmol/L)
Ascorbic Acid[12]	Negative	Negative
Glucose	Normal	50 - 1000 mg/dL (2.8 - 56 mmol/L)
Protein	Negative	15 - 500 mg/dL (0.15 - 5 g/L)
Blood	Negative	10 - 300 Ery/µL
pH	5 - 6	7 - 8
Nitrite	Negative	Positive
Leukocytes	Negative	75 - 500 Leu/µL
Specific Gravity	1.010 - 1.030	1.000 - 1.025
Creatinine	10 - 50 mg/dL (0.9-4.4 mmol/L)	50 - 300 mg/dL (4.4 - 26.5 mmol/L)
Microalbumin	≤ 10 mg/L	150 - 500 mg/L
Analyticon® Combi Screen (Visual)		
Bilirubin	Negative	1+ - 3+
Urobilinogen	Normal	2 - 12 mg/dL (35 - 200 µmol/L)[8]*
Ketones	Negative	(+) - 3+
Ascorbic Acid[12]	Negative	Negative
Glucose	Normal	50 - 1000 mg/dL (2.8 - 56 mmol/L)
Protein	Negative	30 - 500 mg/dL
Blood	Negative[6]	10 - 300 Ery/µL (1+ - 3+)
pH	5 - 7	6 - 9
Nitrite	Negative[6]	Positive
Leukocytes	Negative	25 - 500 Leu/µL
Specific Gravity	1.010 - 1.020	1.000 - 1.010
Creatinine	10 - 100 mg/dL (0.9 - 8.8 mmol/L)	100 - 300 mg/dL (8.8 - 26.5 mmol/L)
Microalbumin	10 - 80 mg/L	150 - 500 mg/L
Analyticon® Urilyzer® 100 Pro and Urilyzer® Auto		
Bilirubin	Negative	1 - 4 mg/dL, 17 - 70 µmol/L (1+ - 3+)
Urobilinogen	Normal	2 - 12 mg/dL 35-200 µmol/L (1+ - 4+)[8]*
Ketones	Negative	10 - 300 mg/dL, 1.0 - 30 mmol/L (+) - 3+
Ascorbic Acid[12]	Negative - 20 mg/dL, Negative - 1+	Negative - 20 mg/dL, Negative- 1+
Glucose	Normal	50 - 1000 mg/dL, 2.8 - 56 mmol/L (1+ - 5+)
Protein	Negative	30 - 500 mg/dL, 0.3 - 5 g/L (1+ - 3+)
Blood	Negative[6]	10 - 300 Ery/µL (1+ - 3+)
pH	5 - 7	6 - 8
Nitrite	Negative[6]	Positive
Leukocytes	Negative	25 - 500 Leu/µL (1+ - 3+)
Specific Gravity	1.010 - 1.030	1.000 - 1.020
Creatinine	10 - 50 mg/dL (0.9 - 4.4 mmol/L)	50 - 300 mg/dL, (4.4 - 26.5 mmol/L)
Microalbumin	10 - 80 mg/L	150 - 500 mg/L
CHUNGDO Visual / Analyzers		
Blood	Negative	10 - 250 RBC/µL (1+ - 3+)
Bilirubin	Negative	Neg - 1.0 mg/dL (Neg - 2+)
Urobilinogen	Normal (0.1)	1 - 12 mg/dL (1+ - 4+)
Ketones	Negative	5 - 100 mg/dL (± - 3+)
Protein	Negative	10 - 100 mg/dL (± - 2+)
Nitrite	Negative	Positive
Glucose	Negative	100 - 500 mg/dL (± - 2+)
pH	5.0 - 6.0	6.5 - 8.5
Specific Gravity	1.015 - 1.030	1.005 - 1.015
Leukocytes	Negative	75 - 500 WBC/µL (1+ - 3+)
Ascorbic Acid[12]	Normal	Normal

Analytes	Level 1 - 240921	Level 2 - 240922
CYPRESS DIAGNOSTICS Urine Strips • CYANStrip • CYANStrip Mini • Visual		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/uL (1+~3+)
pH	5~6.5	7~9
Protein	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~ 3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/uL (Trace~3+)
Microalbumin	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Creatinine	10 mg/L	30~150 mg/L
DiaLab Urine Strip Analyzer 500/Urine Strip 10C/Urine Strip 2MC		
Leukocytes	Negative	15 - 500 Leu/µL
Nitrite	Negative	Positive
Urobilinogen	0.2 (Norm) mg/dL	0.2 - 4 mg/dL
Protein	Negative	30 - 200 mg/dL
pH	5.0 - 6.5	7.0 - 8.5
Blood	Negative	1+ - 3+
Specific Gravity	1.010 - 1.030	1.005 - 1.020
Ketones	Negative	5 - 160 mg/dL
Bilirubin	Negative	1 - 4 mg/dL
Glucose	Negative	100 - 500 mg/dL
Creatinine	10 - 50 mg/dL	50 - 300 mg/dL
Microalbumin	1 - 3 mg/dL	3 - 15 mg/dL
DFI CYBOW • ComboStik • DUS Urine Reagent Strips (Visual)		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/uL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/uL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Microalbumin	10 mg/L	30~150 mg/L
DFI CYBOW R-50 (50S) • ComboStik R-50 (50S) • DUS R-50 (50S)		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/µL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/µL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Micoalbumin	10 mg/L	30~150 mg/L
DFI CYBOW Reader 300 • ComboStik R-300 • DUS R-300		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/µL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/µL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Micoalbumin	10 mg/L	30~150 mg/L
DFI CYBOW Reader 600S • ComboStik R-600S • DUS R-600S • Reader 720 • Combostik R-700 • DUS R-720 • DFI CYBOW Reader 720 • ComboStik R-700 • DUS R-720		
Urobilinogen	Normal (0.1~1mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/uL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/uL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Microalbumin	10 mg/L	30~150 mg/L

Analytes	Level 1 - 240921	Level 2 - 240922
DFI's CYBOW R-60(60S)/ComboStik R-60(60S)/DUS R-60(60S)		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/µL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/µL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Microalbumin	10 mg/L	30~150 mg/L
ERBA LACHEMA DekaPHAN LAURA STRIPS & LAURA Urine Analyzer ERBA Mannheim Uro-dip 10e STRIPS & Uro-dipcheck 400e Urine Analyzer		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6.5	7 - 9
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.015 - 1.030	1 - 3 mg/dL (17 - 51 µmol/L) (1+ - 2+)
Urobilinogen	Normal	1 - 3 mg/dL (17 - 51 µmol/L) (1+ - 2+)
ERBA LACHEMA DekaPHAN LAURA STRIPS & LAURA M Urine Analyzer ERBA Mannheim Uro-dip 10e STRIPS & LAURA M Urine Analyzer		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	6	7 - 9
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1,020 - 1,030	1.000 - 1.015
Urobilinogen	Normal	Norm - 3 mg/dL (Norm - 51 µmol/L) (Norm - 2+)
ERBA LACHEMA DekaPHAN LAURA STRIPS & LAURA Smart Urine Analyzer ERBA Mannheim Uro-dip 10e STRIPS & Uro-dipcheck 240e Urine Analyzer		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6.5	7 - 9
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.020 - 1.030	1.000 - 1.015
Urobilinogen	Normal	Norm - 3 mg/dL (Norm - 51 µmol/L) (Norm - 2+)
ERBA LACHEMA DekaPHAN LAURA STRIPS (Visual) ERBA Mannheim Uro-dip 10e STRIPS (Visual)		
Bilirubin	Negative	3 - 6 mg/dL (51 - 103 µmol/L) (2+ - 3+)
Blood	Negative	10 - 250 Ery/µL (1+ - 3+)
Glucose	Negative	300 - 1000 mg/dL (17 - 55 mmol/L) (3+ - 4+)
Ketones	Negative	52 - 156 mg/dL (5 - 15 mmol/L) (2+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6	7 - 9
Protein	Negative	30 - 100 mg/dL (0.3 - 1 g/L) (1+ - 2+)
Specific Gravity	1.020 - 1.030	1.000 - 1.015
Urobilinogen	Normal	1 - 3 mg/dL (17 - 51 µmol/L) (1+ - 2+)

Analytes	Level 1 - 240921	Level 2 - 240922
Mindray EU-5600, EU-5300, EU-3000		
Leukocytes	Negative	70~500 Leu/µL(1+~3+)
Urobilinogen	Normal	2~8 mg/dL(1+~3+)
Microalbumin	10~80mg/L	30~150 mg/L
Protein	Negative	30~300 mg/dL(1+~3+)
Bilirubin	Negative	1~6 mg/dL(1+~3+)
Glucose	Negative	100~500 mg/dL(1+~3+)
Specific Gravity	1.010~1.025	1.000~1.015
Ketones	Negative	15~80 mg/dL(1+~3+)
Nitrite	Negative	Positive
Creatinine	0.9~8.8 mmol/L	8.8~26.5 mmol/L
pH	5.0~6.5	7.0~9.0
Blood	Negative	25~200 Ery/µL(1+~3+)
Ascorbic Acid	Negative	Negative
Mindray UA-5600		
Leukocytes	Negative	70~500 Leu/µL(1+~3+)
Urobilinogen	Normal	2~8 mg/dL(1+~3+)
Microalbumin	10~80 mg/L	30~150mg/L
Protein	Negative	30~300 mg/dL(1+~3+)
Bilirubin	Negative	1~6 mg/dL(1+~3+)
Glucose	Negative	250~1000 mg/dL(2+~4+)
Specific Gravity	1.010~1.025	1.005~1.020
Ketones	Negative	15~80 mg/dL(1+~3+)
Nitrite	Negative	Positive
Creatinine	0.9~8.8 mmol/L	8.8~26.5 mmol/L
pH	5.0~6.5	6.5~8.5
Blood	Negative	25~200 Ery/µL(1+~3+)
Ascorbic Acid	Negative	Negative
Mindray EU-5300 Pro, EU-5600 Pro		
Leukocytes	Negative	70~500 Leu/µL(1+~3+)
Urobilinogen	Normal	2~8 mg/dL(1+~3+)
Microalbumin	10~80 mg/L	30~150mg/L
Protein	Negative	30~300 mg/dL(1+~3+)
Bilirubin	Negative	1~6 mg/dL(1+~3+)
Glucose	Negative	250~1000 mg/dL(2+~4+)
Specific Gravity	1.015~1.030	1.005~1.020
Ketones	Negative	15~80 mg/dL(1+~3+)
Nitrite	Negative	Positive
Creatinine	0.9~8.8 mmol/L	8.8~26.5 mmol/L
pH	5.0~6.5	6.5~8.5
Blood	Negative	25~200 Ery/µL(1+~3+)
Ascorbic Acid	Negative	Negative
ROCHE VISUAL TESTING (Visual Test Strips Only)		
Specific Gravity	1.015 - 1.030	1.000 - 1.010
pH	5 - 6	7 - 9
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
Protein	Negative	30 -100 mg/dL (1+ - 2+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Ketones	Negative	50 - 150 mg/dL (2+ - 3+)
Urobilinogen[8]*	Normal	1 - 12 mg/dL (1+ - 4+)
Bilirubin[8]*	Negative	1+ - 3+
Blood	Negative	50 - 250 Ery/µL (3+ - 4+)
Microalbumin[5]	Negative	50 - 100 mg/L
ROCHE cobas 6500 (cobas u 601)		
Blood	Negative	150 - 250 Ery/µL
Leukocytes	Negative	100 - 500 Leu/µL
Nitrite	Negative	Positive
Ketones	Negative	15 - 150 mg/dL
Glucose	Normal	300 - 1000 mg/dL
Protein	Negative[6]	75 - 150 mg/dL[7]
Urobilinogen	Normal	1 - 8 mg/dL[7]*
Bilirubin	Negative	3 - 6 mg/dL*
pH	5.0 - 6.5	8 - 9
Specific Gravity	1.017 - 1.029	1.009 - 1.020
Color	Yellow - Pale Yellow	Brown
Clarity	Clear	Clear
ROCHE Urisys 1100 Urine Analyzer or ROCHE Urilux S Urine Analyzer		
Blood	Negative	50 - 250 Ery/µL (3+ - 4+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (2+ - 3+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative[6]	25 - 150 mg/dL (1+ - 3+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.015

Analytes	Level 1 - 240921	Level 2 - 240922
ROCHE Cobas u 411 Urine Analyzer		
Blood	Negative	150 - 250 Ery/µL (4+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (3+ - 4+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative[6]	75 - 150 mg/dL (2+ - 3+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
ROCHE Urisys 1800 Urine Analyzer		
Blood	Negative	150 - 250 Ery/µL (4+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (3+ - 4+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative[6]	75 - 150 mg/dL (2+ - 4+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
YD Diagnostics URiSCAN Urine Test Strips (Visual)		
Blood	Negative	10~250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5~3.0 mg/dL (1+~3+)*[7]
Urobilinogen	Normal	1~12 mg/dL (1+~4+)
Ketones	Negative	10~100 mg/dL (1+~3+)
Protein	Negative	30~1000 mg/dL (1+~4+)
Nitrite	Negative	Positive
Glucose	Negative	250~2000 mg/dL (1+~4+)
pH	5.0~6.5	6.5 - 8.5
Specific Gravity	1.015~1.030	1.005~1.020
Leucocytes	Negative	25~500 WBC/uL (1+~3+)
YD URiSCAN PRO, URiSCAN Optima & Optima II		
Blood	Negative	10~250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5~3.0 mg/dL (1+~3+)*[7]
Urobilinogen	Normal	1~12 mg/dL (1+~4+)
Ketones	Negative	10~100 mg/dL (1+~3+)
Protein	Negative	30~1000 mg/dL (1+~4+)
Nitrite	Negative	Positive
Glucose	Negative	100~1000 mg/dL (±~3+)
pH	5.0~6.5	6.5~8.5
Specific Gravity	1.010~1.030	1.005~1.020
Leucocytes	Negative	25~500 WBC/uL (1+~3+)
Microalbumin	Negative~30 mg/L	30~150 mg/L
Creatinine	10~100 mg/dL	50~300 mg/dL
YD Diagnostics URiSCAN Super		
Blood	Negative	10~250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5~3.0 mg/dL (1+~3+)*[7]
Urobilinogen	Normal	1~12 mg/dL (1+~4+)
Ketones	Negative	10~100 mg/dL (1+~3+)
Protein	Negative	30~1000 mg/dL (1+~4+)
Nitrite	Negative	Positive
Glucose	Negative	100~1000 mg/dL (±~3+)
pH	5.0~6.5	6.5~8.5
Specific Gravity	1.014~1.030	1.006~1.022
Leucocytes	Negative	25~500 WBC/uL (1+~3+)
YD Diagnostics URiSCAN Super +		
Blood	Negative	10~250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5~3.0 mg/dL (1+~3+)*[7]
Urobilinogen	Normal	1~12 mg/dL (1+~4+)
Ketones	Negative	10~100 mg/dL (1+~3+)
Protein	Negative	30~1000 mg/dL (1+~4+)
Nitrite	Negative	Positive
Glucose	Negative	100~1000 mg/dL (±~3+)
pH	5.0~6.5	6.5~8.5
Specific Gravity	1.014~1.030	1.006~1.022
Leucocytes	Negative	25~500 WBC/uL (1+~3+)

ENGLISH
1 Values only apply to Clinitek Microalbumin Reagent Strips when read on the Clinitek 50 & Status.
2 Values only apply to Multistix Pro™ Reagent Strips
3 Values only apply to Multistix Pro and Clinitek Microalbumin Reagent Strips when read on Clinitek Urine Analyzers
4 VISUAL: Some customers may obtain false negatives.
5 Values apply to Chemstrip® Micral Reagent Strips
6 Some customers may obtain false positives.
7 Some customers may obtain false negatives.
8 Atypical color
10 Absorbance at 620 nm
11 The urobilinogen reaction produces an atypical color which may result in a normal (0.2 E.U./dL) reading. Should this occur, a visual observation of the intensification of the pad color indicates a positive response.
12 For information purposes only.
* See Limitations

DEUTSCH
1 Werte gelten nur für Clinitek Mikroalbumin-Reagenzstreifen wenn diese auf Clinitek 50 und Status
2 Werte gelten nur für Multistix Pro™ Reagenzstreifen
3 Werte gelten nur für Multistix Pro und Clinitek Mikroalbumin-Reagenzstreifen, wenn diese auf Clinitek Urin-Analysatoren gelesen werden
4 VISUAL: Manche Kunden erhalten möglicherweise falsch negative Ergebnisse.
5 Werte gelten für Chemstrip® Micral Reagenzstreifen
6 Manche Kunden erhalten möglicherweise falsch positive Ergebnisse.
7 Manche Kunden erhalten möglicherweise falsch negative Ergebnisse.
8 Atypische Farbe
10 Absorption bei 620 nm
11 Die Urobilinogen-Reaktion erzeugt eine atypische Farbe, die zu einem normalen Messwert (0,2 EU/dl) führen kann. In diesem Fall kann eine positive Reaktion anhand der sichtbar veränderten Farbintensität des Testfeldes festgestellt werden.
12 Nur für Informationszwecke.
* Siehe Einschränkungen

FRANÇAIS
1 Valeurs s'appliquant uniquement aux bandes de réactif Clinitek micro-albumine lues sur Clinitek 50 et Status
2 Valeurs s'appliquant uniquement aux bandes de réactif Multistix Pro™
3 Valeurs s'appliquant uniquement aux bandes de réactif Multistix Pro et Clinitek micro-albumine lues sur Clinitek Analyseurs d'urine
4 VISUAL: Certains clients sont susceptibles d'obtenir des faux négatifs.
5 Valeurs s'appliquant aux bandes de réactif Chemstrip® Micral
6 Certains clients sont susceptibles d'obtenir des faux positifs.
7 Certains clients sont susceptibles d'obtenir des faux négatifs.
8 Couleur atypique
10 Absorbance à 620 nm
11 La réaction de l'urobilinogène produit une couleur atypique pouvant donner lieu à une lecture normale (0,2 unité Ehrlich/dl). Si cela se produit, l'observation visuelle de l'intensification de la couleur de la zone de test indique une réponse positive.
12 Fourni uniquement à titre d'information.
* Voir Limitations

ITALIANO
1 I valori si riferiscono esclusivamente alle Strisce reagenti per microalbumina Clinitek lette su Clinitek 50 e Status
2 I valori si riferiscono esclusivamente alle Strisce reagenti Multistix Pro™
3 I valori si riferiscono esclusivamente alle Strisce reagenti per microalbumina Multistix Pro e Clinitek lette su Clinitek Analizzatori urine
4 VISUAL: Alcuni pazienti possono ottenere risultati falsi negativi.
5 I valori si riferiscono alle Strisce reagenti Micral Chemstrip®
6 Alcuni pazienti possono ottenere risultati falsi positivi.
7 Alcuni pazienti possono ottenere risultati falsi negativi.
8 Colore atipico
10 Assorbanza a 620 nm
11 La reazione dell'urobilinogeno produce un colore atipico che può determinare una lettura normale (0,2 U.E./dl). In questo caso, se si nota visivamente un'intensificazione del colore del cuscinetto, questo indica una reazione positiva.
12 Solo a scopo informativo.
* Vedere limiti

ESPAÑOL
1 Los valores son aplicables únicamente a las tiras reactivas Clinitek Microalbumin cuando se leen en equipos Clinitek 50 y Status
2 Los valores son aplicables únicamente a las tiras reactivas Multistix Pro™
3 Los valores son aplicables únicamente a las tiras reactivas Multistix Pro y Clinitek Microalbumin cuando se leen en equipos Clinitek Analizadores de orina
4 VISUAL: Algunos pacientes pueden obtener resultados negativos falsos.
5 Los valores son aplicables a las tiras reactivas Chemstrip® Micral
6 Algunos pacientes pueden obtener resultados positivos falsos
7 Algunos pacientes pueden obtener resultados negativos falsos.
8 Color anormal
10 Absorbencia a 620 nm
11 La reacción del urobilinógeno genera un color atípico que puede dar lugar a una lectura normal (0,2 E.U./dL). Si ocurriera esto, la respuesta es positiva si se observa visualmente una intensificación del color de la almohadilla.
12 Solo para fines informativos.
* Ver las limitaciones

POLSKI
1 Wartości mają zastosowanie wyłącznie do pasków odczynnikowych Clinitek Microalbumin podczas odczytu za pomocą urządzenia Clinitek 50 lub Status.
2 Wartości mają zastosowanie wyłącznie do pasków odczynnikowych Multistix Pro™.
3 Wartości mają zastosowanie wyłącznie do pasków odczynnikowych Multistix Pro oraz Clinitek Microalbumin podczas odczytu za pomocą analizatorów moczu.
4 ODCZYT WIZUALNY: Niektórzy klienci mogą uzyskiwać wyniki pozornie ujemne.
5 Wartości dotyczą pasków odczynnikowych Chemstrip® Micral
6 Niektórzy klienci mogą uzyskiwać wyniki pozornie dodatnie.
7 Niektórzy klienci mogą uzyskiwać wyniki pozornie ujemne.
8 Nietypowe zabarwienie
10 Absorbancja przy długości fali 620 nm
11 Reakcja urobilinogenu powoduje nietypowe zabarwienie, co może doprowadzić do uzyskania prawidłowego (0,2 E.U./dl) odczytu. W takiej sytuacji obserwacja intensyfikacji zabarwienia wkładki wskazuje na odpowiedź dodatnią.
12 Wyłącznie do celów informacyjnych.
* Patrz „Ograniczenia"

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Temperature limitation Temperaturbegrenzungen Limites de température limiti di temperatura límite de temperatura Ograniczenie temperaturowe	Lot Number Bezeichnung Désignation du lot Numero di lotto Denominación de lote Numer partii	Biological Risk Biogefährdung Risque biologique Rischio biologico Peligro biológico Ryzyko biologiczne	Contents of kit Inhalt der Packung Contenu du coffret Contenuto della confezione Contenido del estuche Zawartość zestawu	
Consult instructions for use Gebrauchsanweisung beachten Consulter les instructions d'utilisation Consultare le istruzioni l'uso Consulte las instrucciones de uso Patrz instrukcja użycia	For in vitro diagnostic use In-vitro Diagnostikum Pour diagnostic in vitro Per uso diagnostico in vitro De uso diagnóstico in vitro Do użytku diagnostycznego in vitro	Use by (last day of month) Verwendbar bis (letzter Tag des Monats) Utilisable jusqu'à (dernier jour du mois indiqué) Da utilizzare prima del (ultimo giorno del mese) Estable hasta (ultimo día del mes) Termin ważności (ostatni dzień miesiąca)	Caution, See Product Insert Achtung, Siehe Packungsbeilage Attention, voir notice d'utilisation Attenzione, vedere il foglietto illustrativo del prodotto Atención, consulte el folleto del producto Uwaga, patrz ulotka dołączona do produktu	

Level 1 LOT **240921**

Level 2 LOT **240922**

Level 1&2 Expiration Date
2026-04-30

Quantimetrix

2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278-1205 USA
phone: (310) 536-0006
fax: (310) 536-9977
www.quantimetrix.com

E-M047092B-12/24

Quantimetrix Corporation
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278
+1.310.536.0006

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

LabStrip URINALYSIS Urine Test Strip 12 mALB/CREA

EN IVD CE

REF (Catalogue number)	Name of product	Contents
U12 - 9901-1	LabStrip U12 mALB/CREA	150 reagent strips

Intended purpose:

The **LabStrip U12 mALB/CREA** urine test strip is an in vitro diagnostic medical device for use as a preliminary screening test for diabetes, liver diseases, haemolytic diseases, urogenital and kidney disorders and metabolic abnormalities by the rapid semi-quantitative determination of bilirubin, urobilinogen, ketones, ascorbic acid, glucose, protein, creatinine, blood, pH-value, albumin and leucocytes, as well as qualitative determination of nitrite in human urine and providing albumin-to-creatinine ratio and protein-to-creatinine ratio.

Urinalysis is considered a routine, non-invasive screening method. As per this definition, for this method there are no limitations about the patient groups. Analysis of urine can be performed on all patients irrespective of age, gender, race, medical condition, etc. Also, because of the urinalysis is a non-invasive test, can be repeated at any time

The product is designed for professional, laboratory use and is intended to be used with **LabUMat 2** automated urine chemistry analyzer.

Test Principal [1] – [6]:

Bilirubin (BIL): A red azo compound is obtained in the presence of acid by coupling of bilirubin with a diazonium salt. The presence of bilirubin leads to a color of red-orange peach.

Urobilinogen: The test is based on the coupling of urobilinogen with a stabilized diazonium salt to a red azo compound. The presence of urobilinogen leads to a color change from light to dark pink.

Ketones (KET): The test is based on the reaction of acetone and acetoacetic acid with sodium nitroprusside in alkaline solution to give a violet colored complex (Legal's test).

Ascorbic acid (ASC): The test is based on the discoloration of Tillman's reagent. In the presence of ascorbic acid, the color changes from grey-blue to orange.

Glucose (GLU): The test is based on the glucose oxidase-peroxidasechromogen reaction. The presence of glucose leads to a color change from yellow via lime green to dark teal.

Protein (PRO): The test is based on the „protein error" principle of an indicator. The test is especially sensitive in the presence of albumin. Other proteins are indicated with less sensitivity. The presence of proteins leads to a color change from yellowish to mint green.

Creatinine (CREA): The test is based on the peroxidase-like activity of a copper-creatinine complex. This complex acts as a catalysator for the color reaction, changing the color of the test pad from light green to dark teal.

Blood (BLD): The test is based on the pseudo-peroxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide and a chromogen producing a green color. Intact erythrocytes are reported by punctual colorations on the test pad, whereas hemoglobin and myoglobin are reported by a homogeneous green coloration.

pH: The test paper contains pH indicators, which clearly change color between pH 5 and pH 9 (from orange to green to turquoise).

Nitrite (NIT): The test is based on the principle of the Griess reaction. Any degree of pink-orange coloration should be interpreted as a positive result.

Albumin (mALB): The test is based on the so-called 'protein error of indicators' phenomenon, the indicator being a tetrabromophenol-sulfonephthalein derivative in this case. In an acidic environment, the dye binds to the albumin, causing the color of the test strip to change from light to dark turquoise.

Leucocytes (LEU): The test is based on the esterase activity of granulocytes. This enzyme cleaves heterocyclic carboxylates. If the enzyme is released from the cells, it reacts with a diazonium salt producing a violet dye.

Albumin-to-creatinine ratio (ACR): There is no specific test pad on the test strip for ACR, which is calculated from the result of the Albumin and the Creatinine test pad.

Protein-to-creatinine ration (PCR): There is no specific test pad on the test strip for PCR, which is calculated from the result of the Protein and the Creatinine test pad.

Reagents:

Bilirubin:	Diazonium salt	**3.1 %**
Urobilinogen:	Diazonium salt	**3.6 %**
Ketones:	Sodium nitroprusside	**2.0 %**
Ascorbic acid:	2.6-dichloro-phenol-indophenol	**0.7 %**
Glucose:	Glucose oxidase	**2.1 %**
	Peroxidase	**0.9 %**
	O-Tolidine hydrochloride	**5.0 %**
Protein:	Tetra-bromophenol blue	**0.2 %**
Creatinine:	Copper sulphate	**1.5 %**
	Cumolhydroperoxide	**4.0 %**
	Tetramethylbenzidine	**1.7 %**
Blood:	Isopropylbenzol-hydroperoxide	**21.0 %**
	Tetramethylbenzidine-dihydrochloride	**2.0 %**
pH:	Bromthymol blue	**10.0 %**
	Methyl red	**2.0 %**
Nitrite:	Sulfanilic acid	**1.9 %**
	Tetrahydrobenzol[h]quinolon-3-ol	**1.5 %**
Albumin:	Tetrabromophenol-sulfonephthalein derivative	**1.6 %**
Leucocytes:	Carboxylic acid ester	**0.4 %**
	Diazonium salt	**0.2 %**

Concentrations given are based on reagent composition (w/w) at time of manufacture and may vary within manufacturing tolerances.

Kit Components:

Each kit contains everything needed to perform 150 tests:

- 150 pcs **LabStrip U12 mALB/CREA** test strips,
- 1 pc registration card for registering test strips of **LabUMat 2** automated urine chemistry analyzer,

Other required appliances for urine analysis:

- **LabUMat 2** automated urine chemistry analyzer
- Clean, detergent free and dry container for urine collection

Specimen Collection and Preparation:

- Collect urine in a clean, dry container.
- Do not add preservatives.
- Test the specimen as soon as possible, with the sample well mixed but not centrifuged.
- The use of fresh morning urine is recommended.
- If immediate testing is not possible, the sample should be stored in the refrigerator (+2 to +8 °C) and then brought to room temperature (+15 to +25 °C) before used in the test.
- Non-preserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination.
- If cleanly voided specimens are not collected from females, positive results for leukocytes may be found du to contamination from outside the urinary tract.
- Skin cleansers containing chlorhexidine may affect positive protein test result if specimen contamination occurs.

Procedure and Notes:

- Use only fresh, well mixed, non-centrifuged urine. First morning urine is recommended. Perform the urine analysis in 4 hours after sample collection! Keep urine away from light.
- Load the test strips into the analyzer immediately after opening the test strip container.
- Do not touch test pads of the reagent strip.
- Do not perform urine analysis at temperatures below +15˚C or above +35˚C
- Use only **LabUMat 2** automated urine chemistry analyzer for **LabStrip U12mALB/CREA** test strip urine analysis.
- A registration card is provided in each **LabStrip U12 mALB/CREA** test strip package for registering test trips with **LabUMat 2** automated urine chemistry analyzer.

Carefully read the instructions for use of **LabUMat 2** automated urine chemistry analyzer.

Results:

The **LabUMat 2** automated urine chemistry analyser measures the colour change of the test pads after 60 seconds incubation time via an optical measurement head. Consult the instrument's user manual for further details.

Storage and Stability:

Keep test strips in tightly closed original tubes in a dry, dark and cool place (between +2 and +25 °C). Load the test strips into the analyzer immediately after opening the test strip container. Consult the instructions for use for test strip loading and removal in the analyzer.

Keep test strips away from moisture, direct sunlight, elevated temperature and chemical fumes. Under proper conditions test strips are stable up to the stated expiry date even after opening. Do not touch the test pads.

Quality control:

Performance of urine test strips should be checked with appropriate control materials, listed in the **LabUMat 2** automated urine chemistry analyzer's instruction for use. Perform quality control measurements according to the internal guidelines of the laboratory and local regulations. The following quality control solutions are recommended: the Dipper (Quantimetrix), the Dropper (Quantimetrix), Dip & Spin (Quantimetrix), Liqua-Trol (Kova International) and Liquichek (BioRad). Consult the instructions for use of the specific control solution for further details.

Limitations of the Procedure [1] – [6]:

Bilirubin: The reaction is unaffected by pH of urine. False low or negative results may be simulated by large amounts of ascorbic acid (up to 100 mg/dl) or nitrite or by longer exposure of the sample to direct light. Increased concentration of urobilinogen can reinforce the sensitivity of the pad. Different urine constituents (e.g. urine indicane) can lead to atypical coloration. For metabolites of drugs see urobilinogen.

Urobilinogen: The reaction is unaffected by pH of urine. Higher concentration of formaldehyde or exposure of the urine to light for a longer period of time may lead to lowered or falsely negative results. Beetroot (excreted pigments) or metabolites of drugs which give a colour at low pH (phenazopyridine, azo dyes, p-aminobenzoic acid or other medicaments which have a red intrinsic coloration in acidic medium) may produce false positive results. Prolonged exposure to light is to be avoided.

Ketones: Phthalein compounds and derivatives of anthraquinone interfere by producing a red coloration in the alkaline range which may mask the coloration of ketones.

Ascorbic acid: No interferences are known on the ascorbic acid test pad.

Glucose: High concentrations of ascorbic acid in urines (greater than 80 mg/dl) with a low glucose concentration (up to 150 mg/dl) may inhibit the reaction and lead to lower or false negative results. Repeat the test 10 hours after stopping the intake of vitamin C. Pay attention to the ascorbic acid pad. In addition, an inhibitory effect is produced by gentisic acid, a pH value of <5 and high specific gravity. False positive reactions can also be produced by a residue of peroxide containing cleansing agents or others.

Protein (albumin): Falsely positive results are possible in high alkaline urine samples (pH >9) and in the presence of high specific gravity, after infusions with polyvinylpyrrolidone (blood substitute) after intake of medicaments containing quinine and also by disinfectant residues containing quaternary ammonium groups in the urine sampling vessel.

Creatinine: Detergents, cleaning agents, disinfectants and preservatives may lead to false values for the creatinine concentration. Different urine contents, especially high concentrations of hemoglobin, riboflavin or bilirubin, can lead to atypical coloration on the test pad.

Blood: Microhaematuria does not affect the colour of urine and is only detectable by microscopic or chemical tests. From a level approx. 25 Ery/µl and above, even at high concentrations of ascorbic acid (up to 80 mg/dl) normally no negative results are observed. Falsely positive reactions can also be produced by a residue of peroxide containing cleansing agents, activities of microbial oxidase due to infections of the urogenital tract or by formalin. For establishing an individual diagnosis, it is therefore indispensable to take into consideration also the clinical manifestations.
The number of erythrocytes which are detected by sediment analysis may be lower than the result of the test strip, because lysed cells are not detected by sediment analysis.

pH: No interferences are known on the pH pad.

Nitrite: Before testing the patient should ingest vegetable-rich meals, reduce fluid intake and discontinue antibiotic and vitamin C therapy 3 days prior to the test. False positive results may occur in stale urine samples, in which nitrite has been formed by contamination of the specimen and in urines containing dyes (derivatives of pyridinium, beetroot). A negative result even in the presence of bacteriuria can have the following reasons: bacteria not containing nitrate reductase, antibiotic treatment, diet with low nitrate content, high diuresis, high content of ascorbic acid or insufficient incubation of the urine in the bladder.

Albumin: Detergents, cleaning agents, disinfectants and preservatives may lead to false values for the albumin concentration. Different urine contents, especially high concentrations of hemoglobin, riboflavin or bilirubin, can lead to atypical coloration on the test pad.

Leukocytes: Strongly coloured compounds (e.g. nitrofurantoin) may disturb the colour of the reaction. High concentrations of glucose, oxalic acid, drugs containing cephalexin, cephalothin or tetracycline can lead to weakened reaction. False-positive reactions may be caused by contamination of vaginal secretion. The number of leucocytes which are detected by sediment analysis may be lower than the result of the strip, because lysed cells are not detected by sediment analysis. Partial cytolysis intensifies the colour response, particularly in the region of the maximum analytical sensitivity. Leucocyte esterase results may be positive in the absence of observable cells if the leucocytes have lysed. False-positive reactions may be caused by formaldehyde (preservative). Protein concentrations above 5 g/l or a high specific gravity may diminish the colour response. Bacteria, trichomonas and erythrocytes however do not react with the test pad.

Notes:

- Diagnostic or therapeutic decisions should not be based on any single result or method.
- Not all cases of interference with every component of any medicine are known. The colour reaction of the pads might change, therefore, another test at the end of any medication with drugs is recommended.
- In rare occasions, the varying test conditions, due to the heterogenity of different urine (for reason of different levels of activators, inhibitors, or different ion concentrations) may cause variation in the intensity and contrast of the colours.

Expected values, measuring ranges, analytical sensitivity:

Parameter	Expected value	Unit	Measuring range	Analytical sensitivity
BIL	neg.	µmol/l	neg., 8.5, 17, 50, 100	≥1 mg/dl (for trace category 0.5-0.7 mg/dl)
		mg/dl	neg., 0.5, 1, 3, 6	
		arb.	neg., (+), +, ++, +++	
UBG	norm.	µmol/l	norm., 35, 70, 140, 200	1.2-1.4 mg/dl
		mg/dl	norm., 2, 4, 8, 12	
		arb.	norm., +, ++, +++, ++++	
KET	neg. - trace	mmol/l	neg., 0.5, 1.5, 5, 15	7-9 mg/dl (for trace category 3-4.5 mg/dl)
		mg/dl	neg., 5, 15, 50,150	
		arb.	neg., (+), +, ++, +++	
ASC	n.a.	g/l	neg., 0.2, 0.4, 1	10-12 mg/dl
		mg/dl	neg., 20, 40, 100	
		arb.	neg., +, ++, +++	
GLU	norm.	mmol/l	norm., 1.7, 2.8, 8, 28, 56	25 mg/dl (for trace category 15 mg/dl)
		mg/dl	norm., 30, 50, 150, 500, 1000	
		arb.	norm., (+), +, ++, +++, ++++	
PRO	neg. - trace	g/l	neg., 0.15, 0.3, 1, 5	27-30 mg/dl (for trace category 15 mg/dl)
		mg/dl	neg., 15, 30, 100, 500	
		arb.	neg., (+), +, ++, +++	
CREA	n.a.	mmol/l	0.9, 4.4, 8.8, 17.7, 26.5	n.a.
		mg/dl	10, 50, 100, 200, 300	
BLD	neg.	Ery/µl	neg., 5-10, 50, 300	5-6 Ery/ µl
		arb.	neg., +, ++, +++	
pH	pH 5 - 8		5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9	n.a.
NIT	neg.	arb.	neg., pos.	0.1 mg/dl
mALB	norm.	mg/l	10, 30, 80, 150, 500	≤30 mg/l
		arb.	norm., +, ++, +++, ++++	
LEU	neg.	Leu/µl	neg., 25, 75, 500	12.5-15 Leu/µl
		arb.	neg., +, ++, +++	
ACR*	norm.	mg/mmol	≤3.4, 3.5-33.8, ≥33.9	n.a.
		mg/g	≤30, 31-299, ≥300	
		arb.	norm., +, ++	
PCR	norm.	mg/mmol	≤56.7, >56.7, ≥113, ≥340	n.a.
		mg/g	≤500, >500, ≥1000, ≥3000	
		arb.	norm., +	

*If the CREA=10 mg/dl and the mALB=10 mg/l, then the sample is too diluted. Repeate the measurement with recollected sample.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Performance Characteristics:
Method comparison data of 1279 samples are provided below:

Parameter	Sensitivity [%]	Specificity [%]	Diagnostic accuracy [%]	Extended concordance [%]	NPV* [%]	PPV** [%]
BIL	97.1	97.5	73	95.1	99.5	90.1
UBG	84.1	93.9	92	98.9	96.1	76.7
KET	81.4	95.7	92.9	99.6	95.4	82.4
ASC	n.a.	n.a.	98.1	100	n.a.	n.a.
GLU	95.5	97.5	97.1	98.4	98.9	91
PRO	87.1	93.8	91.6	99.7	93.7	87.4
CREA	n.a.	n.a.	92	98	n.a.	n.a.
BLD	82.1	84.3	83.3	99.8	84.3	82.1
pH	n.a.	n.a.	n.a.	81.6	n.a.	n.a.
NIT	83.9	93.4	92.5	100	98.2	57.8
mALB	93	83	90	93	82	94
LEU	85.2	83.8	84.5	99.8	85.1	83.9
ACR	93	83	90	99	84	92
PCR	56	98	83	94	80	94

*Negative Predictive Value
**Positive Predictive Value

Repeatability
Repeatability was determined by measuring two levels (normal, abnormal) of control Ua solution 20 times. The negative and positive values were correctly identified 100 % of time for all the parameters.

Reproducibility
Reproducibility was determined by measuring two levels (normal, abnormal) of control solution over 20 days. The negative and positive values were correctly identified 100 % of time for all the parameters.

Warnings:
- Keep strips away from heat and direct sunlight.
- Do not reuse test strips.
- Store the test strips in original packages until used. Strips in each vial should not be mixed.
- Diagnoses and therapies cannot be derived from one single test result only, instead they should be based on all available medical diagnoses.
- Inform your 77 Elektronika service representative and your local competent authority about any serious incidents which may occur when using this product.

Biological risk
Handle all specimens and used test strips as if they were contaminated infectious agents. When the assay procedure is completed, dispose of specimens and strips carefully. Follow the relevant local instructions.
- Always follow the general working instruction of the laboratories.
- The test strips do not contain toxic materials

Literature:

[1] **Brunzel, Nancy A.**: Fundamentals of Urine and Body Fluid Analysis-E-Book. Elsevier Health Sciences, 2016, ISBN: 9780323374798
[2] **Kouri, Timo, et al.**: „European urinalysis guidelines." Scandinavian journal of clinical and laboratory investigation 60.sup231 (2000): 1-96.
[3] **Mundt, Lillian A.**: Graff's Textbook of Routine Urinalysis and Body Fluids. LIPPINCOTT WILLIAMS & WILKINS, 2011 ISBN: 978-1582558752
[4] **Roberts, James R.** „Urine dipstick testing: everything you need to know." Emergency Medicine News 29.6 (2007): 24-27.
[5] **Simerville, Jeff A., William C. Maxted, and John J. Pahira.** „Urinalysis: a comprehensive review." American family physician 71.6 (2005): 1153-1162.
[6] **Strasinger, Susan King, and Marjorie Schaub Di Lorenzo.**: Urinalysis and body fluids. FA Davis, 2014.

REF U12-9901-1

Manufacturer:

77 ELEKTRONIKA Kft.
HUNGARY
1116 Budapest, Fehérvári út 98.
Tel: + 36 (1) 2061480
Fax: + 36 (1) 2061481
E-mail: sales@e77.hu
Website: www.e77.hu

Symbols:

IVD	In vitro diagnostic medical device
REF	Catalogue Number
LOT	Lot Number
CE	The CE mark identifies that the product complies with the applicable directives of the European Union
	Use by
+2°C +25°C	Temperature Limitation
	Manufacturer
	Keep away from sunlight
	Consult instructions for use
	Caution
	Biological Risks
Σ 150	Contents sufficient for 150 tests
	Do NOT Reuse
	Do not use if package is damaged
EN	English language
	Not for self-testing
	Not for near patient testing

Modification history

Version	Date (dd.mm.yyyy.)	Modifications
2	08.06.2023.	• Updated data for Analytical Sensitivities and Performance Characteristics based on original and additional measurements. • Updated document format.
1	22.03.2022.	First release

U12-9201EN-2

Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 2024081**

Certificate Holder: **77 Elektronika Műszeripari Kft.**
Fehérvári út 98.
1116 Budapest
Hungary

77 ELEKTRONIKA

Including the locations according to annex.

Scope: design, development, manufacturing, sales and service of in vitro diagnostic (IVD) medical devices and veterinary devices.

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity: The certificate is valid from 06.10.2024 until 05.10.2027.

24.09.2024

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 2024081**

No.	Location	Scope
/01	c/o 77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design, development, manufacturing, sales and service of invitro diagnostic (IVD) medical devices, and veterinary devices.
/02	c/o 77 Elektronika Műszeripari Kft. Sztregova u. 1. 1116 Budapest Hungary	Design, development, manufacturing, sales and service of invitro diagnostic (IVD) medical devices, and veterinary devices.

24.09.2024

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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Precisely Right.

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 2024081**

Certificate Holder: **77 Elektronika Műszeripari Kft.**
Fehérvári út 98.
1116 Budapest
Hungary

77 ELEKTRONIKA

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/02	c/o 77 Elektronika Műszeripari Kft. Sztregova u. 1. 1116 Budapest Hungary	Design, development, manufacturing, sales and service of invitro diagnostic (IVD) medical devices, and veterinary devices.

24.09.2024

TÜV Rheinland Cert GmbH
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Precisely Right.

Dip&Spin® Urinalysis Dipstick /Microscopics Control Level 1

Safety Data Sheet

According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

Revision date: 21/12/2015 Date of issue: 21/12/2015 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name : Dip&Spin Urinalysis Dipstick /Microscopics Control, Level 1

Product code : 1470-01

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Laboratory Quality Control Material. For professional use only.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Company

Quantimetrix Corp.
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278
310-536-0006
www.quantimetrix.com

1.4. Emergency telephone number

Emergency number : 310-536-0006

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Sens. 1 H317

Full text of classification categories and H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H317 - May cause an allergic skin reaction

Precautionary statements (CLP) : P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
1,2-Propylene glycol	(CAS No) 57-55-6 (EC no) 200-338-0	5	Not classified
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	(CAS No) 55965-84-9 (EC no) 611-341-5 (EC index no) 613-167-00-5	0,003	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	(CAS No) 55965-84-9 (EC no) 611-341-5 (EC index no) 613-167-00-5	(C >= 0,0015) Skin Sens. 1, H317 (0,06 =< C < 0,6) Eye Irrit. 2, H319 (0,06 =< C < 0,6) Skin Irrit. 2, H315 (C >= 0,6) Skin Corr. 1B, H314

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area.

First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least 15 minutes.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : May cause an allergic reaction in sensitive individuals.

Symptoms/injuries after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/injuries after skin contact : May cause sensitisation of susceptible persons by skin contact.

Symptoms/injuries after eye contact : May cause eye irritation.

Symptoms/injuries after ingestion : If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.

Chronic symptoms : None expected under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

If medical advice is needed, have product container or label at hand.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray, fog.

Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity : Hazardous reactions will not occur under normal conditions.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Use appropriate personal protection equipment (PPE).
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb and/or contain spill with inert material, then place in suitable container.
Methods for cleaning up : Clean up spills immediately and dispose of waste safely.

6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Keep container closed when not in use.
Incompatible products : Strong acids. Strong bases. Strong oxidizers.

7.3. Specific end use(s)

Laboratory Quality Control Material. For professional use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

1,2-Propylene glycol (57-55-6)		
Croatia	GVI (granična vrijednost izloženosti) (mg/m³)	474 mg/m³ (total particles and vapor) 10 mg/m³ (particles)
Croatia	GVI (granična vrijednost izloženosti) (ppm)	150 ppm
Latvia	OEL TWA (mg/m³)	7 mg/m³
United Kingdom	WEL TWA (mg/m³)	474 mg/m³ (total particulates and vapour) 10 mg/m³ (particulates)
United Kingdom	WEL TWA (ppm)	150 ppm (total particulates and vapour)
United Kingdom	WEL STEL (mg/m³)	1422 mg/m³ (calculated-total particulate and vapour) 30 mg/m³ (calculated-particulate)
United Kingdom	WEL STEL (ppm)	450 ppm (calculated-total particulate and vapour)
Ireland	OEL (8 hours ref) (mg/m³)	470 mg/m³ (total vapour and particulates) 10 mg/m³ (particulate)
Ireland	OEL (8 hours ref) (ppm)	150 ppm (total vapour and particulates)
Ireland	OEL (15 min ref) (mg/m3)	1410 mg/m³ (calculated-total vapour and particulates) 30 mg/m³ (calculated-particulate)
Ireland	OEL (15 min ref) (ppm)	450 ppm (calculated-total vapour and particulates)
Lithuania	IPRV (mg/m³)	7 mg/m³

1,2-Propylene glycol (57-55-6)		
Norway	Grenseverdier (AN) (mg/m³)	79 mg/m³
Norway	Grenseverdier (AN) (ppm)	25 ppm
Norway	Grenseverdier (Korttidsverdi) (mg/m3)	79 mg/m³
Norway	Grenseverdier (Korttidsverdi) (ppm)	25 ppm

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)		
Austria	MAK (mg/m³)	0,05 mg/m³
Austria	OEL chemical category (AT)	Skin notation, Skin sensitizer

8.2. Exposure controls

Appropriate Engineering Controls: Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Protective goggles. Gloves. Protective clothing.

Materials for Protective Clothing: Chemically resistant fabrics and materials.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use an approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Amber Yellow
Odour	:	Odourless
Odour threshold	:	No data available
pH	:	6
Evaporation rate	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Solubility	:	No data available
Relative density	:	1 (Water=1)
Partition coefficient: n-octanol/water	:	No data available
Viscosity	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity
Hazardous reactions will not occur under normal conditions.

10.2. Chemical stability
Product is stable.

10.3. Possibility of hazardous reactions
Hazardous polymerization will not occur.

10.4. Conditions to avoid
Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials
Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products
The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute toxicity : Not classified

1,2-Propylene glycol (57-55-6)	
LD50 oral rat	20 g/kg
LD50 dermal rabbit	20800 mg/kg

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)	
LD50 oral rat	53 mg/kg

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
Specific target organ toxicity (single exposure) : Not classified
Specific target organ toxicity (repeated exposure) : Not classified
Aspiration hazard : Not classified
Symptoms/injuries after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms/injuries after skin contact : May cause sensitisation of susceptible persons by skin contact.
Symptoms/injuries after eye contact : May cause eye irritation.
Symptoms/injuries after ingestion : If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.
Chronic symptoms : None expected under anticipated conditions of normal use.

SECTION 12: Ecological information

12.1. Toxicity

2,4-Pentanedione (123-54-6)	
LC50 fish 1	98,3 - 110 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	34,4 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	50,3 - 71,8 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])

12.2. Persistence and degradability

Urinalysis Dipstick Controls- Dipper®/Dropper®/Dropper® Plus, Level 1	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Urinalysis Dipstick Controls- Dipper®/Dropper®/Dropper® Plus, Level 1	
Bioaccumulative potential	Not established.

2,4-Pentanedione (123-54-6)	
Log Pow	0,34

12.4. Mobility in soil
No additional information available

12.5. Results of PBT and vPvB assessment
No additional information available

12.6. Other adverse effects
Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste disposal recommendations : Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: Transport information
In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No

14.6. Special precautions for user
No additional information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations
Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

2,4-Pentanedione (123-54-6)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Lithium hydroxide (1310-65-2)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

15.1.2. National regulations
No additional information available

15.2. Chemical safety assessment
No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date : 24/11/2015
Data sources : According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Flam. Liq. 3	Flammable liquids, Category 3
Met. Corr. 1	Corrosive to metals, Category 1
Press. Gas	Gases under pressure
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Sens. 1	Sensitisation — Skin, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H226	Flammable liquid and vapour
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

EU GHS SDS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Dip&Spin® Urinalysis Dipstick / Microscopics Control Level 2

Safety Data Sheet

According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

Revision date: 21/12/2015 Date of issue: 21/12/2015 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name : Dip&Spin® Urinalysis Dipstick / Microscopics Control, Level 2

Product code : 1470-01

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Laboratory Quality Control Material. For professional use only.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Company

Quantimetrix Corp.
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278
310-536-0006
www.quantimetrix.com

1.4. Emergency telephone number

Emergency number : 310-536-0006

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Sens. 1 H317

Full text of classification categories and H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H317 - May cause an allergic skin reaction

Precautionary statements (CLP) : P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2,4-Pentanedione	(CAS No) 123-54-6 (EC no) 204-634-0 (EC index no) 606-029-00-0	0,11	Flam. Liq. 3, H226 Acute Tox. 4 (Oral), H302
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	(CAS No) 55965-84-9 (EC no) 611-341-5 (EC index no) 613-167-00-5	0,003	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	(CAS No) 55965-84-9 (EC no) 611-341-5 (EC index no) 613-167-00-5	(C >= 0,0015) Skin Sens. 1, H317 (0,06 =< C < 0,6) Eye Irrit. 2, H319 (0,06 =< C < 0,6) Skin Irrit. 2, H315 (C >= 0,6) Skin Corr. 1B, H314

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area.

First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least 15 minutes.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : May cause an allergic reaction in sensitive individuals.

Symptoms/injuries after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/injuries after skin contact : May cause sensitisation of susceptible persons by skin contact.

Symptoms/injuries after eye contact : May cause eye irritation.

Symptoms/injuries after ingestion : If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.

Chronic symptoms : None expected under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

If medical advice is needed, have product container or label at hand.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray, fog.

Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity : Hazardous reactions will not occur under normal conditions.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Use appropriate personal protection equipment (PPE).
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb and/or contain spill with inert material, then place in suitable container.
Methods for cleaning up : Clean up spills immediately and dispose of waste safely.

6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Keep container closed when not in use.
Incompatible products : Strong acids. Strong bases. Strong oxidizers.

7.3. Specific end use(s)

Laboratory Quality Control Material. For professional use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

2,4-Pentanedione (123-54-6)		
Germany	TRGS 900 Occupational exposure limit value (mg/m³)	126 mg/m³ (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed)
Germany	TRGS 900 Occupational exposure limit value (ppm)	30 ppm (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed)
Germany	TRGS 900 chemical category	Skin notation
USA ACGIH	ACGIH TWA (ppm)	25 ppm
Spain	VLA-ED (mg/m³)	83 mg/m³
Spain	VLA-ED (ppm)	20 ppm
Spain	VLA-EC (mg/m³)	166 mg/m³
Spain	VLA-EC (ppm)	40 ppm
Spain	OEL chemical category (ES)	skin - potential for cutaneous exposure
Switzerland	VLE (mg/m³)	166 mg/m³
Switzerland	VLE (ppm)	40 ppm
Switzerland	VME (mg/m³)	83 mg/m³
Switzerland	VME (ppm)	20 ppm
Switzerland	OEL chemical category (CH)	Skin notation

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)		
Austria	MAK (mg/m³)	0,05 mg/m³
Austria	OEL chemical category (AT)	Skin notation, Skin sensitizer

8.2. Exposure controls

Appropriate Engineering Controls: Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Protective goggles. Gloves. Protective clothing.

Materials for Protective Clothing: Chemically resistant fabrics and materials.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use an approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Amber Yellow
Odour	:	Odourless
Odour threshold	:	No data available
pH	:	6
Evaporation rate	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Solubility	:	No data available
Relative density	:	1 (Water=1)
Partition coefficient: n-octanol/water	:	No data available
Viscosity	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

2,4-Pentanedione (123-54-6)	
LD50 oral rat	760 mg/kg
LD50 oral	570 mg/kg
LD50 dermal rabbit	770 mg/kg
LD50 dermal	790 mg/kg
LC50 inhalation rat (ppm)	1224 ppm/4h
LC50 inhalation rat (Vapours - mg/l/4h)	5,01 mg/l/4h

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)	
LD50 oral rat	53 mg/kg

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
Specific target organ toxicity (single exposure) : Not classified
Specific target organ toxicity (repeated exposure) : Not classified
Aspiration hazard : Not classified
Symptoms/injuries after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms/injuries after skin contact : May cause sensitisation of susceptible persons by skin contact.
Symptoms/injuries after eye contact : May cause eye irritation.
Symptoms/injuries after ingestion : If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea.
Chronic symptoms : None expected under anticipated conditions of normal use.

SECTION 12: Ecological information

12.1. Toxicity

1,2-Propylene glycol (57-55-6)	
LC50 fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC50 fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and degradability

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 2	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Urinalysis Dipstick Controls-Dipper®/Dropper®/Dropper® Plus, Level 2	
Bioaccumulative potential	Not established.

1,2-Propylene glycol (57-55-6)	
BCF fish 1	< 1
Log Pow	-0,92

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No

14.6. Special precautions for user

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

1,2-Propylene glycol (57-55-6)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date : 24/11/2015
Data sources : According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Met. Corr. 1	Corrosive to metals, Category 1

Press. Gas	Gases under pressure
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Sens. 1	Sensitisation — Skin, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

EU GHS SDS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

Scope: Design and development, production, distribution, installation and servicing of blood glucose measuring systems, urine analyzers and rapid test readers, including related consumables.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design and development, production, distribution, installation and servicing.
/02	77 Elektronika Műszeripari Kft. Telephely Sztregova utca 1 1116 Budapest Hungary	Manufacture and warehouse of blood glucose measuring systems, urine analyzers, related consumables and parts. Manufacturing of SMT technology.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Автоматическая мочевая станция

LabUMat 2 + UriSed® 3 PRO

77 ELEKTRONIKA

Автоматическая мочевая станция
LabUMat 2 + UriSed® 3 PRO

LabUMat 2 – автоматический анализатор физико-химических свойств мочи, использующий метод отражательной фотометрии и прямое измерение физических параметров.

UriSed® 3 PRO – автоматический анализатор осадка мочи, использующий комбинацию светлопольной и фазово-контрастной микроскопии.

Интеграция в единый комплекс двух анализаторов позволяет выполнить стандартизированное исследование в одной пробе всех показателей общеклинического анализа мочи с формированием единого отчета.

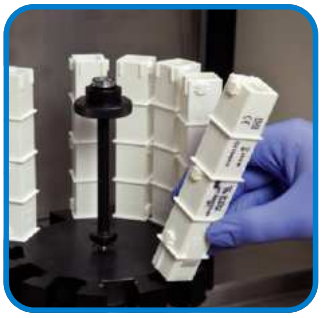
- Производительность до 240 тестов в час
- Отсутствие жидких реагентов и калибраторов
- Настройка выборочной отправки пробы на анализ осадка
- Перекрестная проверка результатов (CrossCheck)
- Результаты исследования в оптимальном виде (в полях зрения, в мкл, в «крестах»)
- Единовременная загрузка до 100 проб
- Автоматический анализ более 30 параметров в образце

UriSed® 3 PRO	
Эритроциты	Бактерии-палочки
Лейкоциты	Дрожжи
Скопления лейкоцитов	Слизь
Гиалиновые цилиндры	Сперматозоиды
Патологические цилиндры	Кристаллы
Плоский эпителий	Моногидрат оксалата кальция
Неплоский эпителий	Дигидрат оксалата кальция
Бактерии	Мочевая кислота
Бактерии-кокки	Трипельфосфат

LabUMat 2	
Билирубин	pH
Уробилиноген	Нитриты
Кетоны	Лейкоциты
Аскорбиновая кислота	Удельный вес
Глюкоза	Цвет
Белок (альбумин)	Мутность
Кровь	

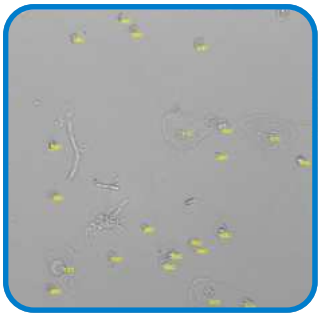
Четыре шага к получению результата
77 Elektronika

Загрузите тест-полоски



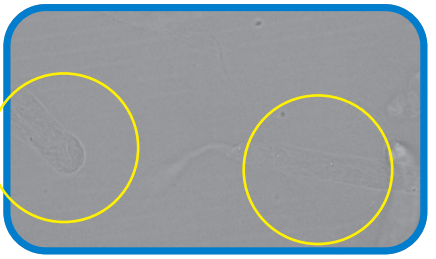
Установите кюветы

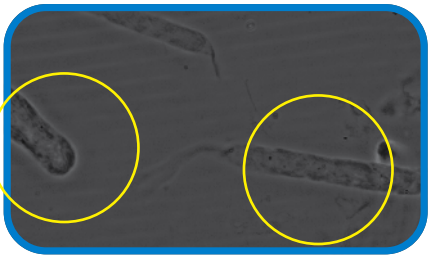
Установите стандартные пробирки



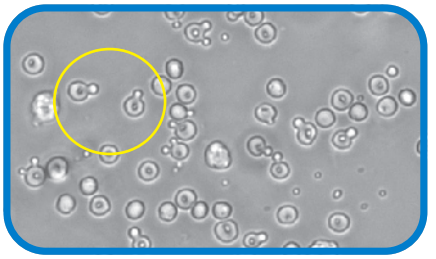
Получите результат на экране

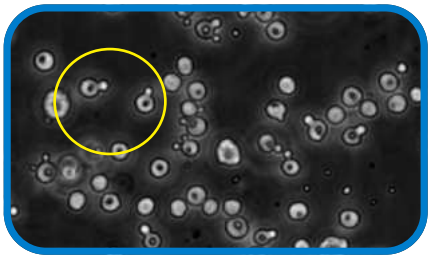
Возможности фазово-контрастной микроскопии
UriSed® 3 PRO



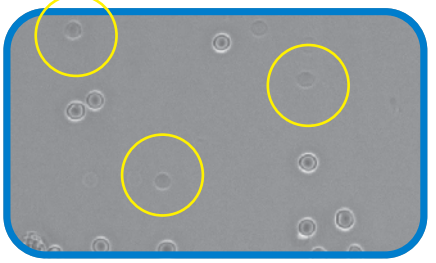


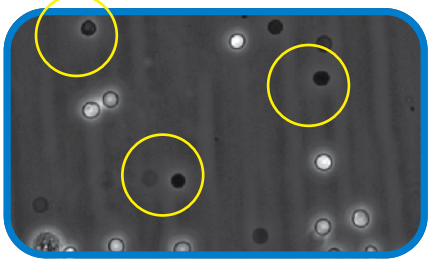
Фазово-контрастная микроскопия предоставляет новые возможности визуализации морфологии даже прозрачных элементов осадка.





UriSed 3 PRO отмечает пробы с подозрением на гломерулярную гематурию при обнаружении среди эритроцитов ≥30 % теней эритроцитов и/или ≥5 % акантоцитов.





Гематурия является основным синдромом заболеваний мочевыводящих путей и почек. Фазово-контрастная микроскопия предлагает наилучший поход к оценке морфологии эритроцитов, что позволяет определить локализацию кровотечения.

Поэтому фазово-контрастная микроскопия рекомендована при исследовании осадка мочи и обязательна при обнаружении дисморфных эритроцитов международным руководством[1].

[1] European Urinalysis Guideline, p.23, European Confederation of Laboratory Medicine, 2000

Автоматическая мочевая станция в конфигурации

LabUMat 2 + UriSed® 3 PRO + UriSed® 3 PRO (Cascade)

- Производительность до 240 тестов в час при 100% микроскопии осадка
- Одновременно в работе могут находиться до 300 проб (30 штативов)
- Непрерывная дозагрузка проб
- Два расходных материала, прозрачная стоимость одного анализа

UriSed® 3 PRO

- Максимальная производительность до 130 тестов в час
- Автоматический подсчет и распределение элементов осадка по 18 классам
- Светлопольное, фазово-контрастное и комбинированное изображение
- Вывод результатов исследования в единицах измерения: в полях зрения, в мкл, в «крестах»

LabUMat 2

- Автоматический анализ по 13 параметрам
- Производительность до 240 тестов в час
- Встроенный блок для измерения физические параметров (удельный вес и мутность)
- Двустороннее подключение к LIS

UriSed® 3 PRO + UriSed® 3 PRO

- Производительность до 240 тестов в час
- Самое эффективное решение по производительности при 100 % микроскопии осадка
- Объединение через соединительный блок для параллельного передвижения до 20 штативов с пробирками

150 тест-полосок

600 кювет

Расходные материалы

- Увеличенный срок годности
- Удобный менеджмент

Спецификации
LabUMat 2 + UriSed® 3 PRO + UriSed® 3 PRO (Cascade)

Основные характеристики

Производительность	До 240 тестов в час
Единовременная загрузка	До 300 проб
Автоматическое обнаружение и дифференцировка элементов осадка мочи	Эритроциты, Лейкоциты, Скопления лейкоцитов, Гиалиновые цилиндры, Патологические цилиндры, Плоский эпителий, Неплоский эпителий, Бактерии, Бактерии-кокки, Бактерии-палочки, Дрожжи, Слизь, Сперматозоиды, Кристаллы, Моногидрат оксалата кальция, Дигидрат оксалата кальция, Мочевая кислота, Трипельфосфат
Автоматическое определение физико-химических параметров	Билирубин, Уробилиноген, Кетоны, Аскорбиновая кислота, Глюкоза, Белок (альбумин), Кровь, pH, Нитриты, Лейкоциты, Удельный вес, Цвет, Мутность
Технология	Отражательная фотометрия, прямое измерение физических параметров. Автоматическая микроскопия и обработка изображений в одноразовой кювете
Полученные изображения	Фазово-контрастное, светлопольное и комбинированное
Считыватель штрих-кодов	Встроенный
Принтер	Опциональный, внешний (подключается к ПК)
Интерфейс	USB, LAN, RS232
ЛИС	Двустороннее подключение, LIS2-A2 или HL7

Мы оставляем за собой право изменять спецификации без предварительного уведомления.

Медика Продакт

Официальный дистрибьютор: МЕДИКА ПРОДАКТ
ул. Шереметьевская, 85, стр. 5, Москва, 129075
тел.: +7 (495) 787-44-01, факс. +7 (495) 787-44-01
news@medicaproduct.ru, www.e77.ru