For submission at the competent Authorities of the Republic of Moldova

analyticon®

Letter of Authorization

WHEREAS, **Analyticon Biotechnologies GmbH**, who is an established, and well-known manufacturer and producer of Medical Diagnostics having production facilities at 35104 Lichtenfels (Germany), Am Muehlenberg 10, do hereby declare that

Sanmedico SRL
A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova
Tel: +373 60 15-57-88
E-Mail: sanmedico.office@gmail.com

is authorized to register, import, promote and sell our urinalysis and hematology products non-exclusively within the territory of the Republic of Moldova as a Distributor for our products. We authorize Sanmedico SRL to overtake the procedures regarding the registration of the mentioned products and the Renewal of expiring Licenses for Sale of our product range of these In-Vitro-Diagnostic products at the Authorities of the Republic of Moldova. Sanmedico SRL is authorized to participate in tenders only in the territory of the Republic of Moldova. This Letter of Authorization is valid for three (3) years from the date of issue. It could be elongated from Analyticon Biotechnologies AG for another period in accordance with Sanmedico SRL. Cancellation must be in writing with a cancellation period of 3 Months for each party.

The construction of this agreement, validity and performance of this agreement and all subsequent agreements shall be exclusively governed by the laws of Germany. This agreement shall be interpreted under German Law. The laws of the Federal Republic of Germany are legally binding; this excludes the validity of the UN purchasing laws, particularly the United Nations treaty on contracts regarding the international sale of moveable property. This is also valid should the DISTRIBUTOR not be of German nationality or his head office be situated outside Germany. The parties submit to the exclusive jurisdiction of the District Courts at Korbach, Postal Code D-34497, Germany / the regional court of the city of Kassel, Germany. This Authorisation letter will replace all other existing Authorisation letters between the parties.

For and on behalf of Analyticon Biotechnologies GmbH
Signed on 14th June 2023, at Lichtenfels (Germany)

Analyticon Biotechnologies GmbH · Am Muehlenberg 10 · 35104 Lichtenfels · Germany

Digitally signed by Monastîrschii Viorica
Date: 2023.08.07 15:10:47 EEST
Reason: MoldSign Signature
Location: Moldova

Dennis Kasper
Business Area Manager Europe (East) & Africa
Analyticon Biotechnologies GmbH

/ 77 ELEKTRONIKA KFT.
H-1116 Budapest, Fehérvári út 98.
/ Telefon +36 1 206 1480
/ Web: E77.HU

For submission at the competent

Authorities of Republic of Moldova

Letter of Authorization

Whereas, **77 Elektronika Kft** (based at Fehérvári út 98, 1116 – Budapest (Hungary) as manufacturer of Urilyzer® Cell (Urine Microscopy Analyzer) and Urilyzer® Cell Cuvettes (Cuvette for Urine Microscopy Analyzer) do hereby declare that

Sanmedico SRL, str. Petricani 88/1, 0259 Chisinau - Republic of Moldova

is authorized to register, import, promote sell and support the above-mentioned products under the trademark "Urilyzer®" non-exclusively within the territory of Republic of Moldova as a Distributor. We authorize **Sanmedico SRL** to overtake the procedures regarding the registration of the mentioned products at the Authorities of Republic of Moldova. **Sanmedico SRL** is authorized to participate in tenders only in the territory of Republic of Moldova.

Analyticon Biotechnologies GmbH (based at Am Muehlenberg 10, 35104 Lichtenfels (Germany) as distributor of 77 Elektronika Kft is the owner of the trademark "Urilyzer®". 77 Elektronika Kft confirms, that Analyticon Biotechnologies GmbH is the brand owner of the above-mentioned products.

This Letter of Authorization is valid until 31.12.2023. It could be elongated by 77 Elektronika Kft for another period in accordance with **Sanmedico SRL** Cancellation must be in writing with a cancellation period of 3 Months for each party.

For and on behalf of 77 Elektronika Kft

Signed on 17th July 2023, Budapest, Hungary

Sándor Zettwitz

managing director

77 Elektronika Műszeripari Kft.
H-1116 Budapest,
Fehérvári út 98.
23.

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Analyticon Biotechnologies GmbH

Scope of certification:

Development, production and distribution of in-vitro diagnostics from the field of urine diagnostics for professional and near- patient applications
Distribution, service and installation of in-vitro-diagnostic analyzers from the field of urine diagnostics.
Distribution of in-vitro diagnostic devices from the field of hematology
Distribution and service of in-vitro-diagnostic analyzers from the field of hematology

Certified location:

Am Mühlenberg 10, 35104 Lichtenfels, Germany
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard.
The conformity was adduced with audit report no. 51519-R1-00.

Certificate registration no.:	51519-14-02_EN	Certificate valid from:	2023-03-06
Validity of previous certificate:	2023-03-05	Certificate valid to:	2025-01-10

Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2023-03-06

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Annex to the Certificate No. 51519-14-02

valid from 2023-03-06 to 2025-01-10

The following locations/companies belong to the certificate above:

	Headquarters		**Scope of certification**
	Analyticon Biotechnologies GmbH	Am Mühlenberg 10 35104 Lichtenfels Germany	see page 1
	at the following locations/at the companies at the following locations		**Scopes of certification**
1.		Am Teichsberg 10 Lichtenfels-Sachsenberg Germany	Reception, shipping and storage of raw materials, semi-finished goods, finished goods and analyzers from the fields of urine diagnostics and hematology.

Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2023-03-06

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 TÜVRheinland 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 TÜVRheinland® Zertifizierungsstelle

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

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

Konformitätserklärung – Urin Diagnostik /
Declaration of Conformity – Urine Diagnostics

Analyticon Biotechnologies GmbH

Am Mühlenberg 10,
35104 Lichtenfels, Germany

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte für die In-vitro-Diagnostik
We declare under our sole responsibility that the in vitro diagnostic medical devices

Bezeichnung und Artikelnummer: siehe Anhang
Description and article number: see annex

mit folgender Klassifizierung nach der Richtlinie über In-Vitro-Diagnostika 98/79/EG
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

( ) Produkt der Liste A, Anhang II / Device of List A, Annex II
( ) Produkt der Liste B, Anhang II / Device of List B, Annex II
( ) Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist /
Device for self-testing not listed in Annex II
(X) Sonstiges Produkt / *Other device*

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.
meet all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

Konformitätsbewertungsverfahren *Conformity assessment procedure*	IVD 98/79/EG, Artikel 9 (1) und Anhang III / *IVD 98/79/EC Article 9 (1) and Annex III*
EDMA-Code und Registrierungsnummer *EDMS-Code and Registration-No.*	siehe Anhang *see annex*
Konformitätsbewertungsstelle *Notified Body (if consulted)*	nicht erforderlich, die Bewertung wurde in Eigenverantwortung des Herstellers durchgeführt *not applicable, evaluation was carried out under the manufacturer's own responsibility*

Ort, Datum / *Place, date*

Lichtenfels, 27.04.2022

Name und Funktion / *Name and function*

Dr. Jürgen Schmich
(Sicherheitsbeauftragter gem. §30(2) MPG)
(safety officer for med. devices acc. §30(2) MDD)

Analyticon Biotechnologies GmbH
Am Mühlenberg 10,
35104 Lichtenfels, Germany

Anhang zur Konformitätserklärung – Urin Diagnostik /
Declaration of Conformity, Annex – Urine Diagnostics

CombiScreen Urine Controls

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® Dip Check	93010	11.50.90.02.00	DE/CA30/56863/D/019/Ä
CombiScreen® Drop Check	93015	11.50.90.02.00	DE/CA30/56863/D/019/Ä

Konformitätserklärung – Urin Diagnostik / Declaration of Conformity – Urine Diagnostics

Analyticon Biotechnologies GmbH

Am Mühlenberg 10,
35104 Lichtenfels, Germany

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte für die In-vitro-Diagnostik
We declare under our sole responsibility that the in vitro diagnostic medical devices

Bezeichnung und Artikelnummer: siehe Anhang
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( ) Produkt der Liste A, Anhang II / Device of List A, Annex II
( ) Produkt der Liste B, Anhang II / Device of List B, Annex II
( ) Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist / *Device for self-testing not listed in Annex II*
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allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.
meet all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

Konformitätsbewertungsverfahren *Conformity assessment procedure*	IVD 98/79/EG, Artikel 9 (1) und Anhang III / *IVD 98/79/EC Article 9 (1) and Annex III*
EDMA-Code und Registrierungsnummer *EDMS-Code and Registration-No.*	siehe Anhang *see annex*
Konformitätsbewertungsstelle *Notified Body (if consulted)*	nicht erforderlich, die Bewertung wurde in Eigenverantwortung des Herstellers durchgeführt *not applicable, evaluation was carried out under the manufacturer's own responsibility*

Ort, Datum / *Place, date*	Name und Funktion / *Name and function*
Lichtenfels, 18.01.2023	Dr. Jürgen Schmich (Direktor Qualitätssicherung / Director Quality Assurance)

Analyticon Biotechnologies GmbH
Am Mühlenberg 10,
35104 Lichtenfels, Germany

Test strips visual and semi-automated systems

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® 11SYS	93100	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS	93150	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120B	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3	93108A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GAK	93107	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GAK	93107A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GP	93104	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GPK	93105	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94100	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94150	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94150BC	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL PLUS	94120	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9 PLUS	94115	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9+Leuko PLUS	94250	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9+Leuko PLUS	94200	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 7SYS PLUS	94110	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 7SYS PLUS	94110A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5SYS PLUS	94109	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+Leuko PLUS	94517	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+Leuko PLUS	94117	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+N PLUS	94535	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+N PLUS	94135	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3 PLUS	94508	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3 PLUS	94108	11.70.02.02.00	DE/CA30/00017200
CombiScreen® Glu PLUS	94501	11.70.02.02.00	DE/CA30/00017200
CombiScreen® Nitrit PLUS	94506	11.70.02.02.00	DE/CA30/00017200
CombiScreen® mALB / CREA	94025	11.70.02.02.00	DE/CA30/00017200

/ 77 ELEKTRONIKA KFT.
H-1116 Budapest, Fehérvári út 98.

EU-DECLARATION OF CONFORMITY

Manufacturer name:	**77 Elektronika Műszeripari Kft.**
Address:	Fehérvári út 98., H-1116 Budapest
SRN number:	HU-MF-000004266

Product(s) name:	**Urilyzer Cell Cuvettes**
Reference number:	ULC001
Basic UDI-DI:	59973457CUV9W
GMDN / EMDN	61032 / W02010785
Intended purpose of the device:	Urilyzer Cell Cuvettes are disposable, single use polycarbonate specimen receptacles used to analyse uncentrifuged, human urine samples with Urilyzer Cell urine sediment analysers. It is intended for professional, laboratory use. It is intended for in vitro diagnostic use.
Classification:	A class

The manufacturer declares under its sole responsibility that the above-mentioned product complies with the requirements of the following legislation (s):

Applicable legalisations:	Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices

Notified Body name:	N/A
Notified Body address:	N/A
Notified Body Identification Number:	N/A
Conformity assessment procedure:	N/A
EC Certificate of conformity's type, number and validity:	N/A

Budapest, 25.05.2022.

.....

Oliver Babinszki
Quality and Environmental Management Director

77 Elektronika Műszeripari Kft.
1116 Budapest, Fehérvári út 98.
Adószám: 10229064-2-44
BBRT: 10102093-01196703-00000005
36.

Authorization Certificate

analyticon

Vitalie Goreacii

SANMEDICO SRL

This is to certify that the above named general manager has successfully completed the full application and technical training which was specifically prepared and carried out on the Analyticon Biotechnologies GmbH equipment mentioned below on May 22nd to 23rd, 2023

Urilyzer® Cell

We hereby state that the general manager is authorized and qualified by Analyticon to do installation, operation, user and technical training, service and maintenance of the equipment listed above.

Analyticon
Biotechnologies GmbH
Customer Support & Trainings

Analyticon Biotechnologies GmbH · Germany · Lichtenfels · 35104 · Mühlenberg 10 · analyticon

Nathalie Mütze
Manager Customer Support

Nils Albrecht
Customer Support

CS_FB_OR_9999

Urilyzer® 100 Pro

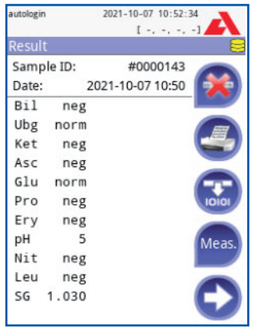
analyticon®

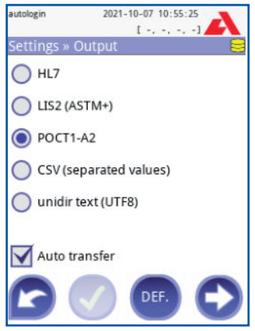
A new way in urinalysis

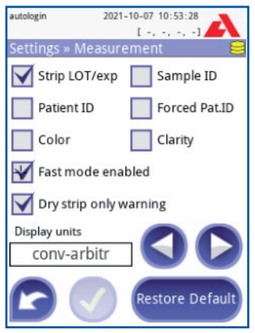
- Easy-to-use
- Smart and safe operation
- Extended connectivity capabilities
- POCT-features

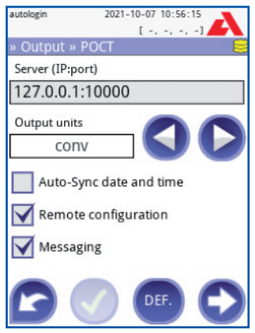
Easy-to-use

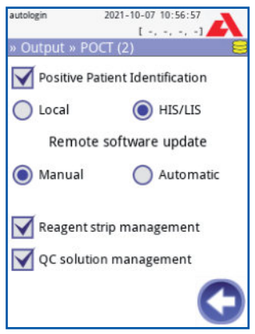
- A Start-Up Wizard leads the operator through the user-defined settings upon first start of the device.
- Automatic start of the measurement after placing the urine test strip allows hygienic and clean operation of the analyzer
- Positive results, reminders and warnings are shown in color (e.g. red or yellow) and can be easily identified
- The user interface offers a high level of customization with flexible testing and reporting options

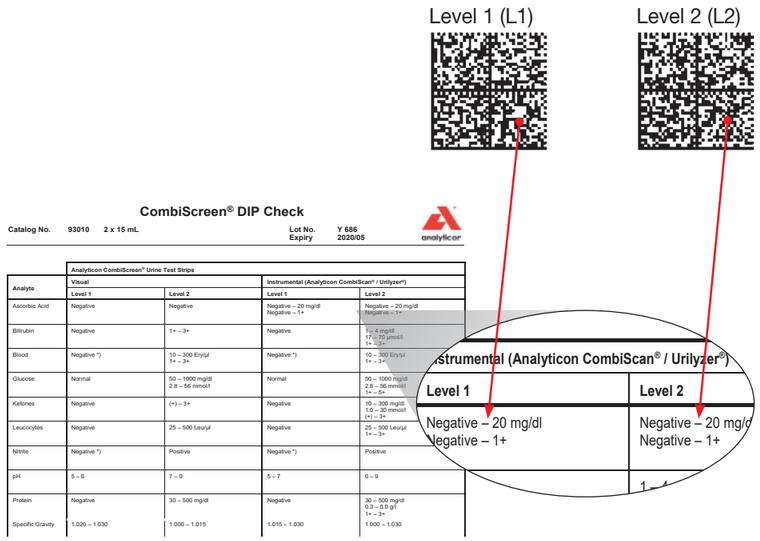


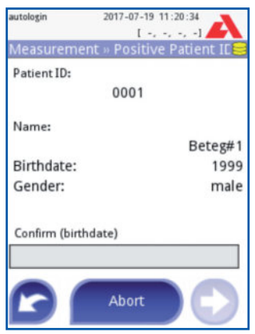










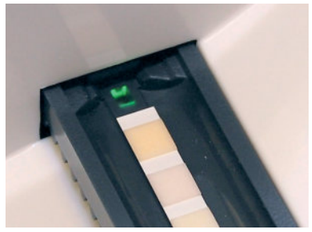


Smart and safe operation

- Tracking of LOT-No. for urine strips and quality control solutions
- Data management provides multiple filter options
- QC ranges can be entered via QR-Code
- Automated QC analysis with customizable QC test reminders including lockout function
- System allows the allocation of different security levels to individual users

Connectivity capabilities

- Data can be transferred via serial connection or Ethernet
- A variety of interfaces for connecting external barcode scanner and/or keyboard (USB or PS2)
- Implemented protocols: HL7, LIS2 (ASTM+), POCT1-A2



POCT1-A2 features

- Validated for use with Siemens UniPOC™ and POCcelerator™*
- Remote configuration via middleware
- Automated synchronization of date and time via the middleware
- Messaging function allows the POCT datamanager to send messages to addressed operators or instruments
- Positive Patient Identification (PPID)
- Remote software update
- Test strip management
- QC solution management
- Proficiency test feature

* please contact us for other middleware options

Technical Specifications

Type	Semi-automated urine test strip analyzer
Measurement technology	Reflectance photometer with 4 discrete wavelengths 505, 530, 620, 660 nm
Parameters	11 Parameter: Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes, Specific Gravity 7 Parameter: Ketones, Glucose, Protein (Albumin), Blood (Hemoglobin), Nitrite, Leucocytes, pH 5 Parameter: Glucose, Protein (Albumin), Blood (Hemoglobin), Nitrite, Leucocytes 2 Parameter: Albumin, Creatinine
Throughput	Up to 50 tests/hour (in normal mode) Up to 120 tests/hour (in fast mode)
Data storage	Patient database: 3.000 tests QC database: 1.000 tests
Display	3.5” QVGA touchscreen LCD
Interfaces	Serial RS232, USB Type A, USB Type B, PS2 (external keyboard, barcode reader), Ethernet
Dimensions	208 x 290 x 80 mm (WxDxH)
Weight	1.2 kg
Power supply	7.5 V DC / 3 A
Operating environment	Temperature: +15°C to +32°C Relative humidity (non-condensing): 30% to 80% Atmospheric pressure: 70 kPa to 106 kPa
Printer	Built-in thermal printer
Barcode reader	External
Protocols	LIS2 (ASTM+), HL7, POCT1-A2
Features	• Start-Up Wizard upon first usage • Operator Management with advanced system security options • Test strip & QC Management (full traceability via LOT and Expiry entry) • Data Management, Power Management • Autostart of measurement (automatic strip detection) • Automatic printout or transfer of result • Flexible advanced information entry (e.g. sample color and turbidity) • Flexible advanced testing and reporting options (e.g. sediment recommendation flag)
Laguages	Czech, Danish, English, Finish, French, German, Greek, Hungarian, Italian, Norwegian, Polish, Romanian, Russian, Spanish, Swedish

Art.-No.: UL0100Pro

Consumables

Urine test strips	**Pack size**	**Art.-No.**
CombiScreen® 11SYS PLUS	100/150 strips	94100/94150
CombiScreen® 7SYS PLUS	100/150 strips	94110/94110A
CombiScreen® 5SYS PLUS	100 strips	94109
CombiScreen® 11SYS	100/150 strips	93100/93150
CombiScreen® mALB / CREA	25 strips	94025

Control	**Pack size**	**Art.-No.**
CombiScreen® Dip Check	2 x 15 ml	93010
CombiScreen® Drop Check	2 x 5 ml	93015

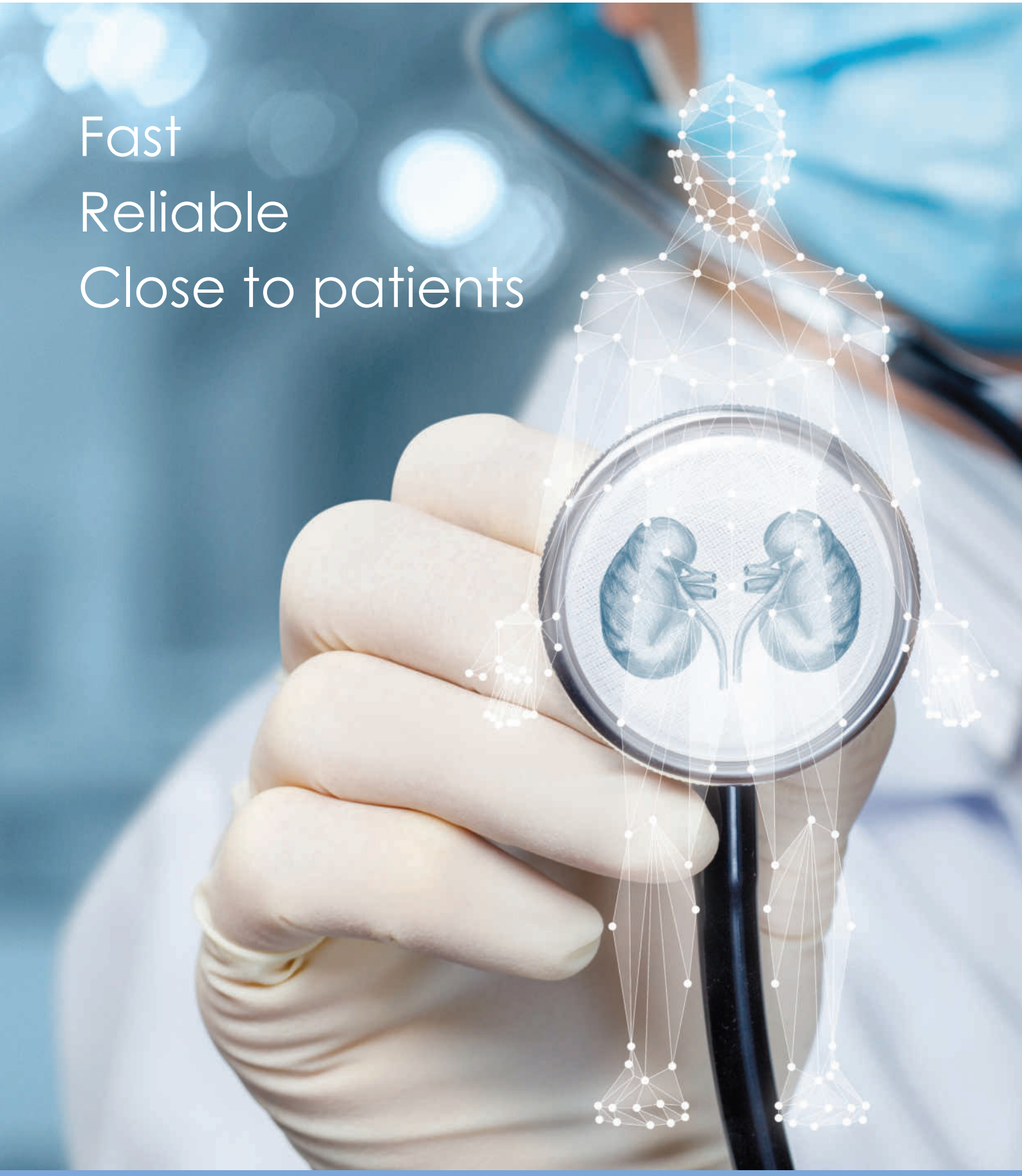
Distributor information

Analyticon Biotechnologies GmbH
Am Muehlenberg 10
35104 Lichtenfels - Germany
Phone: +49 6454 7991-0
info@analyticon-diagnostics.com
www.analyticon-diagnostics.com

MUL100_GB_62_001_09.01_20210924

Products 2023

analyticon



agile - affordable - accurate

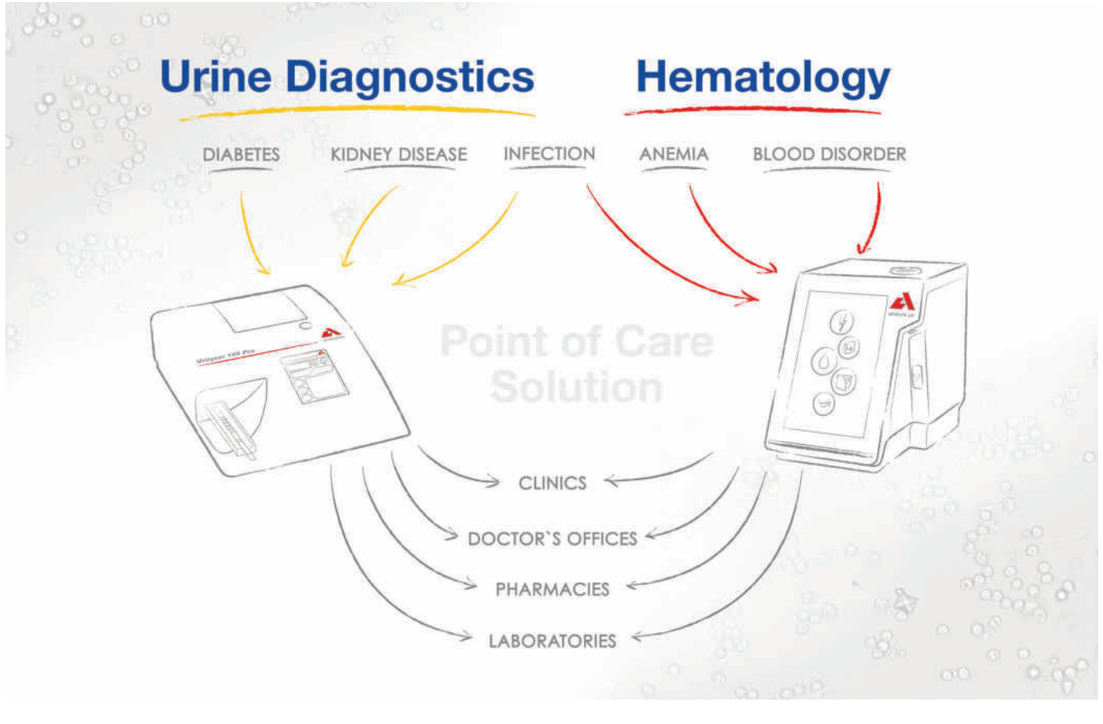
Content

Pictures
Cover: www.istockphoto.com
Inside pages: www.istockphoto.com
Analyticon Biotechnologies GmbH

MP2023_en_61_001_01.01_20221024

General conditions

Products are delivered on the general terms and conditions of Analyticon Biotechnologies GmbH only. Information stated in catalogues and product flyers is provided only for informative purposes and does not bind the seller. Analyticon Biotechnologies GmbH reserves the right to modify products at any time on behalf of further development. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.



Vision

Our vision is to develop and distribute innovative urinalysis and hematology solutions for the in vitro diagnosis of diabetes, kidney disease, and infectious diseases, among other medical conditions. In this way, we help improve patient quality of life around the world.

Mission

Our mission is to provide the highest quality diagnostic systems and solutions that deliver accurate results while optimizing workflows to boost laboratory efficiency.

We make every effort to ensure that our solutions meet end-user needs but remain affordable at all times and in any country.

About us

Analyticon is an agile and global diagnostics company focused on customized solutions for urine diagnostics and hematology. Our products support accurate and cost-effective onsite diagnostics in doctors' offices, hospitals and clinical laboratories. Analyticon distributes products to up to 100 countries via a worldwide network of partner companies and distributors. All products are manufactured according to DIN EN ISO 13485 standards.

Analyticon is also a reliable physical manufacturer for many international IVD companies.

Business areas

With our focus on Point of Care Solutions Analyticon is dedicated to develop and distribute innovative urinalysis and hematology systems for the in vitro diagnosis of diabetes, kidney diseases and infectious diseases, among other medical conditions.

Our Point of Care Solutions facilitate a fast and reliable diagnosis. This is achieved by ease of use, state of the art data management, unique and intuitive user interface structures and a quality focused development and production.

Our Urine Diagnostics Portfolio comprises a broad selection of urine test strips, semi-automated analyzers and controls. Especially the Urilyzer® 100 Pro system including POCT features is unique in it's class. With the introduction of the Urilyzer® Cell, a compact and reliable solution for sediment diagnostics is now available to increase productivity and reproducibility in the medium throughput range.

The Hematology line comprises 3-part and 5-part analyzers with a selection of reagent packs and controls. Hemolyzer® 3 NG and Hemolyzer® 5 NG (open and closed) offer a reliable diagnosis with minimum sample and reagent consumption.

Analyticon continues to increase its research and development efforts in order to provide further parameters and to expand our family of products.

Markets

We distribute our products all over the world in Europe, the Middle East, Africa, Asia-Pacific and Americas in currently up to 100 countries. The products are distributed in those markets by our high-qualified partners. Analyticon takes pride in setting high standards for their authorized representatives in order to meet the high expectations of the customers served in doctors' offices, clinics and laboratories. We invite you to share our positive market experience and together improve the onsite diagnostics in your market.

Quality statement

Analyticon is committed to meeting or exceeding the needs and expectations of our customers and partners worldwide with high-quality products for routine diagnostics, compelling solutions, and responsive service and support. We lay great value on listening to our customers, recognizing their needs, and translating them into innovative products and solutions.

We continuously work to improve our products and services. Our internal processes are reviewed and optimized through frequent dialog with our employees and customers. The thorough quality assurance of all our operational processes is guaranteed by our certified quality management system, which complies with the internationally valid standards DIN EN ISO 13485. We assure seamless and continuous quality control of development, production, and distribution, and our products meet all quality standards of the strict IVD Directive 98/79/EC.

Furthermore, Analyticon regularly participates in external ring trials and has registered portions of its portfolio with national authorities (e.g., the Chinese National Medical Products Administration (NMPA), Scandinavian Laboratory Equipment Assessment Authority (SKUP), College of American Pathologists (CAP)).

Your Analyticon Team

Ressourcen

Analyticon is committed to ensuring the continuity and reliability of product supplies. More than 90% of our suppliers are located in the European Union. Through well-planned and foresighted stock management, Analyticon is strategically well positioned to respond to challenging global situations.

Customer Support

Our excellent customer support makes the difference. We aim to reduce downtimes of our systems to a minimum and we ensure extremely short response times. Requested information will be precise and highly professional. Part of our excellent customer support is a sophisticated training for Field Service Engineers and Application Specialists, which qualifies the trained specialists to train their end users on our systems, to perform the daily troubleshooting on the systems and to perform the necessary maintenance.

Please note that our customer support provides second level support to all our professional partners around the globe. Requests from end users will therefore be forwarded to our qualified partners as the primary support providers.

All these efforts serve one objective: to keep systems running, wherever in the world they are located!


Highest quality solutions
in Urinalysis

CombiScreen® Urine Test Strips

Application of urine test strips

Urine test strips are easy-to-use, cost-effective and provide fast and reliable information on pathological changes in the organism. Urine test strips are intended to be used as a screening test for:

- Kidney diseases and urinary tract infections
- Metabolic disorders like diabetes mellitus
- Liver and hemolytic diseases

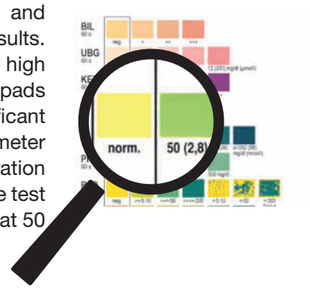
Furthermore, they are often used to monitor the success of a prescribed therapy or to self-monitor the metabolic situation of diabetic patients.

Easy-to-use

The CombiScreen® urine test strips have a consistent reading time of 60 seconds (up to 120s for leucocytes). The long handle end prevents contact with the test pads, ensuring hygienic evaluation of the urine test strips. The aluminum vial sealed with a desiccant stopper protects the strips from light as well as humidity and allows one-hand operation.

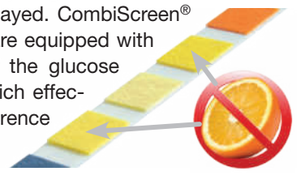
Distinct color changes in the clinically relevant range

The clear color change in the clinically relevant area of the CombiScreen® urine test strip and the true-color printing of the tube labels make it easier to distinguish between normal and suspicious results. Furthermore, the high sensitivity of our test pads shows clinically significant results for each parameter even at low concentration levels (e.g. the glucose test pad will react already at 50 mg/dl).

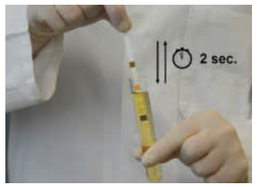


Excellent ascorbic acid protection for glucose and blood pad

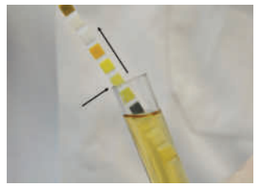
Ascorbic acid (Vitamin C) is absorbed by food, nutritional supplements and as a preservative in the body. Excess ascorbic acid is excreted; nevertheless, significant ascorbic acid levels in the urine are observed in a high proportion of the population.
This can affect the sensitivity of conventional tests and cause false negative results at high concentration levels. Due to that fact, necessary diagnostic or therapeutic actions might be delayed. CombiScreen® PLUS urine test strips are equipped with an active protection of the glucose and blood test pad, which effectively precludes interference by ascorbic acid.



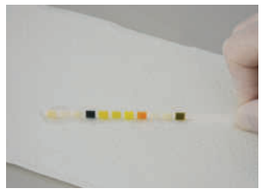
Four simple steps to achieve a multi-parameter result



- Collect the midstream specimen of urine (preferably morning urine).
- Dip the strip about 2 sec.
- Take care all pads are wet.



- Wipe off excessive urine at the edge of the tube.

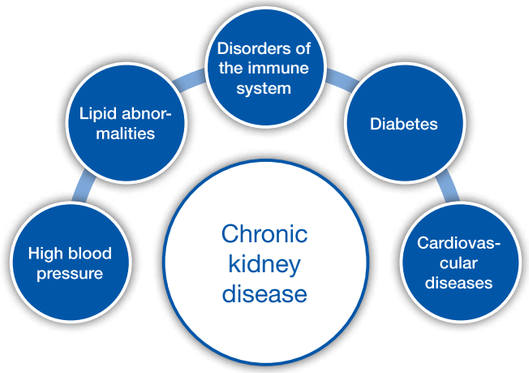


- Dip the strip on a tissue and keep it horizontal. Incubation time: 60 sec., Leucocytes up to 120 sec.

- Compare the color of the test pads with the label after 60 sec. In this example glucose and ascorbic acid is positive.
- Note the result.

CombiScreen® mALB / CREA

- The albumin-to-creatinine ratio provides accurate information on albumin level in urine, regardless of the urine concentration.
- The low detection limit of 22 mg/L albumin enables reliable screening of risk patients.
- Cost-effective and fast method. No 24 h sample collection is necessary.
- The albumin-to-creatinine ratio and the diagnostic relevant result is calculated automatically after a measurement with the Urilyzer® 100 Pro.



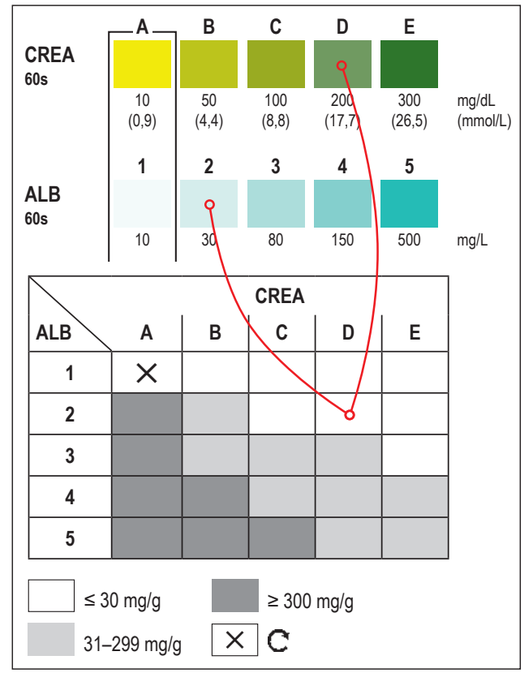
Intended Use
Screening of microalbuminuria for people with chronic conditions, such as diabetes and high blood pressure that puts them at an increased risk of developing a kidney disease. It may also be associated with some lipid abnormalities and various immune disorders.

Precise
No 24h sample collection is necessary. The albumin-to-creatinine ratio delivers information about the patient's urinary albumin concentration using a spontaneous voided morning urine sample.

Easy-to-use
The included result table directly shows the diagnostic relevant result. A calculation of the albumin-to-creatinine ratio is not necessary.

Sensitive
The detection limit of approx. 22 mg/L albumin offers a screening assay with high sensitivity.

Extended Albumin concentration range
Detection of microalbuminuria or macroalbuminuria by the extended albumin concentration range (up to 500 mg/L).



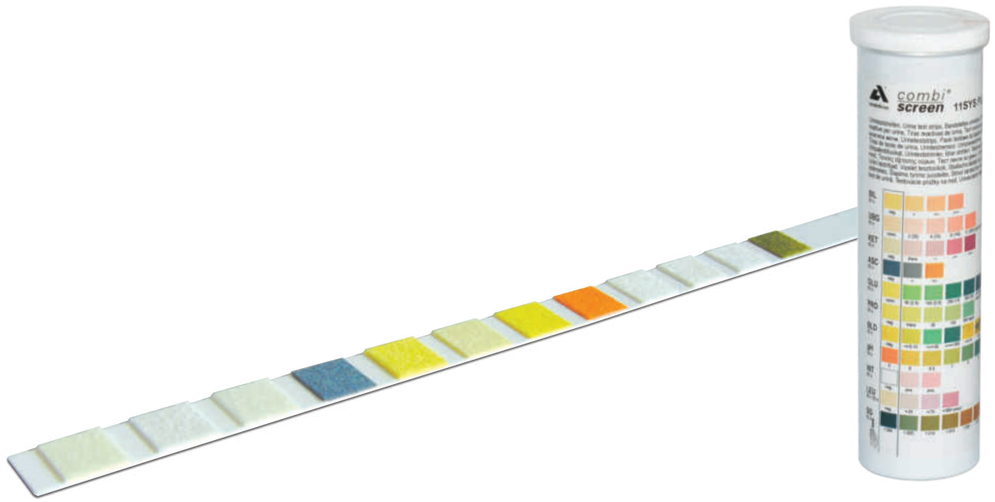
The evaluation of the result is extremely simple and reliable due to the table on the label.

CombiScreen® Parameter Overview

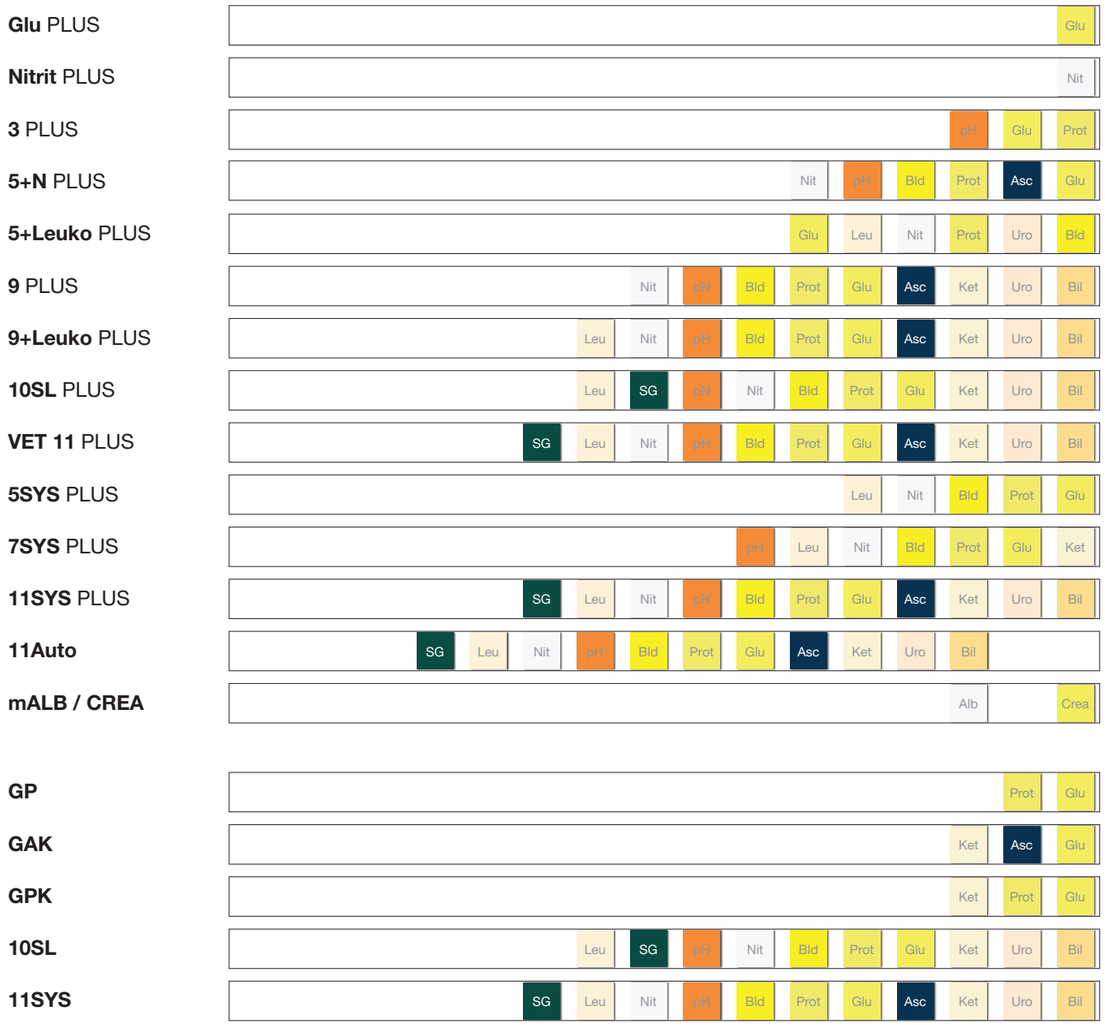
combi® screen PLUS
– with ascorbic acid protection

Name	Art.-No.	Cont.	Glucose	Ascorbic Acid	Ketones	Protein	pH-Value	Blood	Nitrite	Leucocytes	Spec. Gravity	Bilirubin	Urobilinogen	Creatinine	Albumin
			Parameter												
Glu Plus	94501	50	■												
Nitrit Plus	94506	50							■						
3 Plus	94508 / 94108	50 / 100	■			■	■								
5+N Plus	94535 / 94135	50 / 100	■	■		■	■	■	■						
5+Leuko Plus	94517 / 94117	50 / 100	■			■		■	■	■			■		
9 Plus	94115	100	■	■	■	■	■	■	■			■	■		
9+Leuko Plus	94250 / 94200	50 / 100	■	■	■	■	■	■	■	■		■	■		
10SL Plus	94120	100	■		■	■	■	■	■	■	■	■	■		
VET 11 Plus	94100V	100	■	■	■	■	■	■	■	■	■	■	■		
5SYS Plus[1)]	94109	100	■			■		■	■	■					
7SYS Plus[1)]	94110 / 94110A	100 / 150	■		■	■	■	■	■	■					
11SYS Plus[2)]	94100 / 94150	100 / 150	■	■	■	■	■	■	■	■	■	■	■		
11Auto[3)]	95150	150	■	■	■	■	■	■	■	■	■	■	■		
mALB / CREA[1)]	94025	25												■	■
CombiScreen® classic line – without ascorbic acid protection															
GP	93104	100	■			■									
GAK	93107	100	■	■	■										
GPK	93105	100	■		■	■									
10SL	93120 / 93120A	100 / 150	■		■	■	■	■	■	■	■	■	■		
11SYS[2)]	93100 / 93150	100 / 150	■	■	■	■	■	■	■	■	■	■	■		

[1)] System test strips to be used with Urilyzer® 100 Pro instruments
[2)] System test strips to be used with Urilyzer® 100/500 Pro instruments
[3)] System test strips to be used with Urilyzer® Auto instruments

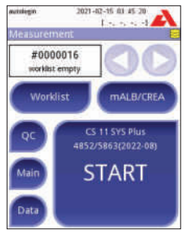


CombiScreen® Details



Urilyzer® 100 Pro

The Urilyzer® 100 Pro is a semi-automated urine test strip analyzer for single test strip reading. The system is provided with state of the art operator and QC management as well as enhanced connectivity capabilities to meet the growing demands for compliance management and data capture. The Urilyzer® 100 Pro including POCT features is unique in it's class.



Throughput	Up to 120 tests/hour (fast mode) Up to 50 tests/hour (normal mode)
Data storage	Patient database: 3000 tests QC database: 1000 tests
Test strips	CombiScreen® 11SYS PLUS CombiScreen® 7SYS PLUS CombiScreen® 5SYS PLUS CombiScreen® 11SYS CombiScreen® mALB / CREA

Quantity delivered	Art.-No.
1 x Urine analyzer Urilyzer® 100 Pro	**UL0100Pro**
1 x User Manual 1 x Thermal printer paper (57 mm x 25 m) 2 x Test strip tray 1 x Check strip 1 x Power supply (AC adapter 100–240 V, 50/60 Hz) 1 x Power supply cord	
Consumer materials: Thermal printer paper (57 mm x 25 m)	**A93010**
Extras: External Barcode Reader for Urilyzer® 100 / 500 Pro	**A93025**

Easy-to-use
- A Start-Up Wizard leads the operator through the user-defined settings upon first start of the device
- Automatic start of the measurement after placing the urine test strip allows hygienic and clean operation of the analyzer
- Positive results, reminders and warnings are shown in color (e.g. red or yellow) and can be easily identified
- The user interface offers a high level of customization with flexible testing and reporting options

Smart and safe operation
- Tracking of LOT-No. for urine test strips and quality control solutions
- Data management provides multiple filter options
- QC ranges can be entered via QR-Code
- Automated QC analysis with customizable QC test reminders including lockout function
- System allows the allocation of different security levels to individual users

Connectivity capabilities
- Data can be transferred via serial connection or Ethernet
- A variety of interfaces for connecting external barcode scanner and/or keyboard (USB or PS2)
- Implemented protocols: HL7, LIS2 (ASTM+), POCT1-A2

POCT1-A2 features
- Ready to use with Siemens UniPOC™ and POCcelerator™ middleware*
- Remote configuration via middleware
- Automated synchronization of date and time via the middleware
- Messaging function allows the POCT datamanager to send messages to addressed operators or instruments
- Positive Patient Identification (PPID)
- Remote software update
- Test strip management
- QC solution management
- Proficiency test feature

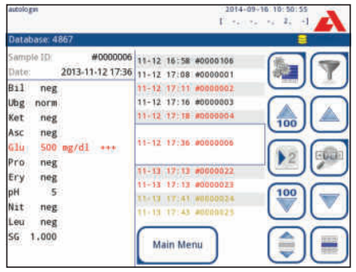
* please contact us for other middleware options

Specifications

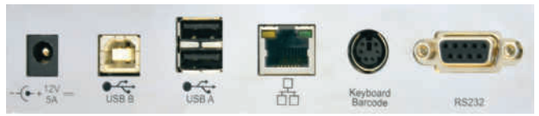
Type	Semi-automated urine test strip analyzer
Measurement technology	Reflectance photometer with 4 wavelengths: 505, 530, 620, 660 nm
Parameters	11 Parameter: Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes, Specific Gravity 7 Parameter: Ketones, Glucose, Protein (Albumin), Blood (Hemoglobin), Nitrite, Leucocytes, pH 5 Parameter: Glucose, Protein (Albumin), Blood (Hemoglobin), Nitrite, Leucocytes 2 Parameter: Albumin, Creatinine
Interfaces	Serial RS232, USB Type A, USB Type B, PS2 (external keyboard, barcode reader), Ethernet
Printer	Built-in thermal printer
Barcode Reader	External
Protocols	LIS2 (ASTM+), HL7, POCT1-A2
Features	Operator Management with advanced system security options Test strip & QC Management (full traceability via LOT and Expiry entry) Data Management, Power Management Start-Up Wizard Autostart of measurement (automatic strip detection) Automatic printout or transfer of result Flexible advanced information entry (e.g. sample color and turbidity) Flexible advanced testing and reporting options (e.g. sediment recommendation flag)

Urilyzer® 500 Pro

The Urilyzer® 500 Pro is a semi-automated urine test strip analyzer with continuous loading function. The system is provided with state of the art operator and QC management as well as enhanced connectivity capabilities to meet the growing demands for compliance management and data capture. Moreover, the system provides the user with a high level of customization with flexible testing and reporting options.



Throughput	Up to 500 tests/hour (continuous loading sytem)
Data storage	Patient database: 5000 tests QC database: 5000 tests
Test strips	CombiScreen® 11SYS PLUS, CombiScreen® 11SYS



Quantity delivered	Art.-No.
1 x Urine analyzer Urilyzer® 500 Pro	**UL0500Pro**
1 x Quick Reference Guide 1 x Thermal printer paper (57 mm x 25 m) 1 x Drop tray 1 x Strip timer rake 1 x Test strip tray/waste bin 1 x Grey check strip 1 x Power supply (AC adapter 100–240 V, 50/60 Hz) 1 x Power supply cord	
Consumer materials: Thermal printer paper (57 mm x 25 m)	**A93010**
Extras: External Barcode Reader for Urilyzer® 100 / 500 Pro	**A93025**

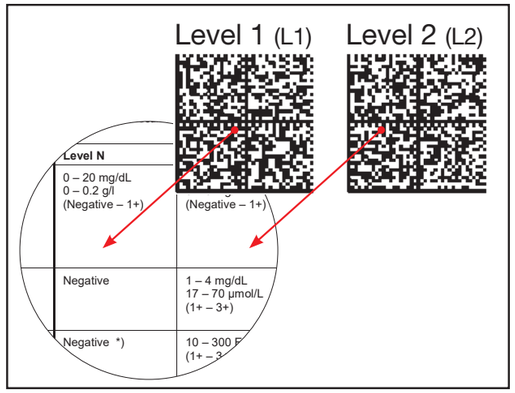
Start-Up Wizard
- On first usage the operator can select the language. Afterwards, the Start-Up Wizard leads through the user-defined settings
- The Start-Up Wizard enables the user to perform measurements without having to go through the complete user manual

Operator Management
- Multiple authorization levels
- Programmable operator management provides customized access levels & prevents unauthorized use

Data Management
- Flexible, customized testing and reporting options
- Advanced data entry (e.g. color, clarity, LOT, expiry)
- Worklist transmission through LIS2 and HL7
- Optional barcode reader and external keyboard

Quality Control Management
- QC ranges can be entered via QR-Code
- Customizing of the QC protocol according to regulatory requirements and laboratory standards
- Enables QC reminder functions or lockout protocol in a customizable time interval
- QC results are compared to the entered reference values and the last 5000 QC records are stored

Easy-to-use
- Automatic strip detection (autostart)
- Easy-to-use software
- Color touchscreen operation
- High throughput of up to 500 tests/hour
- Microscopy flag (sediment recommendation)
- Standby function
- Minimal maintenance and convenient cleaning
- Continuous loading system



QC ranges can be entered via QR code

Specifications

Type	Semi-automated urine test strip analyzer with continous loading
Measurement technology	Reflectance photometer with 4 wavelengths: 505, 530, 620, 660 nm
Parameters	Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes, Specific Gravity
Interfaces	Serial RS232, USB Type A, USB Type B, PS2 (external keyboard, barcode reader), Ethernet
Printer	Built-in thermal printer
Barcode Reader	External
Protocols	LIS2 (ASTM+), HL7
Features	Operator Management with advanced system security options Test strip & QC Management (full traceability via LOT and Expiry entry) Data Management Start-Up Wizard Autostart of measurement (automatic strip detection) Automatic printout or transfer of result Flexible advanced information entry (e.g. sample color and turbidity) Flexible advanced testing and reporting options (e.g. sediment recommendation flag)

Urilyzer® Auto

The Urilyzer® Auto is a fully automatic urine test strip analyzer with a combined pipetting and measuring head technology for the analysis of CombiScreen® 11 Auto urine test strips. In addition, the system has a physical measurement cell module for determination of specific gravity, color and turbidity.

- Throughput of up to 240 tests/hour with a loading capacity of up to 100 samples in one batch
- Comfortable color touchscreen
- Built-in barcode reader
- Patient and QC database: 10.000 tests
- Loading capacity (urine test strips): 300 (two tubes)
- Minimum sample volume: 2 ml (native urine)
- Operator Management
- Test strip & QC Management (full traceability via LOT and Expiry entry)
- Only distilled water permanently connected (at least 300 tests can be performed with 5 L distilled water)

Filling the strip container directly with two tubes of CombiScreen® 11Auto strips. The drying agent may be used to ensure on-board stability.

Quantity delivered	Art.-No.
1 x Urilyzer® Auto	**ULA240**

1 x Rack mover unit
1 x Quick reference guide
1 x Power cord and 1 x serial cable
1 x Waste container and 1 x wash container
1 x Container holder
3 x Pipes
1 x Dropping strip tray
1 x Pipetting tray
1 x Strip forwarding comb
2 x Touchscreen pen

CombiScreen® Urine Control

CombiScreen® urine controls cover a wide range of analytes, including pregnancy markers and Microalbumin. The controls are designed for use in manual and automated methods, to monitor the performance of a variety of urine test strips.

CombiScreen® Dip Check Art.-No. 93010

Ready-to-use dipper control

2 x 15 ml (Level 1 + Level 2)
Open vial stability (at 2–8 °C) of 75 days
or 20 determinations (whichever occurs first)

CombiScreen® Drop Check Art.-No. 93015

Ready-to-use dropper control

2 x 5 ml (Level 1 + Level 2)
Open vial stability of 18 months (2–8 °C)
or 30 days (20–25 °C)

Features:

- Based on human standard material
- Suitable for use in POC testing
- Shatter proof vials (polystyrene)
- 2D-barcode on tube vial for direct entry of LOT number and target values into Urilyzer® 100 Pro and Urilyzer® 500 Pro instruments
- Target values for CombiScreen® urine test strips
- Target values for Siemens and Roche urine test strips
- Parameters: Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, pH, Nitrite, Leukocytes, Specific Gravity, Microalbumin, Creatinine and hCG
- Qualitative hCG values

Urilyzer® Cell

The Urilyzer® Cell is a semi-automatic urine sediment analyzer for professional use. After manual pipetting of the sample into the cuvette, sample processing, microscopy and evaluation are performed automatically.
The Urilyzer® Cell increases the reproducibility and accuracy of urine sediment analysis based on the gold standard method. The automation of time-consuming sample processing also increases productivity. The compact design and ease of use make the Urilyzer® Cell ideal for use in medical practices and small laboratories.

- Easy to use
- Throughput of up to 60 tests/hour
- Required sample volume: ~175µl native urine
- No additional reagents required
- Suitable for laboratories and practices with limited space
- Automatic generation of HPF-like images
- Automatic identification of particles
- Real-time microscopy possible in manual mode
- User-friendly, configurable application software for data processing, result validation and generation of complete analysis reports
- Connection to middleware, LIS and Urilyzer® 100 Pro / Urilyzer® 500 Pro possible

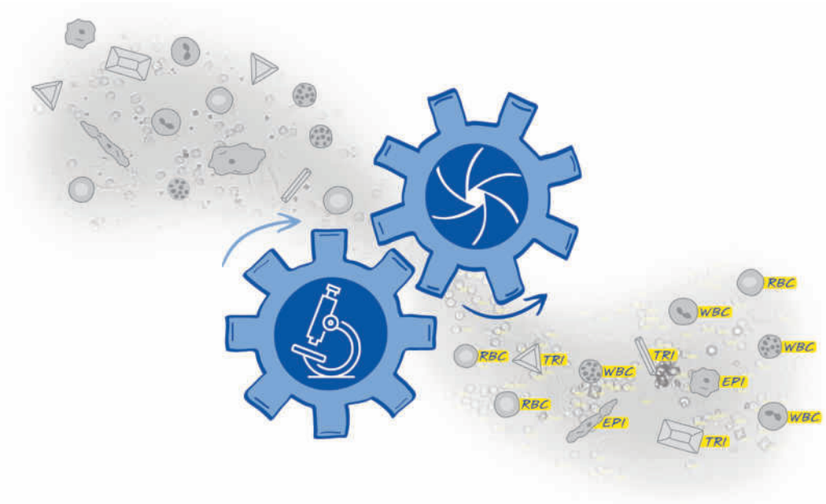
Connectivity options

The connection options to an Urilyzer® 100 Pro or 500 Pro and the connection to a laboratory information system (LIS) or middleware enable a complete urine analysis in less than 3 minutes. The auto-transfer function allows the automatic transfer of the urine test strip result as well as the associated sediment result into the patient's file. In this way, the combined result is accessible in the shortest possible time.

Quantity delivered	Art.-Nr.
1 x Urilyzer® Cell	**ULC060**
1 x Quick reference guide 1 x Monitor 1 x Keyboard und 1x PC-mouse 1 x mains connection cable	
Accessories:	
Urilyzer® Cell Cuvettes (à 600 pieces)	**ULC001**
Extras:	
External Barcode Reader (optional)	**A93025**
Pipette (100 - 1000µl) (optional)	**ULC002**
Connection cable RS 232 (optional)	**A93026**

Artificial Intelligence-based Evaluation Module (AIEM)

After manual pipetting of the sample into the cuvette, sample processing and microscopy are performed automatically. The microscope creates HPF-like brightfield images that are automatically evaluated by a neural network based image processing software algorithm called AIEM, which automatically classifies and counts the urine sediment particles in the images.



Specifications

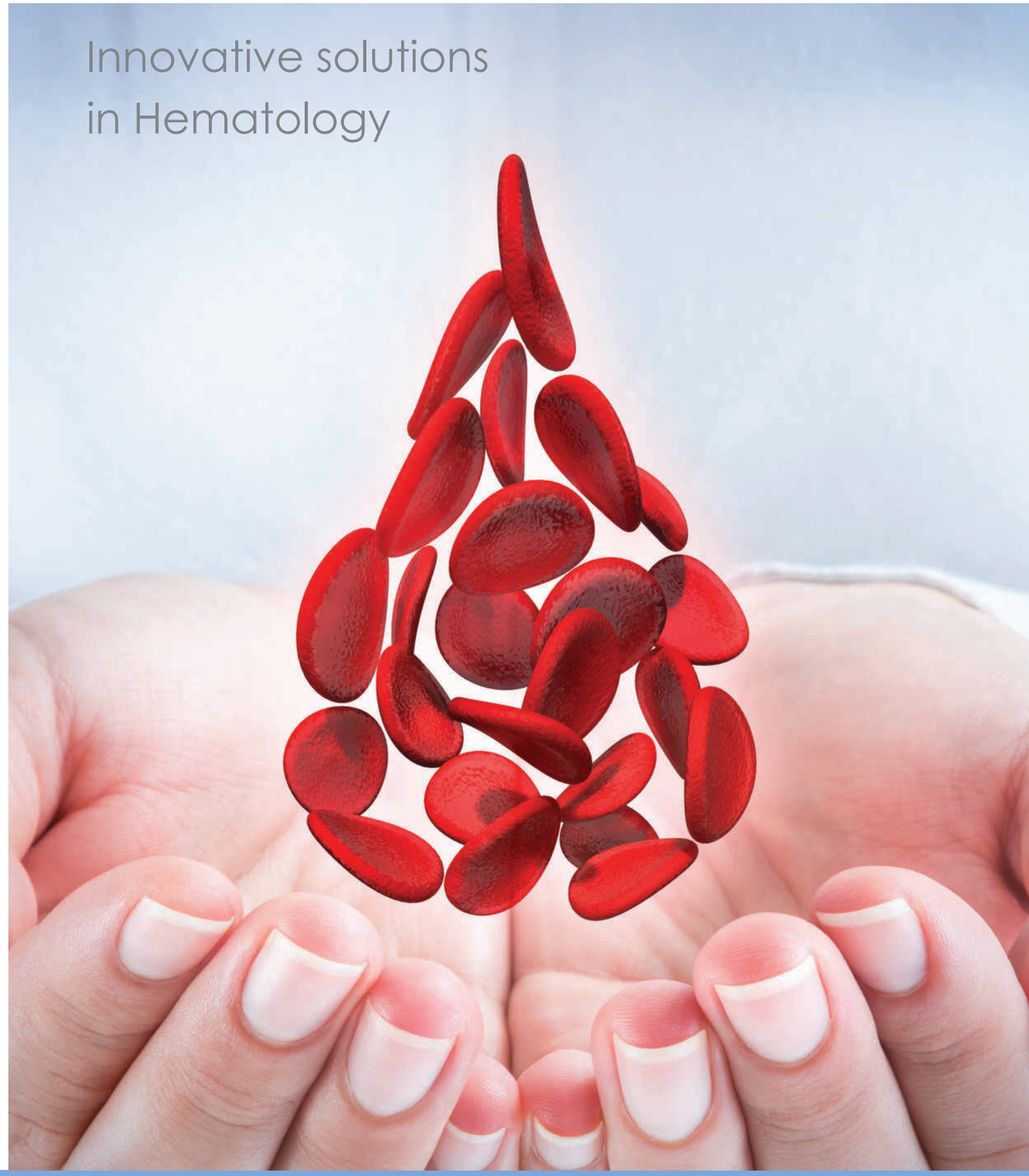
Type	Semi-automated urine sediment analyzer
Measuring technology	Cuvette-based automatic microscopy and image processing
Parameter	Red Blood Cells (RBC), Leukocytes (WBC, WBCc), Hyaline Casts (HYA), Pathological Casts (PAT), Squamous Epithelial Cells (EPI), Non-Squamous Epithelial Cells (NEC), Bacteria Rod (BAC, BACr, BACc), Yeast (YEA), Crystals (CRY) [Calcium-oxalate monohydrate (CaOxm), Calcium-oxalate dihydrate (CaOxd), Uric acid (URI), Triple phospate (TRI)], Mucus (MUC), Sperm (SPRM) Further classes for manual subclassification are available
Throughput	Up to 60 tests/hour
Sample volume	~175 µl
Data storage	Up to 5.000 results (including images)
Display	Monitor, external (included in scope of delivery)
Interfaces	USB, Ethernet, RS 232
Dimensions	305 x 315 x 325 mm (WxDxH)
Weight	10 kg
Power supply	100-250V AC / 50-60 Hz / max. 100W
Operating environment	Temperature: +15°C to +40°C Relative humidity (non-condensing): 20% to 80% at 30° C
Printer	Optional, external
Barcode reader	Optional, external
Protocols	LIS2 (ASTM+), HL7
Features	• Integrated centrifuge, integrated microscope • User management with different access rights • Barcode identification • Automatic validation of results • QC- Management
Languages	German, English, French, Italian, Spanish, Portuguese, Turkish, Polish, Czech, Slovak, Hungarian, Russian

Downloads

Product material

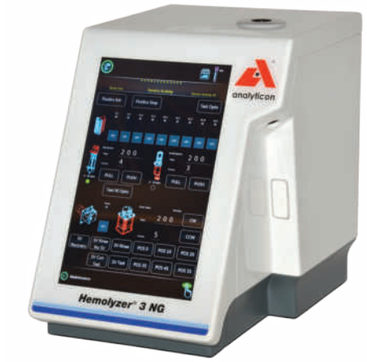
Product videos

Notes


Innovative solutions
in Hematology

Hemolyzer® 3 NG / 5 NG

The next generation of Hemolyzer instruments



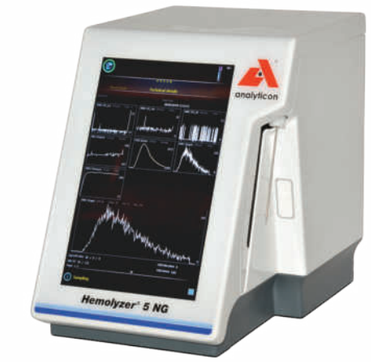
Hemolyzer® 3 NG Art.-No.: **HE3100**

Type	3-part WBC Diff hematology analyzer
Parameter	22 parameters: WBC, LYM, MID, GRA, LYM%, MID%, GRA%, HGB, RBC, HCT, MCV, RDWcv, RDWsd, MCH, MCHC, PLT, MPV, PCT, PDWcv, PDWsd, P-LCR%, P-LCC
Sampling mode	Closed or open vials
Throughput	Closed vial mode: 60 tests/hour Open vial mode: 45 tests/hour

Hemolyzer® 5 NG (closed mode) Art.-No.: **HE5100**

Type	5-part WBC Diff hematology analyzer
Parameter	27 parameters: WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS% BAS%, RBC, HGB, HCT, MCV, RDWsd/cv, MCH, MCHC, PLT, MPV, PCT, PDWcv, PDWsd, P-LCR%, P-LCC, NLR
Sampling mode	Closed vial mode
Throughput	60 tests/hour

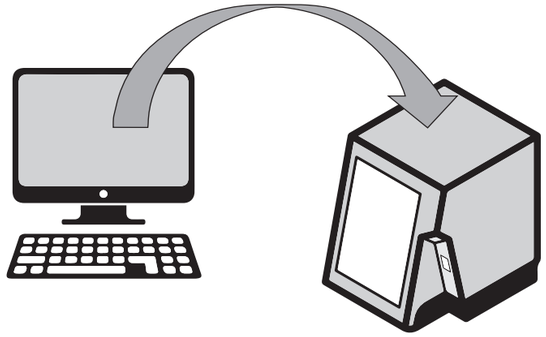
Autosampler Art.-No.: **HE0350**
suitable for Hemolyzer® 5 NG (closed); 50 positions



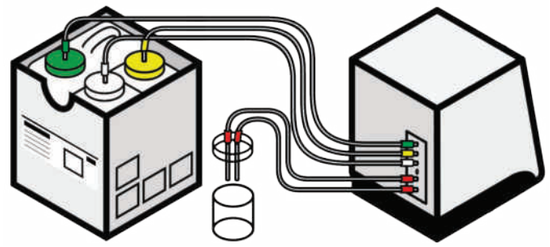
Hemolyzer® 5 NG (open mode) Art.-No.: **HE5200**

Type	5-part WBC Diff hematology analyzer
Parameter	27 parameters: WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS% BAS%, RBC, HGB, HCT, MCV, RDWsd/cv, MCH, MCHC, PLT, MPV, PCT, PDWcv, PDWsd, P-LCR%, P-LCC, NLR
Sampling mode	Open vial mode
Throughput	57 tests/hour

- Time saving and efficient operation
- Low sample volume and small footprint offer numerous application from emergency room to central lab
- The Hemolyzer® NG combines proven reliability and speed with ecological and economical performance



- Remote access provides online support for efficient troubleshooting and reducing downtime



- Microfluidic reagent handling provides minimal reagent volume usage resulting in an optimized and compact reagent concept (reagent packs & Cubitainer)

- 2D code scan via integrated camera

- Gesture-driven user interface via touchscreen

Quantity delivered

1 x Hemolyzer® NG

1 x Quick reference guide
1 x Reagent connector guide
1 x Reagent Tube set
1 x Power supply
1 x Power cord
1 x Installation report

Hemolyzer® NG Products

Reagent	Hemolyzer®	Art.-No.	Kit size
H3-Compact 100 (Reagent pack: Diluent, Lyse, Cleaner)	3 NG	**HE3701**	100 tests
H3-Compact 500 (Reagent pack: Diluent, Lyse, Cleaner)	3 NG	**HE3705**	500 tests
H5-Compact 100 (Reagent pack: Diluent, Lyse, Cleaner)	5 NG closed	**HE5701**	100 tests
H5-Compact 400 (Reagent pack: Diluent, Lyse, Cleaner)	5 NG closed	**HE5704**	400 tests
H5-Compact 100-O (Reagent pack: Diluent, Lyse, Cleaner)	5 NG open	**HE5707**	100 tests
H5-Compact 250-O (Reagent pack: Diluent, Lyse, Cleaner)	5 NG open	**HE5709**	250 tests
Controls & Calibrators	**Hemolyzer® NG**	**Art.-No.**	**Kit size**
H3-Check Complete (low, normal, high level)	3 NG	**HE3504**	6x2.5 ml
H3-Check Normal (normal level)	3 NG	**HE3505**	6x2.5 ml
H5-Check Complete (low, normal, high level)	5 NG open/closed	**HE5504**	6x3 ml
H5-Check Normal (normal level)	5 NG open/closed	**HE5505**	6x3 ml
H3/5-Cal	3 NG / 5 NG open/closed	**HE3611**	2.5 ml

Consumables	Hemolyzer® NG	Art.-No.	Kit size
H3/5-Hypoclean	3 NG / 5 NG open/closed	**HE3413**	5x 100 ml
H5-Opticlean	5 NG open/closed	**HE3422**	5x 100 ml

Notes

Fast. Reliable. Close to Patients.

Distributor information

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INTENDED USE

For use as a preliminary screening test for diabetes, liver diseases, hemolytic diseases, urogenital and kidney disorders and metabolic abnormalities.

Urine test strips for the rapid semi-quantitative determination of ascorbic acid, bilirubin, blood, glucose, ketones, leucocytes, nitrite, pH-value, protein, specific gravity and urobilinogen in human urine.

The CombiScreen® 11 Auto urine test strips are intended to be used in a Urilyzer® Auto test strip analyzer. Visual evaluation is possible as a backup routine. For professional use only.

SUMMARY AND EXPLANATION

Urine test strips are semi-quantitative test systems used to measure certain analytes in urine. These measurements are used in the screening for renal, hepatic and metabolic disorders as well as urinary tract infection of bacterial origin.

The CombiScreen® 11 Auto urine test strips include ascorbic acid protection for the blood and the glucose test pad.

TEST PRINCIPLE

Ascorbic acid: 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.

Bilirubin: 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.

Blood: 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.

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

Ketones: 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).

Leucocytes: 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.

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

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

Protein: 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.

Specific Gravity: For evaluation with the Urilyzer® Auto, the specific gravity is measured with the PMC module (physical measuring cell). The test pad is solely intended for visual evaluation and will not be processed by the Urilyzer® Auto.

Visual evaluation: The test is based on a color change of the reagent from blue green to greenish yellow depending on the concentration of ions in the urine.

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.

REAGENTS

Ascorbic acid: 2,6-dichlorophenolindophenol 0.7 %
Bilirubin: diazonium salt 3.1 %
Blood: tetramethylbenzidine-dihydrochloride 2.0 %, isopropylbenzol-hydroperoxide 21.0 %
Glucose: glucose oxidase 2.1 %; peroxidase 0.9 %; o-tolidine-hydrochloride 5.0 %
Ketones: sodium nitroprusside 2.0 %
Leucocytes: carboxylic acid ester 0.4 %; diazonium salt 0.2 %
Nitrite: tetrahydrobenzo[h]quinolin-3-ol 1.5 %; sulfanilic acid 1.9 %
pH: methyl red 2.0 %; bromothymol blue 10.0 %
Protein: tetrabromophenol blue 0.2 %
Specific Gravity: bromothymol blue 2.8 %
Urobilinogen: diazonium salt 3.6 %

WARNING AND PRECAUTIONS

For In Vitro Diagnostic Use.

For safe handling of urine test strips and for avoiding contact with potentially infectious substances, please follow the general working instructions for laboratories. Do not touch the test pads! Avoid ingestion and contact with eyes and mucous membranes. Keep away from children. Disposal of used test strips should be in accordance with local regulations. The material safety data sheet is available for download from our homepage http://www.analyticon-diagnostics.com.

In case any serious incident has occurred in relation to the device, please report to the manufacturer and, if applicable, to the competent authority of the country in which the users and/or the patients established themselves.

INDICATIONS OF DETERIORATION

Do not use discolored urine test strips. External influences such as humidity, light and extreme temperatures can cause a discoloration of test pads and may indicate deterioration.

STORAGE AND STABILITY

Store the tubes in a cool and dry place (storage temperature 2 – 30 °C). Keep urine test strips protected from direct sunlight, humidity and extreme temperatures. The urine test strips can be used until the given expiry date if stored and handled as specified in the package insert.

SPECIMEN COLLECTION AND PREPARATION

Testing of fresh, native, well-mixed and non-centrifuged urine is recommended. Protect the samples from light. First morning urine is preferable and shall be tested within 2 hours. If immediate testing is not applicable, store samples at 2 – 4 °C. Allow the sample to reach room temperature (15 – 25 °C) and mix them before testing.

Collection tubes must be clean, dry and free from detergents, biocides or disinfectants. Do not add preservatives.

PROCEDURE FOR AUTOMATIC APPLICATION

For application, please read carefully the detailed instructions for use of the instrument. Precise agreement between visual and automated evaluation is not always possible due to the different spectral sensitivities of the human eye and the optical system of the instrument.

PROCEDURE IN CASE OF VISUAL APPLICATION

- Use fresh, well-mixed native urine.
- Remove only the number of urine test strips intended to be used for measurement, and immediately close the vial again tightly with the original cap.
- Dip the urine test strip shortly (approx. 1 – 2 seconds) into the well-mixed urine. Make sure that all test pads are immersed in the sample.
- Wipe the edge of the strip on the rim of the sample container to remove excess urine.
- Dab the edge of the urine test strip on an absorbent paper towel.

  To prevent interaction of adjacent test pads, hold the urine test strip in a horizontal position during incubation. Compare the test pads on the urine test strip with the corresponding color chart on the vial 60 seconds (60 – 120 seconds for leucocytes) after immersion. Color changes that appear more than 2 minutes after immersion should not be evaluated. Visual evaluation should be carried out in daylight (or under daylight lamps), but not under direct sunlight. Any color change that cannot be assigned to the color chart on the vial label, or that is restricted to the rim of the test pads, is without meaning and should not be used for interpretation.

MATERIALS PROVIDED

Package with CombiScreen® 11 Auto strips.

MATERIALS REQUIRED BUT NOT PROVIDED

For the automated evaluation: Analyticon urine analyzer Urilyzer® Auto for the CombiScreen® 11 Auto urine test strips.

QUALITY CONTROL

Performance of urine test strips should be checked with appropriate quality control materials (e.g. REF 93010: CombiScreen® Dip Check; REF 93015: CombiScreen® Drop Check), according to the internal guidelines of the laboratory and the local regulations. It is recommended to perform control measurements after opening a new vial of urine test strips or with a new batch of urine test strips. Each laboratory is obliged to establish its own quality control standards. It is necessary to compare the resulting color development with the label, as some control materials may show atypical color development.

RESULTS AND EXPECTED VALUES

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

The color changes of the test pads correspond to the analyte concentrations described in Table 1.

LIMITATIONS OF THE PROCEDURE

- In order to establish a final diagnosis and prescribe an appropriate therapy, the results obtained with urine test strips need to be evaluated in combination with other medical results and the patient's medical history.
- Not all effects of medicaments, drugs or their metabolic products on the urine test strip are known. In case of doubt, it is recommended to repeat the test after discontinuation of the medication. However, a current medication should only be stopped after respective instruction of the doctor.
- Detergents, cleaning agents, disinfectants and preservatives may interfere with the reaction on the test pads. Various colored urine contents, especially high concentrations of hemoglobin (≥ 5 mg/dL) or bilirubin (≥ 2 mg/dL), can lead to atypical coloration on the test pads.
- The content of the urine is variable (e.g. content of activators or inhibitors and ion concentration in the urine), therefore the reaction conditions are not constant. In rare cases, this may lead to variations in the color of the test pad.

Bilirubin: Low or negative results may be caused by large amounts of vitamin C or nitrite and by a prolonged exposure of the sample to direct light. Increased concentrations of urobilinogen may increase the sensitivity of the bilirubin test pad. Various urine contents (e.g. urine indican) can lead to an atypical coloration. Regarding the metabolites of drugs, refer to urobilinogen.

Blood: Erythrocyte results of the urine test strip and the sediment may vary as lysed cells cannot be detected by the sediment analysis. False positive reactions can be caused by residuals of peroxide containing cleansing agents, by formalin, or activities of microbial oxidase due to infections of the urogenital tract.

The influence of ascorbic acid has been largely eliminated. From a level at approx. 25 Ery/µl and above, even at high concentrations of ascorbic acid normally no negative results are observed.

Glucose: An inhibitory effect is caused by gentisic acid, a pH value of < 5 and a high specific gravity. False positive reactions can also be induced by a residue of peroxide containing cleansing agents.

The influence of ascorbic acid has been largely eliminated. From a glucose level at approx. 100 mg/dL (5.5 mmol/L) and above, even at high concentrations of ascorbic acid normally no negative results are observed.

Ketones: Phenylketones in higher concentrations produce variable colors. The keton body β-Hydroxybutyric acid is not detected. Phthalein compounds and derivatives of anthrachinone interfere by producing a red coloration in the alkaline range which may mask the coloration caused by ketones.

Leucocytes: Leucocyte results of the urine test strip and the sediment may vary as lysed cells cannot be detected by the sediment analysis. Strongly colored compounds in the urine (e.g. nitrofurantoin) may disturb the color of the reaction. Glucose or oxalic acid in high concentrations, or drugs containing cephalexine, cephalothine or tetracycline can lead to weakened reactions. False positive results may be caused by contamination with vaginal secretion.

Nitrite: Negative results do not exclude significant bacteriuria since not all infectious species are capable of nitrite production (lack of nitrate reductase). In addition, high diuresis can reduce the retention time of the urine in the bladder and can lead to highly diluted urine which prevents the assimilation of detectable concentrations of nitrite. Moreover, a diet with low nitrate content and a high uptake of vitamin C can also cause false negative results. False positive results may occur for stale urines, in which nitrite has been formed by contamination of the specimen, and in urines containing dyes (derivatives of pyridinium, beetroot). Red or blue borders or edges which may appear must not be interpreted as a positive result.

pH: Bacterial contamination and growth in the urine after sample collection may lead to false results. Red borders which may appear next to the nitrite field must not be taken into consideration.

Protein: Highly alkaline urine samples (pH > 9), high specific gravity, infusions with polyvinylpyrrolidone (blood substitute), medicaments containing quinine and also disinfectant residues in the urine sampling vessel containing quaternary ammonium groups can lead to false positive results.

Specific Gravity: The color scale has been optimized for urine with pH 6. Highly alkaline (pH > 8) urines lead to slightly lower results, highly acidic (pH < 6) urines may cause slightly higher results. Glucose and urea do not interfere with the test.

Urobilinogen: Higher concentrations of formaldehyde or exposure of the urine to light for a longer period of time may lead to lowered or false negative results. Beetroot or metabolites of drugs which give a color at low pH (phenazopyridine, azo dyes, p-aminobenzoic acid) may cause false positive results.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the CombiScreen® 11 Auto urine test strips have been determined on the basis of analytical performance studies. The test performance of the urine test strips was characterized by its agreement with commercially available urine test strips.

Automated evaluation (Urilyzer® Auto)

Sensitivity

Ascorbic acid: > 7 mg/dL, **Bilirubin:** > 1.3 mg/dL (22.2 µmol/L), **Blood:** > 4 Ery/µL, **Glucose:** > 27 mg/dL (1.5 mmol/L), **Ketones:** > 4 mg/dL (0.4 mmol/L), **Leucocytes:** 5 – 10 Leu/µL, **Nitrite:** > 0.18 mg/dL (38 µmol/L), **Protein:** > 12.5 mg/dL, **Urobilinogen:** > 2.2 mg/dL (37.2 µmol/L).

Test Performance (extended concordance)

Ascorbic acid: 99.9 – 100 %, **Bilirubin:** 99.3 – 100 %, **Blood:** 94.2 – 100 %, **Glucose:** 98.7 – 100 %, **Ketones:** 94.5 – 100 %, **Leucocytes:** 95.8 – 100 %, **Nitrite:** 99.7 – 100 %, **pH:** 91.2 – 100 %, **Protein:** 88.4 – 100 %, **SG:** n.a., **Urobilinogen:** 95.9 – 99.8 %.

Visual evaluation

Sensitivity

Ascorbic acid: 10 – 15 mg/dL, **Bilirubin:** > 0.6 mg/dL (10 µmol/L), **Blood:** > 2 Ery/µL, **Glucose:** > 20 mg/dL (1.1 mmol/L), **Ketones:** > 5.4 mg/dL (0.5 mmol/L), **Leucocytes:** 15 – 20 Leu/µL, **Nitrite:** 0.05 – 0.1 mg/dL (11 – 22 µmol/L), **Protein:** > 15 mg/dL, **Urobilinogen:** 1 – 2 mg/dL (16.9 – 33.8 µmol/L).

Test Performance (extended concordance)

Ascorbic acid: n.a., **Bilirubin:** 98.7 – 99.6 %, **Blood:** 99.6 – 100 %, **Glucose:** 99.6 – 100 %, **Ketones:** 100 %, **Leucocytes:** 96.9 – 98.2 %, **Nitrite:** 100 %, **pH:** 99.6 – 100 %, **Protein:** 98.2 – 99.6 %, **SG:** 88.9 – 96.6 %, **Urobilinogen:** 89.5 – 100 %.

n.a.: not available

Table 1: Expected values and measuring ranges of the different urine test strip parameters:

Parameter	Expected Values	Unit	Measuring Range
Ascorbic acid	n.a.	Arbitrary	neg., +, ++
		[mg/dL]	neg., 20, 40
		[g/L]	neg., 0.2, 0.4
Bilirubin	neg.	Arbitrary	neg., +, ++, +++
		[mg/dL]	neg., 1, 2, 4
		[µmol/L]	neg., 17, 35, 70
Blood	neg.	Arbitrary	neg., +, ++, +++
		[Ery/µL]	neg., 5 – 10, ~50, ~300
Glucose	norm.	Arbitrary	norm., +, ++, +++, ++++, 5+
		[mg/dL]	norm., 50, 100, 250, 500, 1000
		[mmol/L]	norm., 2.8, 5.6, 14, 28, 56
Ketones	neg.–trace	Arbitrary	neg., (+) [trace], +, ++, +++
		[mg/dL]	neg., 10 [trace], 25, 100, 300
		[mmol/L]	neg., 1.0 [trace], 2.5, 10, 30
Leucocytes	neg.	Arbitrary	neg., +, ++, +++
		[Leu/µL]	0, ~25, ~75, ~500
Nitrite	neg.	Arbitrary	neg., pos.
pH	pH 5 – 8		5, 6, 6.5, 7, 7.5, 8, 9
Protein	neg. – trace	Arbitrary	neg., (+) [trace], +, ++, +++
		[mg/dL]	neg., 15 [trace], 30, 100, 500
		[g/L]	neg., 0.15 [trace], 0.3, 1.0, 5.0
Specific Gravity*	1.015 – 1.025		1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030
Urobilinogen	norm.	Arbitrary	norm., +, ++, +++, ++++
		[mg/dL]	norm., 2, 4, 8, 12
		[µmol/L]	norm., 35, 70, 140, 200

n.a.: not applicable *Visual evaluation only

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GB DE SE DK FI NO TR ES IT PT NL PL CZ GR RU

CombiScreen®
Urine Test Strips

Name	Art.-No.	Cont	Glucose	Ascorbic Acid	Ketones	Protein	pH-Value	Blood	Nitrite	Leucocytes	Spec. Gravity	Bilirubin	Urobilinogen
CombiScreen® 11Auto – with ascorbic acid protection													
11Auto	95150	150	■	■	■	■	■	■	■	■	■	■	■

SYMBOLS / SYMBOLE / SYMBOLER / MERKIT / SEMBOLLER / SÍMBOLOS / SYMBOLES / SIMBOLI / SÍMBOLOS / SYMBOLEN / SYMBOLY / ΣΥΜΒΟΛΑ / УСЛОВНЫЕ ОБОЗНАЧЕНИЯ

IVD	In vitro diagnostic product / In-vitro-diagnostisches Produkt / Produkt för in vitro-diagnostik / In vitro-diagnostik produkt / In vitro-diagnostiikkatuote / in vitro-diagnostisk produkt / İn vitro tanı ürünü / Producto de diagnóstico in vitro / Produit de diagnostic in vitro / Prodotto per la diagnosi in vitro / Produto para diagnóstico In vitro / Product voor in-vitro diagnostiek / Produkt do diagnostyki in vitro / Diagnostický produkt in vitro / Διαγνωστικό προϊόν in vitro / Продукт для диагностики in vitro
CE	The product complies with European legislation / Das Produkt entspricht der europäischen Richtlinie. / Produkten uppfyller kraven i europeisk lagstiftning. / Produktet overholder europæisk lovgivning / Tuote on Euroopan lainsäädännön mukainen / produktet oppfyller kravene i europeisk lovgivning / Bu ürün Avrupa yasalarına uygundur / El producto cumple con la legislación europea / Le produit est conforme à la législation européenne / Il prodotto è conforme alla legislazione europea / O produto cumpre a legislação europeia / Het product voldoet aan de Europese wetgeving / Potwierdzenie spełnienia norm UE / Produkt vyhovuje evropským právním předpisů / Το προϊόν συμμορφώνεται με την ευρωπαϊκή νομοθεσία / Продукт соответствует европейскому законодательству
(i)	Follow the instructions for use! / Gebrauchsanweisung beachten! / Följ bruksanvisningen! / Følg brugsanvisningen / Noudata käyttöohjetta! / følg bruksanvisningen! / Kullanım talimatlarına uyun! / Tener en cuenta las instrucciones de uso! / Respecter le mode d'emploi ! / Seguire le istruzioni per l'uso! / Siga as instruções de utilização! / Volg de gebruiksinstructies op! / Postępować według instrukcji użycia! / Dodržujte návod k použití! / Ακολουθήστε τις οδηγίες χρήσης! / Соблюдайте инструкцию по применению!
(hourglass)	Use by / Verwendbar bis / Används före / Bruges inden / Viimeinen käyttöpäivä / bruk innen / Son kullanma tarihi / Fecha de caducidad / Date limite d'utilisation / Uso a cura di / Utilizar até / Gebruiken tot / Termin przydatności do użycia / Použít do / Ημερομηνία λήξης / Использовать до
(thermometer)	Permitted storage temperature range / Erlaubte Lagerungstemperatur / Förvaringstemperatur / Tilladte lagertemperaturområde / Säilytyslämpötila / tillatt temperaturområde for lagring / İzin verilen saklama sıcaklığı aralığı / Conservar a / Plage de température de stockage autorisée / Intervallo di temperatura di stoccaggio consentito / Intervalo de temperatura de armazenamento permitido / Toegestaan opslagtemperatuurbereik / Ograniczenie temperatury przechowywania / Povolený rozsah teplot skladování / Επιτρεπόμενο εύρος θερμοκρασίας αποθήκευσης / Допустимый диапазон температур хранения
(2)	Only single use / Nur zum Einmalgebrauch / Endast för engångsbruk / Kun engangsbrug / Kertakäyttöinen / bare til engangsbruk / Sadece tek kullanımlıktır / No reutilizar / À usage unique / Solo monouso / Apenas para utilização única / Uitsluitend voor eenmalig gebruik / Wyłącznie do użytku jednorazowego / Pouze jednorázové použití / Αποκλειστικά μίας χρήσης / Только для одноразового применения
LOT	Batch identification number / Chargenbezeichnung / Partinummer / Partiidentifikationsnummer / Erän tunnistenumero / parti-ID-nummer / Parti tanıtım numarası / Número de identificación del lote / Numéro d'identification du lot / Numero di identificazione del lotto / Número de identificação do lote / Partijnummer / Numer serii / Identifikační číslo šarže / Αριθμός ταυτοποίησης παρτίδας / Идентификационный номер партии
REF	Item number / Artikelnummer / Artikelnummer / Varenummer / Tuotenumero / artikkelnummer / Poz numarası / Número de artículo / Numéro d'article / Numero articolo / Ref.ª / Productnummer / Numer artykułu wyrobu / Číslo položky / Αριθμός προϊόντος / Номер артикула
(factory)	Manufacturer / Hersteller / Tillverkare / Producent / Valmistaja / produsent / Üretici / Fabricante / Fabricant / Produttore / Fabricante / Fabrikant / Wytwórca / Výrobce / Κατασκευαστής / Производитель
(date)	Date of manufacture / Herstellungsdatum / Tillverkningsdatum / Fremstillingsdato / Valmistuspäivämäärä / produksjonsdato / Imalat tarihi / Fecha de fabricación / Date de fabrication / Data di fabbricazione / Data de fabricação / Fabricagedatum / Data produkcji / Datum výroby / ημερομηνία κατασκευής / дата изготовления

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Referenzbereiche für Kinder und Erwachsene von Heil/Ehrhardt (Roche) [pH Referenz daraus entnommen]; oder alternativ aus „Textbook of Urinalysis and Body Fluids" von Landy J. McBride;

Kaplan L.A., Pesce A.J. Clinical chemistry. 3rd ed. St. Louis: The CV Mosby Company, 1996.

Text passages with grey background were changed in the latest revision of this package insert. / Grau hinterlegte Textpassagen wurden in der letzten Überarbeitung dieser Gebrauchsanweisung geändert. / Gråmarkerade delar av texten har ändrats sedan packsedelns senaste revision. / Tekstpassager … / Pakkausselosteessa harmaalla taustalla olevia tekstejä on muutettu viimeksi tehdyssä tarkistuksessa. / Tekstpassasjer med grå bakgrunn ble endret i den seneste revisjonen av dette pakningsvedlegget. / … / Los pasajes de texto con fondo gris se cambiaron en la última revisión de este prospecto. / Les passages de texte sur fond gris ont été modifiés dans la dernière révision de ce mode d'emploi. / I passaggi di testo con sfondo grigio sono stati … / Passagens de texto com fundo cinza foram alteradas na última revisão deste folheto informativo. / Tekstgedeelten met een grijze achtergrond zijn aangepast tijdens de laatste revisie van deze bijsluiter. / Fragmenty tekstu na szarym tle … / Části textu se šedým pozadím se změnily při poslední revizi této příbalové informace. / Τα αποσπάσματα κειμένου με γκρίζο φόντο τροποποιήθηκαν στην τελευταία αναθεώρηση του παρόντος ένθετου συσκευασίας. / Текст … инструкции по применению.

ES

USO PREVISTO

Prueba para la detección precoz de diabetes, enfermedades hepáticas y hemolíticas, trastornos del metabolismo, así como enfermedades urogenitales y renales.
Tiras reactivas de orina para la determinación semicuantitativa rápida de ácido ascórbico, bilirrubina, sangre, glucosa, cetonas, leucocitos, nitrito, valor pH, proteínas, densidad relativa y urobilinógeno en la orina humana.
Las tiras reactivas de orina CombiS-creen® 11 Auto están diseñadas para usarse en un analizador de tiras reactivas Urilyzer® Auto. La evaluación visual es posible como una rutina de respaldo. Solo para uso profesional.

RESUMEN Y EXPLICACIÓN

Las tiras reactivas de orina son un método de ensayo semicuantitativo en el que se miden los analitos de la orina. Estas mediciones se utilizan para la detección de trastornos renales, hepáticos y metabólicos, así como de infecciones del tracto urinario de origen bacteriano.
Las tiras reactivas de orina CombiScreen® 11 Auto incluyen una protección de ácido ascórbico para la sangre y la almohadilla reactiva de glucosa.

PRINCIPIOS DE LA PRUEBA

Ácido ascórbico: La prueba se basa en la decoloración del reactivo de Tillman. La presencia de ácido ascórbico se indica por un cambio del color gris azulado a naranja.

Bilirrubina: Por el enlace de la bilirrubina a una sal de diazonio en el medio ácido, se produce un colorante azoico rojo. La presencia de bilirrubina se indica por un color rojo anaranjado.

Sangre: La prueba se basa en la actividad de la seudoperoxidasa de la hemoglobina y de la mioglobina, que catalizan la oxidación de un indicador en presencia de un hidroperóxido orgánico y un cromógeno, produciendo un color verde. Los eritrocitos intactos se visualizan mediante puntos de color en la almohadilla reactiva, mientras que la hemoglobina y la mioglobina por una coloración verde homogénea.

Glucosa: La prueba se basa en la reacción cromogénica de glucosa oxidasa y peroxidasa. La presencia de glucosa se indica por un cambio del color amarillo pasando por verde lima a azul verdoso oscuro.

Cetonas: La prueba se basa en la reacción del ácido acetoacético y la acetona con nitroprusiato sódico en un medio alcalino, lo que desarrolla un complejo de color violeta (prueba según Legal).

Leucocitos: La prueba se basa en la actividad esterasa de los granulocitos. Esta enzima se desdobla en carboxilatos heterocíclicos. Si las células liberan la enzima, esta reacciona con una sal de diazonio, produciendo un color violeta.

Nitritos: La prueba se basa en el principio de la reacción de Griess. Cualquier grado de coloración rosa-naranja debe interpretarse como un resultado positivo.

pH: El papel reactivo contiene indicadores de pH, que cambian claramente de color entre pH 5 y pH 9 (de naranja pasando por verde a turquesa).

Proteínas: La prueba se basa en el principio de «error proteico» de un indicador. La prueba es especialmente sensible a la albúmina. A otras proteínas tiene menos sensibilidad. La presencia de proteínas se indica por un cambio del color amarillo a verde menta.

Densidad relativa: Para la evaluación con el Urilyzer® Auto, la densidad relativa se mide con el módulo PMC (celda de medición física). La almohadilla de prueba está destinada únicamente para la evaluación visual y no será procesada por el Urilyzer® Auto.

Evaluación visual: La prueba se basa en un cambio de color del reactivo de verde azulado a amarillo verdoso dependiendo de la concentración de iones en la orina.

Urobilinógeno: La prueba se basa en el enlace de urobilinógeno con una sal de diazonio estabilizada a un compuesto azoico rojo. La presencia de urobilinógeno produce un cambio del color rosa claro a oscuro.

REACTIVOS

Ácido ascórbico: 2,6-diclorofenolindofenol 0,7 %
Bilirrubina: sal de diazonio 3,1 %
Sangre: dihidrocloruro de tetrametilbencidina 2,0 %, hidroperóxido de isopropilbenceno 21,0 %
Glucosa: oxidasa de glucosa 2,1 %, peroxidasa 0,9 %; o-tolidina hidrocloruro 5,0 %
Cetona: nitroprusiato sódico 2,0 %
Leucocitos: éster de ácido carboxílico 0,4 %; sal de diazonio 0,2 %
Nitrito: tetrahidrobenzo[h]quinolina-3-ol 1,5 %; ácido sulfanílico 1,9 %
pH: rojo de metilo 2,0 %; azul de bromotimol 10,0 %
Proteínas: azul de tetrabromofenol 0,2 %
Densidad relativa: azul de bromotimol 2,8 %
Urobilinógeno: sal de diazonio 3,6 %

ADVERTENCIAS Y PRECAUCIONES

Para uso diagnóstico in vitro.
Para la manipulación segura de las tiras reactivas de orina y para evitar el contacto con sustancias potencialmente infecciosas, consulte las instrucciones generales de trabajo para laboratorios. ¡No toque las almohadillas reactivas! No las ingiera y evite el contacto con los ojos y las mucosas. Manténgase fuera del alcance de los niños. Deshágase de las tiras reactivas usadas de acuerdo con las regulaciones locales. La hoja de datos de seguridad del material se puede descargar desde nuestra página web http://www.analyticon-diagnostics.com.
En caso de que se haya producido un incidente grave en relación con el dispositivo, informe al fabricante y, si corresponde, a la autoridad competente del país donde los usuarios o los pacientes tienen su domicilio.

INDICIOS DE DETERIORO

No use las tiras reactivas de orina si están decoloradas. Las influencias externas como la humedad, la luz y las temperaturas extremas pueden causar la decoloración de las almohadillas reactivas, lo que podría ser indicativo de deterioro.

ALMACENAMIENTO Y ESTABILIDAD

Guarde los tubos en un lugar fresco y seco (temperatura de almacenamiento de 2 a 30 °C). Mantenga las tiras reactivas de orina protegidas de la luz solar directa, la humedad y las temperaturas extremas. Las tiras reactivas de orina podrán usarse hasta la fecha de caducidad indicada si se almacenan y manipulan como se especifica en el prospecto.

RECOGIDA Y PREPARACIÓN DE MUESTRAS

Se recomienda usar muestras de orina reciente, nativa, bien mezclada y sin centrifugar. Proteja las muestras de la luz. Es preferible la primera orina de la mañana. No debe dejarse reposar más de 2 horas. Si no se realiza el análisis inmediatamente, almacenar las muestras a 2 – 4 °C. Permitir que la muestra adquiera la temperatura ambiente (15 – 25 °C) y mezclar antes de realizar la prueba.
Los tubos de recogida deben estar limpios, secos y sin restos de detergentes, biocidas o desinfectantes. No añadir conservantes.

PROCEDIMIENTO DE APLICACIÓN AUTOMÁTICA

Para la aplicación, lea atentamente las instrucciones detalladas para el uso del instrumento. Los resultados de la evaluación visual y la automatizada no siempre coinciden debido a las diferentes sensibilidades espectrales del ojo humano y el sistema óptico del instrumento.

PROCEDIMIENTO EN CASO DE APLICACIÓN VISUAL

- Usar orina fresca, nativa y bien mezclada.
- Sacar solo el número de tiras reactivas de orina que se necesiten para la medición y volver a cerrar el envase inmediatamente con el tapón original.
- Sumergir la tira reactiva de orina brevemente (durante 1 – 2 segundos aprox.) en la muestra de orina bien mezclada. Asegúrese de que todas las almohadillas reactivas estén sumergidas en la muestra.
- Limpiar el extremo de la tira en el borde del frasco de muestras para eliminar la orina sobrante.
- Pasar suavemente el extremo de la tira reactiva de orina por papel absorbente.Mantener la tira reactiva de orina en posición horizontal durante la incubación para evitar las interacciones delas almohadillas reactivas cercanas. Comparar las almohadillas de la tira reactiva de orina con la tabla de colores del envase correspondiente transcurridos 60 segundos (60 – 120 segundos para los leucocitos) después de la inmersión. Los cambios de color que se muestran durante más de 2 minutos después de la inmersión no se deben evaluar. La evaluación visual debe hacerse a la luz del día (o bajo lámparas de luz diurna) pero no bajo la luz directa del sol. Los cambios de color que no se correspondan con la tabla de colores de la etiqueta del envase o que solo aparezcan en el borde de las almohadillas reactivas, no tienen ningún significado y no se deben utilizar para la interpretación del análisis.

MATERIALES SUMINISTRADOS

Envase con tiras reactivas de orina CombiScreen® 11 Auto.

MATERIALES REQUERIDOS PERO NO SUMINISTRADOS

Para la evaluación automatizada: Analizador de orina Analyticon Urilyzer® Auto para las tiras reactivas CombiScreen® 11 Auto.

CONTROL DE CALIDAD

El funcionamiento de las tiras reactivas de orina debe verificarse con los materiales de control de calidad adecuados (p. ej. REF 93010: CombiScreen® Dip Check; REF 93015: CombiScreen® Drop Check), de acuerdo con las pautas internas del laboratorio y las normativas locales. Se recomienda realizar mediciones de control después de abrir un nuevo envase de tiras reactivas de orina o con un nuevo lote de tiras reactivas de orina. Cada laboratorio está obligado a establecer sus propias normas de control de calidad. Es necesario comparar el desarrollo del color resultante con la etiqueta, ya que algunos materiales de control pueden mostrar un desarrollo de color atípico.

RESULTADOS Y VALORES ESPERADOS

Cada laboratorio debería comprobar si los valores esperados se pueden aplicar a su grupo de pacientes y, si es necesario, establecer sus propios intervalos de referencia.
Los cambios de color de las almohadillas reactivas corresponden a las concentraciones de analito descritas en la Tabla 1.

LIMITACIONES DEL PROCEDIMIENTO

- Para establecer un diagnóstico definitivo y prescribir una terapia apropiada, los resultados obtenidos con las tiras reactivas de orina deben evaluarse en combinación con otros resultados médicos y el historial médico del paciente.
- No se conocen todos los efectos de medicamentos, fármacos o sus productos metabólicos en la tira reactiva de orina. En caso de duda, se recomienda repetir la prueba después de suspender el medicamento. Sin embargo, la medicación actual solo se debe suspender tras recibir las indicaciones del médico.
- Los detergentes, productos de limpieza, desinfectantes y conservantes pueden interferir en la reacción de las almohadillas reactivas. Varios componentes de color de la orina, especialmente las altas concentraciones de hemoglobina (≥ 5 mg/dL) o bilirrubina (≥ 2 mg/dL), pueden provocar una coloración atípica en las almohadillas reactivas.
- El contenido de la orina es variable (por ejemplo, contenido de activadores o inhibidores y concentración de iones en la orina), por lo que las condiciones de reacción no son constantes. En casos excepcionales, esto puede provocar variaciones en el color de la almohadilla reactiva.

Bilirrubina: Los resultados bajos o negativos pueden deberse a grandes concentraciones de vitamina C o nitrito y por una exposición prolongada de la muestra a la luz directa. Las elevadas concentraciones de urobilinógeno pueden aumentar la sensibilidad de la almohadilla reactiva de bilirrubina. Varios componentes de la orina (por ejemplo, indicano de orina) pueden causar coloraciones atípicas. En cuanto a los metabolitos de los fármacos, consulte el urobilinógeno.

Sangre: Los resultados de eritrocitos de la tira reactiva de orina y el sedimento pueden variar, dado que las células lisadas no pueden detectarse mediante el análisis de sedimentos. Se pueden producir reacciones falsas positivas por restos de detergentes con contenido de peróxido, por formalina o por actividades de oxidasa microbiana en infecciones del tracto urogenital.
La influencia del ácido ascórbico ha sido sustancial-mente eliminada. A partir de una concentracion de 25 eri/µl no se observan resultados falsos negativos, aun bajo concentraciones elevadas de ácido ascórbico.

Glucosa: Se produce un efecto inhibidor por el ácido gentísico, un valor de pH < 5 y una alta densidad relativa. Pueden producirse también reacciones falsas positivas por restos de detergentes con contenido de peróxido.
La influencia del ácido ascórbico ha sido sustancialmente eliminada. Para una concentración de glucosa de 100 mg/dL (5,5 mmol/L) no se observan resultados falsos negativos, aun bajo concentraciones mas elevadas de ácido ascórbico.

Cetonas: Las fenilcetonas en concentraciones más altas producen un color diferente. No se detecta el ácido betahidroxibutírico del cuerpo cetónico. Los compuestos de ftaleína y los derivados de la antraquinona interfieren al producir una coloración roja en el medio alcalino, que puede enmascarar la coloración provocada por las cetonas.

Leucocitos: Los resultados de leucocitos de la tira reactiva de orina y el sedimento pueden variar, dado que las células lisadas no pueden detectarse mediante el análisis de sedimentos. Los compuestos de color intenso en la orina (por ejemplo, la nitrofurantoína) pueden alterar el color de la reacción. La glucosa o el ácido oxálico en altas concentraciones, o los medicamentos que contienen cefalexina, cefalotina o tetraciclina, pueden causar reacciones más débiles. Los resultados falsos positivos se pueden producir por impurezas de la secreción vaginal.

Nitritos: Los resultados negativos no excluyen una bacteriuria significativa, ya que no todas las especies infecciosas son capaces de producir nitritos (falta de nitrato reductasa). Además, una diuresis alta puede reducir el tiempo de retención de la orina en la vejiga y puede producir una fuerte dilución de la orina, lo que impediría la asimilación de concentraciones detectables de nitrito. Por otra parte, una dieta con bajo contenido de nitrato y una elevada ingesta de vitamina C también puede causar resultados falsos negativos. Pueden producirse resultados falsos positivos en orinas viejas, en las que el nitrito se ha formado por la contaminación de la muestra, y en las orinas que contienen colorantes (derivados de piridinio, remolacha). Si aparecen bordes rojos o azules, no deberán interpretarse como resultados positivos.

pH: La contaminación bacteriana y su proliferación en la orina después de la recogida de la muestra puede dar resultados falsos. Los bordes rojos que aparezcan al lado del campo de nitrito no deben tenerse en cuenta.

Proteínas: Se pueden producir resultados falsos positivos debido a muestras de orina altamente alcalinas (pH > 9), una elevada densidad relativa, infusiones con polivinilpirrolidona (sustituto de la sangre), medicamentos con contenido de quinina y también restos de desinfectantes con grupos de amonio cuaternario en el recipiente de recogida de la orina.

Densidad relativa: La escala de colores se ha optimizado con un pH de orina 6. Las orinas altamente alcalinas (pH > 8) producen resultados ligeramente inferiores, y las orinas altamente ácidas (pH < 6) pueden causar resultados ligeramente más altos. La glucosa y la urea no tienen ninguna influencia en la prueba.

Urobilinógeno: Las concentraciones más altas de formaldehído o la exposición de la orina a la luz durante un período de tiempo más prolongado pueden originar resultados negativos bajos o falsos. Las remolachas o los metabolitos de los fármacos, que desarrollan un color con un pH bajo (fenazopiridina, colorantes azoicos, ácido p-aminobenzoico), pueden causar resultados falsos positivos.

CARACTERÍSTICAS DE RENDIMIENTO

Las características de rendimiento de las tiras reactivas de orina CombiScreen® 11 Auto se han determinado sobre la base de estudios de rendimiento analítico. El rendimiento de la prueba de las tiras reactivas de orina se caracterizó por su coincidencia con las tiras reactivas de orina disponibles en el mercado.

Evaluación automatizada (Urilyzer® Auto)
Sensibilidad
Ácido ascórbico: > 7 mg/dL, **bilirrubina:** 1,3 mg/dL (22,2 µmol/L), **sangre:** > 4 Eri/µL, **glucosa:** > 27 mg/dL (1,5 mmol/L), **cetonas:** > 4 mg/dL (0,4 mmol/L), **leucocitos:** 5 – 10 Leu/µL, **nitrito:** > 0,18 mg/dL (38 µmol/L), **proteína:** > 12,5 mg/dL, **urobilinógeno:** > 2,2 mg/dL (37,2 µmol/L).

Rendimiento de la prueba (concordancia ampliada)
Ácido ascórbico: 99,9 – 100 %, **bilirrubina:** 99,3 – 100 %, **sangre:** 94,2 – 100 %, **glucosa:** 98,7 – 100 %, **cetonas:** 94,5 – 100 %, **leucocitos:** 95,8 – 100 %, **nitrito:** 99,7 – 100 %, **pH:** 91,2 – 100 %, **proteína:** 88,4 – 100 %, **densidad relativa:** n.a., **urobilinógeno:** 95,9 – 99,8 %.

Evaluación visual
Sensibilidad
Ácido ascórbico: 10 – 15 mg/dL, **bilirrubina:** > 0,6 mg/dL (10 µmol/L), **sangre:** > 2 Eri/µL, **glucosa:** > 20 mg/dL (1,1 mmol/L), **cetonas:** > 5,4 mg/dL (0,5 mmol/L), **leucocitos:** 15 – 20 Leu/µL, **nitrito:** 0,05 – 0,1 mg/dL (11 – 22 µmol/L), **proteína:** > 15 mg/dL, **urobilinógeno:** 1 – 2 mg/dL (16,9 – 33,8 µmol/L).

Rendimiento de la prueba (concordancia ampliada)
Ácido ascórbico: n.a., **bilirrubina:** 98,7 – 99,6 %, **sangre:** 99,6 – 100 %, **glucosa:** 99,6 – 100 %, **cetonas:** 100 %, **leucocitos:** 96,9 – 98,2 %, **nitrito:** 100 %, **pH:** 99,6 – 100 %, **proteína:** 98,2 – 99,6 %, **densidad relativa:** 88,9 – 96,6 %, **urobilinógeno:** 89,5 – 100 %.

n.a.: no aplicable

Tabla 1: Valores esperados y rangos de medición de los diferentes parámetros de la tira reactiva de orina:

Parámetro	Valores esperados	Unidad	Rango de medición
Ácido ascórbico	n.a.	Arbitrario	neg., +, ++
		[mg/dL]	neg., 20, 40
		[g/L]	neg., 0,2, 0,4
Bilirrubina	neg.	Arbitrario	neg., +, ++, +++
		[mg/dL]	neg., 1, 2, 4
		[µmol/L]	neg., 17, 35, 70
Sangre	neg.	Arbitrario	neg., +, ++, +++
		[Eri/µL]	neg., 5 – 10, ~50, ~300
Glucosa	norm.	Arbitrario	norm., +, ++, +++, ++++, 5+
		[mg/dL]	norm., 50, 100, 250, 500, 1000
		[mmol/L]	norm., 2,8, 5,6, 14, 28, 56
Cetonas	neg. – trazas	Arbitrario	neg., (+) [trazas], +, ++, +++
		[mg/dL]	neg., 10 [trazas], 25, 100, 300
		[mmol/L]	neg., 1,0 [trazas], 2,5, 10, 30
Leucocitos	neg.	Arbitrario	neg., +, ++, +++
		[Leu/µL]	0, ~25, ~75, ~500
Nitritos	neg.	Arbitrario	neg., pos.
pH	pH 5 – 8		5, 6, 6,5, 7, 7,5, 8, 9
Proteínas	neg. – trazas	Arbitrario	neg., (+) [trazas], +, ++, +++
		[mg/dL]	neg., 15 [trazas], 30, 100, 500
		[g/L]	neg., 0,15 [trazas], 0,3, 1,0, 5,0
Densidad relativa*	1.015 – 1.025		1,000, 1,005, 1,010, 1,015, 1,020, 1,025, 1,030
Urobilinógeno	norm.	Arbitrario	norm., +, ++, +++, ++++
		[mg/dL]	norm., 2, 4, 8, 12
		[µmol/L]	norm., 35, 70, 140, 200

n.a.: no aplicable *Evaluación visual solamente

de

Verwendungszweck

IN-VITRO DIAGNOSTIKUM

CombiScreen® DIP Check dient für die Anwendung als geprüftes Qualitätskontrollmaterial für verschiedene Urin-Teststreifen und qualitative hCG-Tests.

Zusammenfassung

Die Verwendung von Qualitätskontrollmaterialien für die objektive Überwachung der Genauigkeit und Präzision der in klinischen Labors eingesetzten Verfahren ist eine etablierte Methode. Die CombiScreen® DIP Check Urinkontrolle besteht aus zwei Levels, welche die Überwachung von analytischen Systemen innerhalb des klinischen Messbereiches erleichtern.

Produktbeschreibung

CombiScreen® DIP Check basiert auf menschlichem Urin, dem weitere Bestandteile menschlichen und tierischen Ursprungs sowie gereinigte Chemikalien hinzugefügt wurden. Konservierungsmittel und Stabilisatoren wurden zur Aufrechterhaltung der Produkteigenschaften hinzugefügt. CombiScreen® DIP Check ist eine gebrauchsfertige, flüssige Kontrolle, die kein Rekonstituieren erfordert.

Warnhinweise / Vorsichtsmaßnahmen

In vitro Diagnostikum.

Substanz menschlichen Ursprungs. Potentiell infektiöses Material.

Jede bei der Herstellung dieses Produkts verwendete Spendereinheit wurde unter Verwendung von FDA-zugelassenen Methoden untersucht und als nicht reaktiv für die Gegenwart von HBsAg und Antikörpern gegen HIV 1/2, HCV und HIV-1 Ag befunden. Obwohl diese Methoden äußerst genau sind, kann nicht gewährleistet werden, dass alle infizierten Einheiten entdeckt werden. Da keine bekannte Testmethode eine hundertprozentige Sicherheit geben kann, dass Hepatitis B Virus, Hepatitis C Virus, HIV-Virus oder andere infektiöse Wirkstoffe abwesend sind, sollten alle Produkte, die Substanzen menschlichen Ursprungs enthalten, als potenziell infektiös betrachtet und mit denselben Vorsichtsmaßnahmen wie bei Patientenproben gehandhabt werden.

Dieses Produkt enthält 0,09% Natriumazid als Konservierungsmittel. Natriumazid kann mit Blei- und Kupferrohren reagieren und möglicherweise explosive Verbindungen bilden. Bei der Entsorgung mit reichlich Wasser spülen.

Weitere sicherheitsrelevante Informationen sind im Sicherheitsdatenblatt enthalten. Dieses steht auf unserer Homepage http://www.analyticon-diagnostics.com zum Download bereit.

Anzeichen von Verfall

Ist die Testflüssigkeit eingetrübt oder liegt Keimwachstum bzw. eine Verunreinigung vor, sind die Teströhrchen zu entsorgen. Dies sollte gemäß den örtlichen Richtlinien auf die gleiche Weise wie bei anderen biologischen Proben erfolgen.

Lagerung und Haltbarkeit

CombiScreen® DIP Check ist bis zu dem auf dem Röhrchenetikett aufgedruckten Verfallsdatum stabil, wenn sie ungeöffnet bei 2–8 °C gelagert wird. Nicht einfrieren. Nach dem Öffnen sind Kontrollröhrchen entweder dicht verschlossen bei 2–8 °C bis zu 75 Tage haltbar, oder bis 20 Teststreifen-Eintauchungen stattgefunden haben. CombiScreen® DIP Check Control können bei 20–25 °C 30 Tage lang gelagert werden.

Verfahren

CombiScreen® DIP Check sollen auf gleiche Weise wie Patientenproben behandelt werden und gemäß der Gebrauchsanleitung des verwendeten Testsystems (Instrument, Kit oder Reagenz) eingesetzt werden. Vor der Verwendung warten, bis das Produkt Raumtemperatur erreicht hat.

Qualitätskontrollmaterialien sind in Übereinstimmung mit allen geltenden örtlichen, landes- und/oder bundesweiten Gesetzesvorschriften bzw. Akkreditierungskriterien anzuwenden.

Anweisungen

1. Wenden Sie das Röhrchen vor der Probennahme einige Male vorsichtig, um Homogenität zu gewährleisten. Dies ist wichtig für die Erzielung reproduzierbarer Ergebnisse.
2. *Bei Teststreifen:* Entfernen Sie den Verschluss und tauchen Sie den Reagenzstreifen in das Glas, als wäre es eine Patientenprobe. Lesen Sie die Reagenzstreifen in Übereinstimmung mit den Herstelleranweisungen entweder visuell ab oder mithilfe eines Instruments.
   Bei hCG-Tests: Nach Anweisungen des Herstellers des hCG-Test-Kits benutzen die Kontrollen wie Patientenproben. Gießen Sie bei bestätigenden Schwangerschafts-Testkits eine kleine Menge der Kontrollsubstanz in einen separaten Behälter und verwenden Sie die im Kit enthaltene Pipette, um die korrekte Probenmenge in den Testbehälter zu übertragen.
3. Verschließen Sie den Deckel sofort nach der Verwendung und lagern Sie alles ordnungsgemäß.

Lieferumfang

1x Control L1, 15 ml CONTROL − 1x Control L2, 15 ml CONTROL +

1x Packungsbeilage

Grenzen des Verfahrens

CombiScreen® DIP Check sollte nicht nach dem auf dem Röhrchenetikett aufgedruckten Verfallsdatum verwendet werden.

CombiScreen® DIP Check ist ein stabilisiertes flüssiges Produkt. Zur Gewährleistung konstanter Assay-Werte, muss CombiScreen® DIP Check gemäß den Anweisungen unter Lagerung und Haltbarkeit aufbewahrt und gehandhabt werden.

Genaue und reproduzierbare Ergebnisse sind abhängig von ordnungsgemäß funktionierenden Instrumenten und Reagenzien. Die angegebenen Bereiche dienen lediglich als Richtwerte. Jedes Labor hat auf der Grundlage des vorhandenen Testsystems eigene akzeptable Referenzbereiche und Toleranzgrenzen zu ermitteln.

Zuordnung der Werte

Die in dieser Beilage angegebenen Erwartungswerte stammen aus wiederholten Analysen repräsentativer Proben des Produktes und sind für diese Charge von CombiScreen® DIP Check spezifisch. Die zur Ermittlung der erwarteten Werte herangezogenen Testdaten stammen von mehreren Instrumenten. Alle Werte wurden mit den zum Zeitpunkt des Tests verfügbaren Reagenzien des Herstellers bestimmt. Nachfolgende Änderungen der Instrumente oder Reagenzien machen diese Erwartungswerte möglicherweise ungültig.

Für eine Zusendung der Wertzuweisung per Fax bzw. E-Mail wenden Sie sich bitte an Ihren örtlichen Händler oder info@analyticon-diagnostics.com

Symbole und Abkürzungen

IVD	In-vitro-diagnostisches Produkt		Herstellungsdatum
CE	Das Produkt entspricht der europäischen Verordnung.		Distributor
	Gebrauchsanweisung beachten!	LOT	Chargenbezeichnung
	Verwendbar bis	REF	Artikelnummer
	Erlaubte Lagerungstemperatur		Hersteller
CONT	Inhalt		Warnung, biologische Gefahr
CONTROL −	Negativkontrolle	CONTROL +	Positivkontrolle
hCG	humanes Choriongonadotropin	CONTROL	Kontrolle
ALB	Albumin	BLD	Blut
BIL	Bilirubin	GLU	Glucose
CREA	Kreatinin	LEU	Leukozyten
KET	Keton	pH	pH-Wert
NIT	Nitrit	SG	Spezifisches Gewicht
PRO	Protein	UBG	Urobilinogen

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Intended Use

FOR IN VITRO DIAGNOSTIC USE

CombiScreen® DIP Check is intended for use as an assayed quality control material for various urinalysis reagent strips and qualitative hCG methods.

Summary and Explanation

The use of quality control materials to objectively monitor the accuracy and precision of procedures is well established in clinical laboratories. CombiScreen® DIP Check is provided at two levels to assist in the monitoring of analytical systems within the clinical range.

Product Description

CombiScreen® DIP Check is human urine-based containing constituents of human and animal origin as well as purified chemicals. Preservatives and stabilizers have been added to maintain product integrity. CombiScreen® DIP Check is a ready-to-use liquid control requiring no reconstitution.

Warnings and Precautions

For in vitro diagnostic use.

Human source material. Treat as potentially infectious.

Each donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with excess water upon disposal.

The material safety data sheet contains further safety-related information. It is available for download from our homepage http://www.analyticon-diagnostics.com.

Indications of deterioration

If the controls are turbid or if any evidence of microbial growth or contamination is present, the controls should be discarded. This should be done according to the local guidelines in the same manner as for other biological specimens.

Storage and Stability

CombiScreen® DIP Check is stable until the expiration date on the tube label when stored unopened at 2–8°C. Do not freeze.

Once opened, tubes of control are stable for 75 days when stored tightly capped at 2–8°C or 20 dipstick immersions have taken place, whichever occurs first. CombiScreen® DIP Check may be stored for 30 days at 20–25°C.

Procedure

CombiScreen® DIP Check should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system (instrument, kit, or reagent) being used. Allow the product to reach room temperature prior to use.

QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Instructions

1. Gently invert the tube several times before sampling to ensure homogeneity. This is important to obtain reproducible results.
2. *For dipstick testing*: remove the cap and dip the reagent strip in the tube as if it were a patient sample. In accordance with the manufacturer's instructions, read the reagent strips either visually or with an instrument reader.
   For hCG testing: In accordance with the hCG test kit manufacturer's instructions, use controls as if they were patient specimens. For the control of confirmatory pregnancy test kits, be sure to use the transfer pipette included in the kit to deliver the correct sample amount to test device.
3. Replace the cap immediately after use and store appropriately.

Materials provided

1x Control L1, 15 ml CONTROL − 1x Control L2, 15 ml CONTROL +

1x Kit insert

Limitations of the Procedure

CombiScreen® DIP Check should not be used past the expiration date on the tube label. CombiScreen® DIP Check is a stabilized liquid product. To obtain consistent assay values, CombiScreen® DIP Check requires storage and handling as detailed in Storage and Stability.

Accurate and reproducible results are dependent upon properly functioning instruments and reagents. The ranges given are intended only as a guideline. Each laboratory should establish their own acceptable ranges and tolerance limits based on their test system.

Expected readings

The expected values printed in this insert were derived from replicate analyses of representative samples of the product and are specific to this lot of CombiScreen® DIP Check. Testing data used to establish the expected values were derived from multiple instruments. All values have been assigned with manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these expected values. To request a faxed or emailed copy of the value assignment, contact your local distributor or info@analyticon-diagnostics.com.

Symbols and abbreviations

IVD	In vitro diagnostic product		Date of manufacture
CE	The product complies with the European Regulation.		Distributor
	Follow the instructions for use!	LOT	Batch designation
	Usable until	REF	Article number
	Permitted storage temperature		Manufacturer
CONT	Content		Warning, biological hazard
CONTROL −	Negative control	CONTROL +	Positive control
hCG	Human chorionic gonadotropin	CONTROL	Control
ALB	Albumin	BLD	Blood
BIL	Bilirubin	GLU	Glucose
CREA	Creatinine	LEU	Leucocytes
KET	Ketone	pH	pH value
NIT	Nitrite	SG	Specific gravity
PRO	Protein	UBG	Urobilinogen

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combi screen® Dip Check

Tabelle 1: Bestellübersicht / Table 1: Order overview / Tableau 1 : Vue d'ensemble / Tabella 1: Panoramica dell'ordine / Cuadro 1: Resumen del pedido / Tabela 1: Síntese do pedido / Tabel 1: Bestillingsoversigt / Tabell 1: Bestillingsoversikt / Tabell 1: Beställningsöversikt / Taulukko 1: Tilaustiedot

CombiScreen®	Dip Check
REF	93010
CONT	2×15 ml
ALB	■
BIL	■
BLD	■
CREA	■
GLU	■
KET	■
NIT	■
LEU	■
pH	■
PRO	■
SG	■
UBG	■
hCG	■

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Referenzen / References / Références / Riferimenti / Referencias / Referências / Referencer / Referanser / Referenser / Viitteet:

Kouri, T., Fogazzi, G., Gant, V., Hallander, H., Hofmann, W., & Guder, W. G. (2000). European urinalysis guidelines. Scandinavian journal of clinical and laboratory investigation, 60(sup231), 1-96

CE IVD

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Intended Use

FOR IN VITRO DIAGNOSTIC USE

CombiScreen® DROP Check is intended for use as an assayed quality control material for various urinalysis reagent strips and qualitative hCG methods.

Summary and Explanation

The use of quality control materials to objectively monitor the accuracy and precision of procedures is well established in clinical laboratories. CombiScreen® DROP Check is provided at two levels to assist in the monitoring of analytical systems within the clinical range.

Product Description

CombiScreen® DROP Check is human urine-based containing constituents of human and animal origin as well as purified chemicals. Preservatives and stabilizers have been added to maintain product integrity. CombiScreen® DROP Check is a ready-to-use liquid control requiring no reconstitution.

Warnings and Precautions

For in vitro diagnostic use.

Human source material. Treat as potentially infectious.

Each donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with excess water upon disposal.

The material safety data sheet contains further safety-related information. It is available for download from our homepage http://www.analyticon-diagnostics.com.

Indications of deterioration

If the controls are turbid or if any evidence of microbial growth or contamination is present, the controls should be discarded. This should be done according to the local guidelines in the same manner as for other biological specimens.

Storage and Stability

CombiScreen® DROP Check is stable until the expiration date on the tube label when stored unopened at 2–8°C. Do not freeze.

Once opened, bottles of control are stable for 18 months when stored tightly capped at 2–8°C or for 30 days at 20–25°C.

Procedure

CombiScreen® DROP Check should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system (instrument, kit, or reagent) being used. Allow the product to reach room temperature prior to use.

QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Instructions

1. Gently invert the bottle several times before sampling to ensure homogeneity. This is important to obtain reproducible results.
2. *For dipstick testing*: remove the cap and invert the dropper bottle drawing the dropper tip across all the pads of the hand-held reagent strip. Squeeze to release the control thoroughly saturating each pad. Avoid aspirating excess control into the bottle. Turning the strip sideways, gently tap onto an absorbent material to drain excess control. In accordance with the manufacturer's instructions, read the reagent strips either visually or with an instrument reader.

   For hCG testing: In accordance with the hCG test kit manufacturer's instructions, use controls as if they were patient specimens. For the control of confirmatory pregnancy test kits, be sure to pour a small amount of control into a separate receptacle and use the transfer pipette included in the kit to deliver the correct sample amount to the test device.
3. Wipe the dropper tip, replace the cap immediately after use and store appropriately.

Materials provided

1x Control L1, 5 ml CONTROL − 1x Control L2, 5 ml CONTROL +

1x Kit insert

Limitations of the Procedure

CombiScreen® DROP Check should not be used past the expiration date on the tube label. CombiScreen® DROP Check is a stabilized liquid product. To obtain consistent assay values, CombiScreen® DROP Check requires storage and handling as detailed in Storage and Stability.

Accurate and reproducible results are dependent upon properly functioning instruments and reagents. The ranges given are intended only as a guideline. Each laboratory should establish their own acceptable ranges and tolerance limits based on their test system.

Expected readings

The expected values printed in this insert were derived from replicate analyses of representative samples of the product and are specific to this lot of CombiScreen® DROP Check. Testing data used to establish the expected values were derived from multiple instruments. All values have been assigned with manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these expected values. To request a faxed or emailed copy of the value assignment, contact your local distributor or info@analyticon-diagnostics.com.

Symbols and abbreviations

IVD	In vitro diagnostic product		Date of manufacture
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	Follow the instructions for use!	LOT	Batch designation
	Usable until	REF	Article number
	Permitted storage temperature		Manufacturer
CONT	Content		Warning, biological hazard
CONTROL −	Negative control	CONTROL +	Positive control
hCG	Human chorionic gonadotropin	CONTROL	Control
ALB	Albumin	BLD	Blood
BIL	Bilirubin	GLU	Glucose
CREA	Creatinine	LEU	Leucocytes
KET	Ketone	pH	pH value
NIT	Nitrite	SG	Specific gravity
PRO	Protein	UBG	Urobilinogen

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combi screen® Drop Check

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CombiScreen®	Drop Check
REF	93015
CONT	2×5 ml
ALB	■
BIL	■
BLD	■
CREA	■
GLU	■
KET	■
NIT	■
LEU	■
pH	■
PRO	■
SG	■
UBG	■
hCG	■

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Kouri, T., Fogazzi, G., Gant, V., Hallander, H., Hofmann, W., & Guder, W. G. (2000). European urinalysis guidelines. Scandinavian journal of clinical and laboratory investigation, 60(sup231), 1-96

CE IVD

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