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

Declaration of identity

Urilyzer Cell instrument is a commercial variant of the UriSed mini instrument, which distributes exclusively by Analyticon Biotechnologies GmbH. Urilyzer Cell can perform measurement with Urilyzer Cell Cuvettes.

The two instruments (Urilyzer Cell and UriSed mini) are identical in almost every element:

- Measurement process: The user fills the sample to be tested into disposable cuvettes. After a short centrifugation process, the microscopic optical system of the instrument takes images of the cuvette, which are evaluated by the software running on the built-in computer.
- Optical system: Urilyzer Cell uses the same optical system for imaging, including camera, microscope, objective and illumination.
- Evaluation algorithm: Both devices use the same evaluation module to recognize the same type of urine sediment cells.
- Software: In addition to the evaluation algorithm, the entire software system is the same for both devices, only the logo in the software is different, which in the case of Urilyzer Cell is the Analyticon Biotechnologies GmbH logo.
- Cuvette: Both systems use the same cuvette to test the sample.

The only differences between the two devices are:

- The logo on the instrument
- The logo in the software
- The cuvette sleeve holder, in which the cuvette sleeves can be placed. The cuvettes are inserted into the instrument in a cuvette sleeve. This sleeve has ribs outside that prevent UriSed cuvettes from being used with the Urilyer Cell.

Urilyzer Cell Cuvettes are the commercial variant of UriSed cuvettes.

Urilyzer Cell Cuvettes and UriSed cuvettes are completely identical, they differ only in the sleeve as described above, but this does not result in any difference in the cuvette itself.

Oliver Babinszki
Quality and Environmental Management Director

Digitally signed by Monastîrschii Viorica
Date: 2023.03.16 16:41:29 EET
Reason: MoldSign Signature
Location: Moldova

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

EC DECLARATION OF CONFORMITY

The undersigned, representing the following manufacturer:

Manufacturer:	**77 Elektronika Műszeripari Kft.**
Address:	Fehérvári út 98., H-1116, Budapest, Hungary

herewith declares under sole responsibility that the medical devices:

Product family:	**Automated urine microscopy analyzer**	GMDN code:	57860
Product identification(s) and alternative make(s):	▪ Urilyzer Cell Urine Microscopy Analyzer		
Product category:	in vitro diagnostic medical device (for professional use)		
Product classification:	Non-listed product according to Annex II of the Directive 98/79/EC		

declared by the manufacturer as in vitro diagnostic medical devices in conformity with the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (furthermore: Directive 98/79/EC)

CONFORMS

with the essential requirements of Annex I and other applicable articles of the Directive 98/79/EC and possess the performance intended by the manufacturer.

Conformity Assessment Procedure:	EC Directive 98/79/EC, Annex III. excluding Section 6.
Notified Body (if consulted):	N/A
Notified Body Identification Number (if consulted):	N/A
Type of Notified Body Certificate, Registration No. and Validity of Notified Body Certificate:	N/A

This is to attest that the aforementioned products do not endanger the health and safety of the patient, the operator or any other person if used properly.
I hereby declare that I maintain and update a quality management system whereby I monitor the experience acquired after the manufacture of the products and I take the necessary corrective actions.
I hereby declare that I immediately announce in accordance with Article 11 of the Directive 98/79/EC if any malfunction, deterioration of the features or performance of the product, or any deficiency or inadequacy of the user manual has caused or could have caused the death or severe deterioration of the state of health of the patient or the operator of the product.
I have compiled the technical documentation for aforementioned products in accordance with Article 3 of the Annex III of the Directive 98/79/EC that I shall hand over for supervision upon request by the Division for Medical Device Evaluation, Directorate General of Inspection, National Institute of Pharmacy and Nutrition, up to at least 5 years from the date of manufacture of the last product. The technical documentation is available at manufacturer's headquarters.

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.

Konformitätserklärung – Produkte Klasse A / Declaration of Conformity – Devices Class A

Name des Herstellers *Name of the manufacturer*	**Analyticon Biotechnologies GmbH**
Adresse des Herstellers *Address of the manufacturer*	Am Mühlenberg 10 35104 Lichtenfels Germany
SRN des Herstellers gemäß IVDR Artikel 28 *SRN ("Single Registration Number") of the manufacturer according to IVDR Article 28*	DE-MF-000016251
Klassifizierung mit zugehöriger Klassifizierungsregel gemäß IVDR Art. 47 & Anhang VIII *Classification with associated classification rule according to IVDR Art. 47 & Annex VIII*	*Rule 4b) [IVDR, Annex VIII, 2.4 b)]* *Rule 5b) [IVDR, Annex VIII, 2.5 b)]*
Konformitätsbewertungsverfahren gemäß IVDR *Conformity assessment procedure according to IVDR*	Artikel 48 (10) und Anhang IV Article 48 (10) and Annex IV
Konformitätsbewertungsstelle (falls hinzugezogen) mit (a) Identifikationsnummer: (b) Nummer des EU-QM Zertifikats: *Notified Body (if consulted) with* (a) Notified Body Identification: (b) EU C*ertificate #.:*	nicht erforderlich, da Bewertung in Eigenverantwortung erfolgt *not applicable, lies in the responsibility of the manufacturer*
Gültigkeit *Validity*	2025-01-10

Voraussetzung Konformitätsbewertung, zusätzlich zu IVDR Artikel 8 und 9:
Demonstration of Conformity ,in addition to IVDR Article 8 and 9:

- ☒ Anhang I und II + III (Klasse A, nicht-steril)
  Annex I and II + II (class A, non-sterile)
- ☐ Anhang XI (Klasse C und D + Klasse A, steril)
  Annex XI (class C and D + sterile class A)

Wir, Analyticon Biotechnologies GmbH, erklären als Hersteller, dass die Medizinprodukte für die In-vitro-Diagnostik
We, Analyticon Biotechnologies GmbH, declare as the manufacturer that the in vitro diagnostic medical devices

Bezeichnung, Artikelnummer, Basic UDI-DI : siehe Anhang
Description, article number and Basic UDI-DI: see annex

allen Anforderungen der Verordnung (EU) über In-vitro-Diagnostika 2017/746 entsprechen, die anwendbar sind. Als Hersteller sind wir allein für die Ausstellung der EU-Konformitätserklärung verantwortlich.
meet all the provisions of the Regulation (EU) on in vitro diagnostic medical devices 2017/746 which apply to it. As the manufacturer, we are solely responsible for the issue of the EU declaration of conformity.

Für und im Namen von Analyticon Biotechnologies GmbH
For and on behalf of Analyticon Biotechnologies GmbH,

Ort, Datum / *Place, date*	Name und Funktion / *Name and function*
Lichtenfels, 2022-04-27	Dr. Jürgen Schmich (Verantwortliche Person gem. IVDR Artikel 15) *(responsible person according to IVDR Article 15)*

Anhang/ Annex

Basic UDI-DI gemäß IVDR Anhang VI, Teil C *according to IVDR, Annex VI, Part C*	**426003371U100WU**
Zweckbestimmung ***Intended Purpose***	Der Urilyzer® 100 Pro ist ein semi-automatisches Urinteststreifen-Analysegerät und ermittelt semi-quantitative Parameter-Konzentrationswerte im menschlichen Urin. Das Analysegerät wertet zugehörige CombiScreen® System-Urinteststreifen zum vorläufigen Screening aus. Das Produkt ist für den professionellen Einsatz vorgesehen und kann in patientennaher Umgebung als In-vitro-Diagnostikum verwendet werden. The Urilyzer® 100 Pro is a semi-automatic urine test strip analyzer and provides semi-quantitative parameter concentration values in human urine. The analyzer evaluates dedicated CombiScreen® system urine test strips for preliminary screening. The product is designed for professional use and may be used in a near-patient environment as an in vitro diagnostic medical device.

Product Name	**REF**	**UDI-DI**	**EMDN-Code**
Urilyzer® 100 Pro	UL0100Pro	04260033719065	W020101020102

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
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

Test strips visual and semi-automated systems

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® 11SYS	93100	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 11SYS	93150	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 10SL	93120	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 10SL	93120A	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 10SL	93120B	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 3	93108A	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® GAK	93107	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® GAK	93107A	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® GP	93104	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® GPK	93105	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 11SYS PLUS	94100	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 11SYS PLUS	94150	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 11SYS PLUS	94150BC	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 10SL PLUS	94120	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 9 PLUS	94115	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 9+Leuko PLUS	94250	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 9+Leuko PLUS	94200	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 7SYS PLUS	94110	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 7SYS PLUS	94110A	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 5SYS PLUS	94109	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 5+Leuko PLUS	94517	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 5+Leuko PLUS	94117	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 5+N PLUS	94535	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 5+N PLUS	94135	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 3 PLUS	94508	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® 3 PLUS	94108	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® Glu PLUS	94501	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® Nitrit PLUS	94506	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä
CombiScreen® mALB / CREA	94025	11.70.02.02.00	DE/CA30/HE-0033-10001-001/Ä

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

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

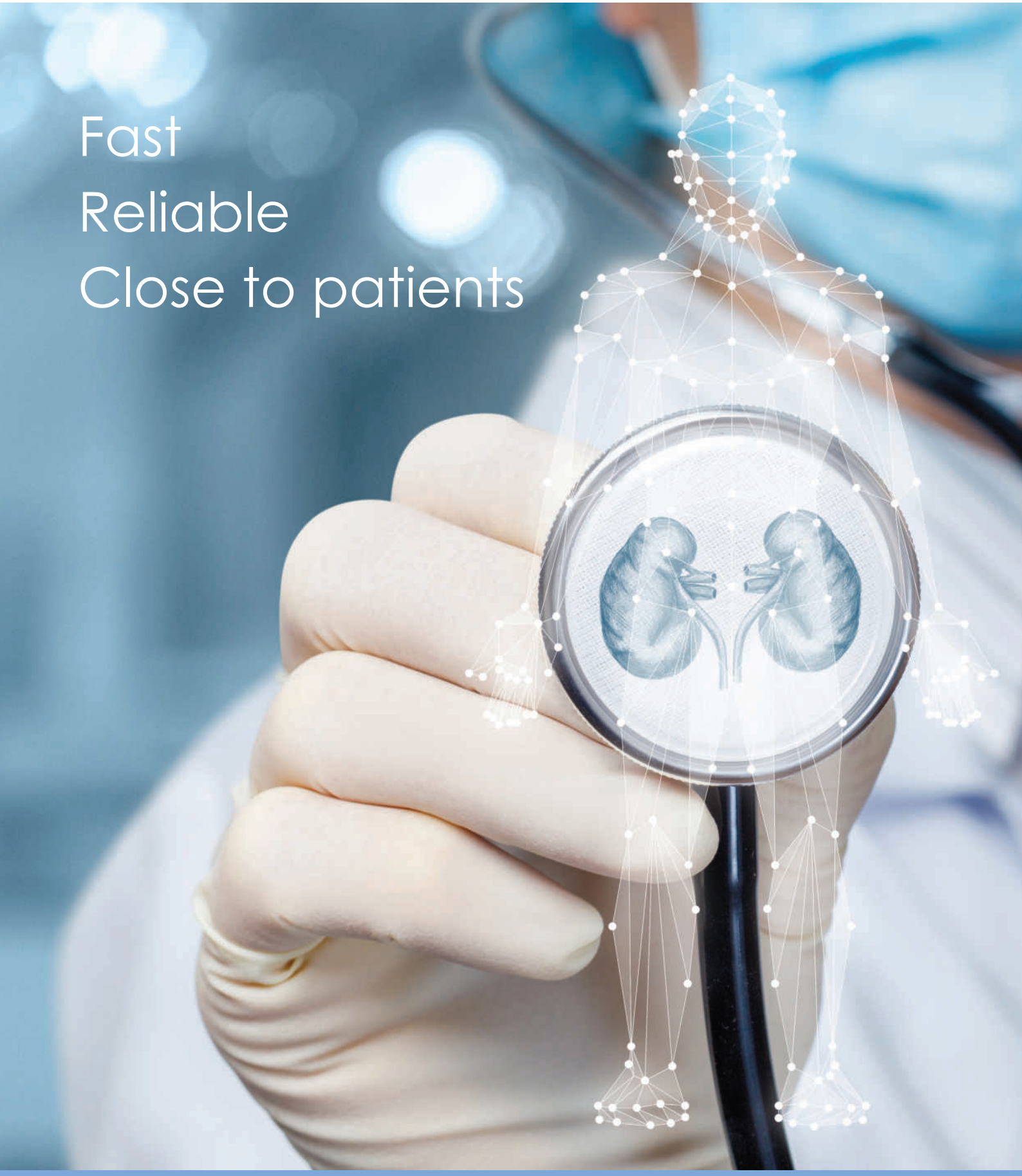
The following locations/companies belong to the certificate above:

	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

Products 2023

analyticon



agile - affordable - accurate

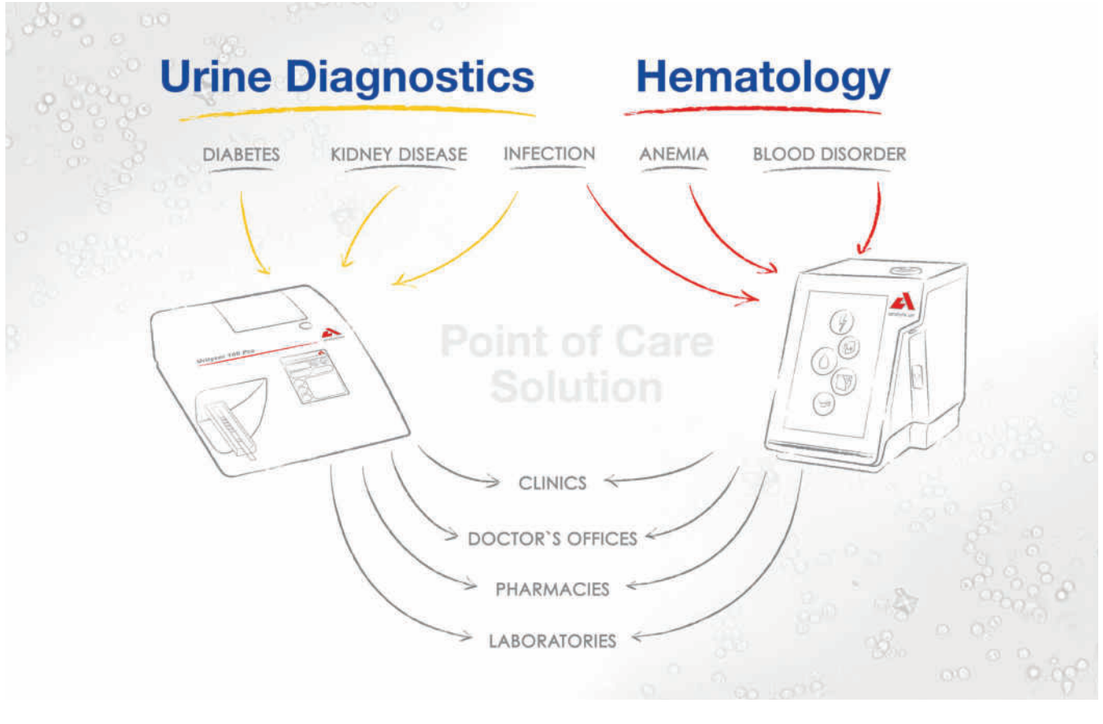
Content

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

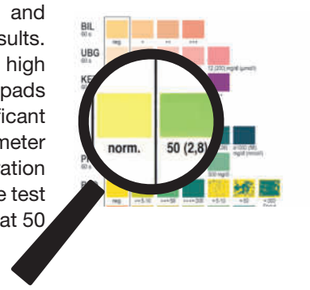
Furthermore, they are often used to monitor the success of a prescribed therapy or to self-monitor the metabolic situation of diabetic patients.

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.

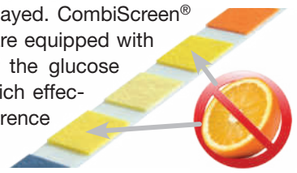
Distinct color changes in the clinically relevant range

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).

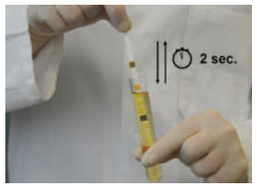


Excellent ascorbic acid protection for glucose and blood pad

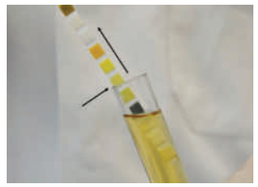
Ascorbic acid (Vitamin C) is absorbed by food, nutritional supplements and as a preservative in the body. Excess ascorbic acid is excreted; nevertheless, significant ascorbic acid levels in the urine are observed in a high proportion of the population.
This can affect the sensitivity of conventional 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.



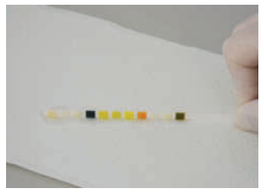
Four simple steps to achieve a multi-parameter result



- 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.

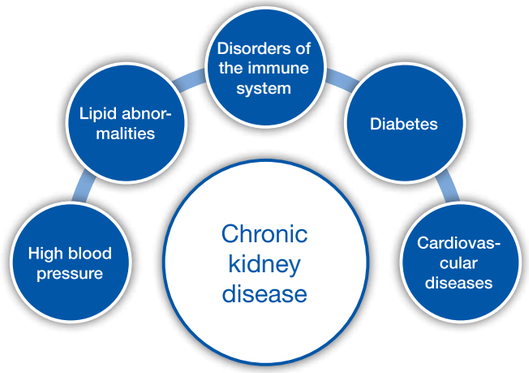


- Dip the strip on a tissue and keep it horizontal. Incubation time: 60 sec., Leucocytes up to 120 sec.

- 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.



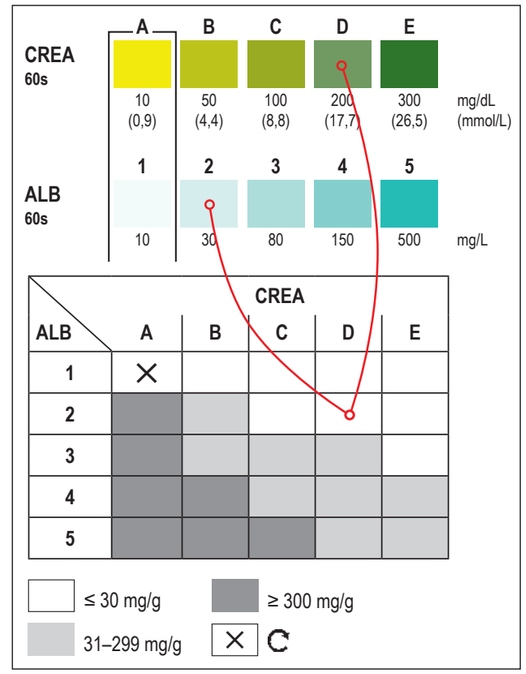
Intended Use
Screening of microalbuminuria for people with chronic conditions, such as diabetes and high blood pressure that puts them at an increased risk of developing a kidney disease. It may also be associated with some lipid abnormalities and various immune disorders.

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).



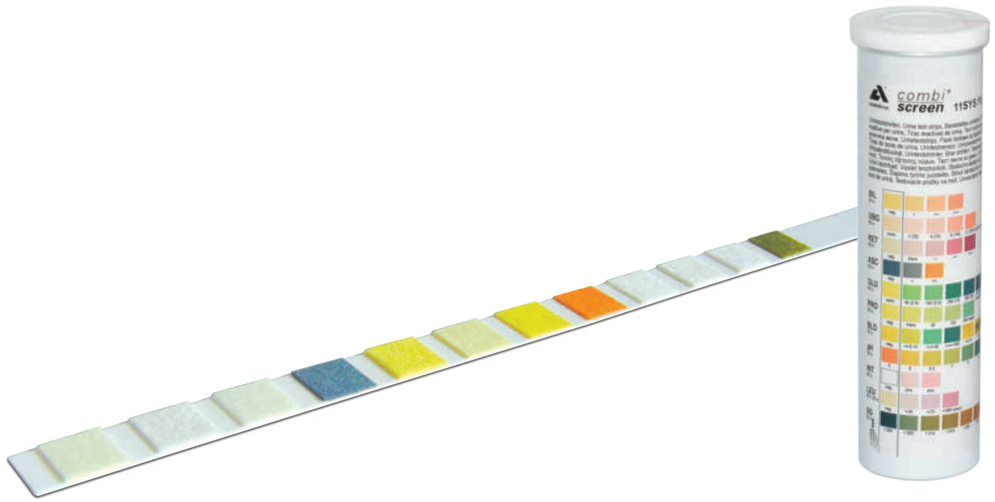
The evaluation of the result is extremely simple and reliable due to the table on the label.

CombiScreen® Parameter Overview

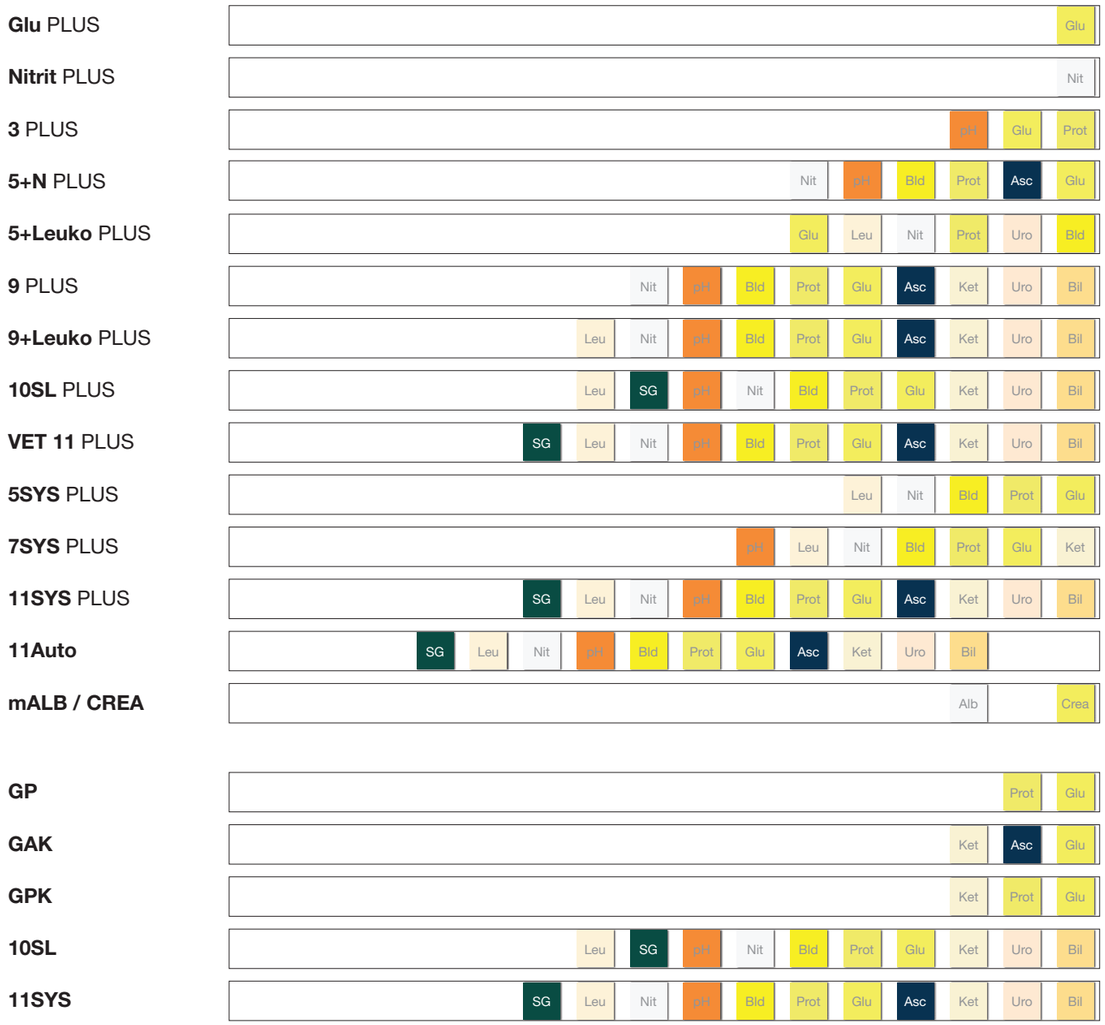
combi® screen PLUS
– with ascorbic acid protection

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

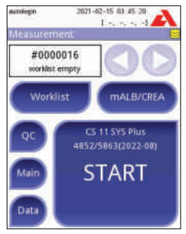


CombiScreen® Details



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

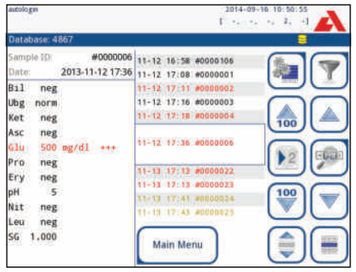
* please contact us for other middleware options

Specifications

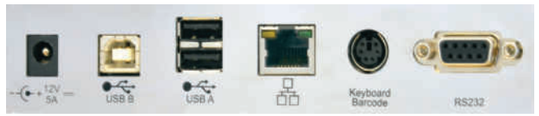
Type	Semi-automated urine test strip analyzer
Measurement technology	Reflectance photometer with 4 wavelengths: 505, 530, 620, 660 nm
Parameters	11 Parameter: Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes, Specific Gravity 7 Parameter: 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**

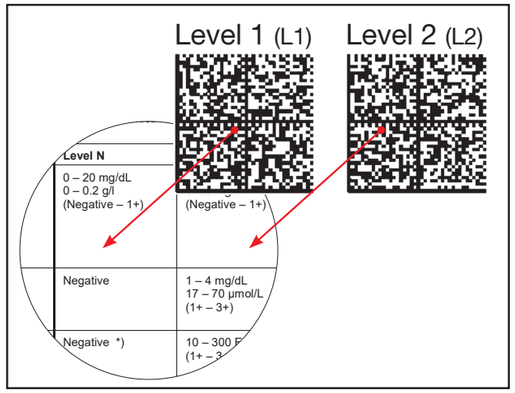
Start-Up Wizard
- On first usage the operator can select the language. Afterwards, the Start-Up Wizard leads through the user-defined settings
- The Start-Up Wizard enables the user to perform measurements without having to go through the complete user manual

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

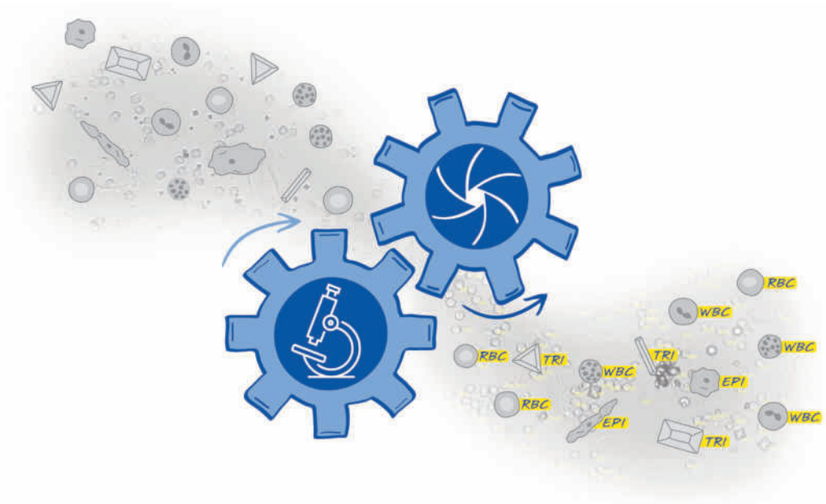
Connectivity options

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

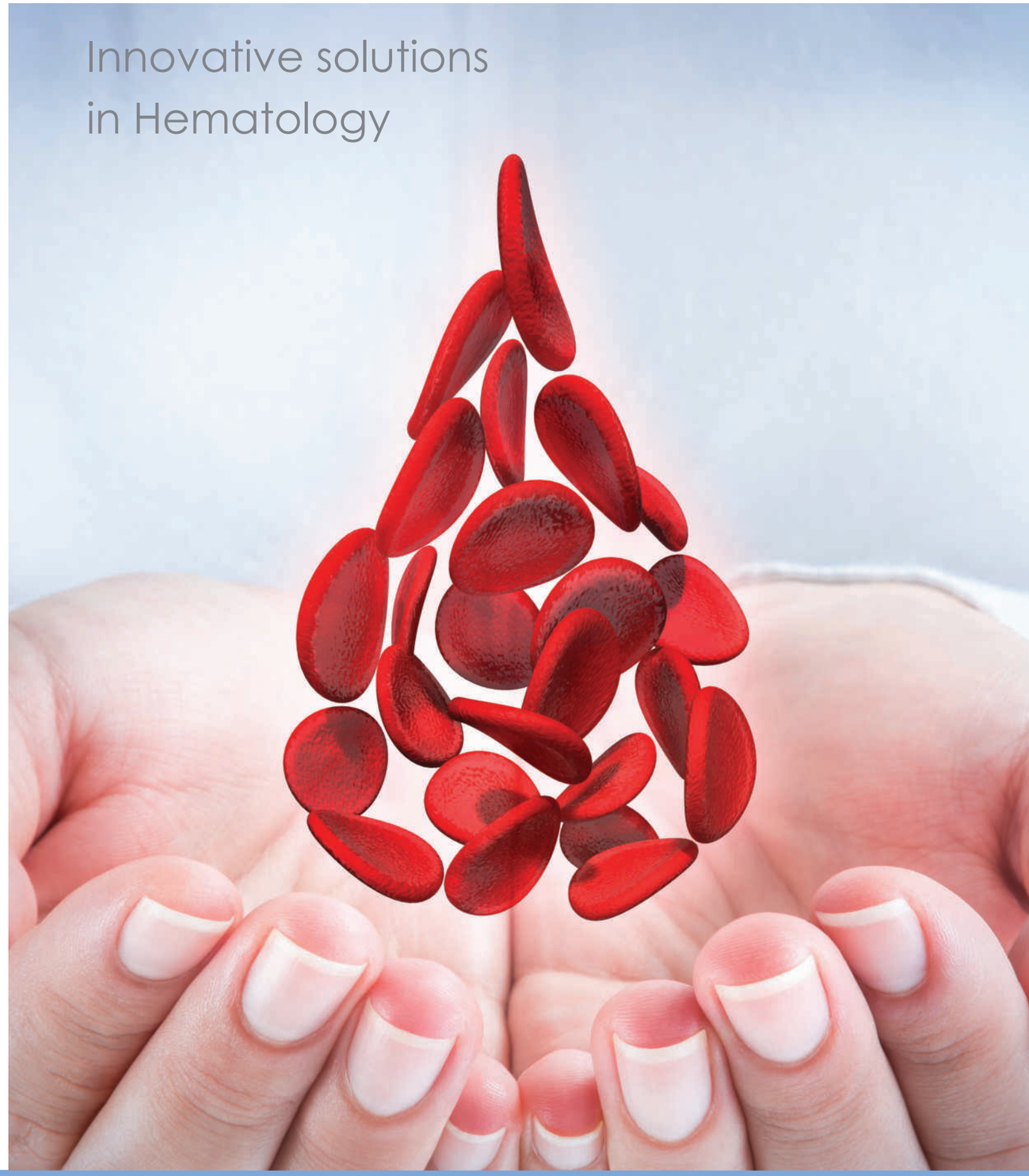
Type	Semi-automated urine sediment analyzer
Measuring technology	Cuvette-based automatic microscopy and image processing
Parameter	Red Blood Cells (RBC), Leukocytes (WBC, WBCc), Hyaline Casts (HYA), Pathological Casts (PAT), Squamous Epithelial Cells (EPI), Non-Squamous Epithelial Cells (NEC), Bacteria 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

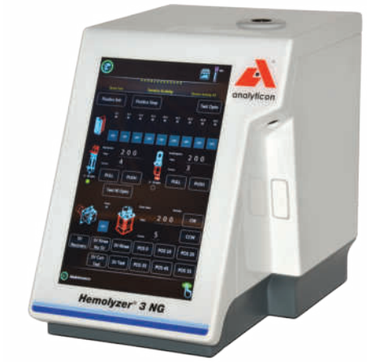
Product videos

Notes


Innovative solutions
in Hematology

Hemolyzer® 3 NG / 5 NG

The next generation of Hemolyzer instruments



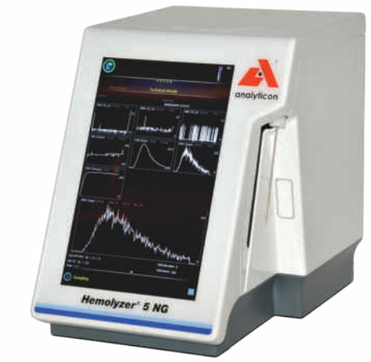
Hemolyzer® 3 NG Art.-No.: **HE3100**

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

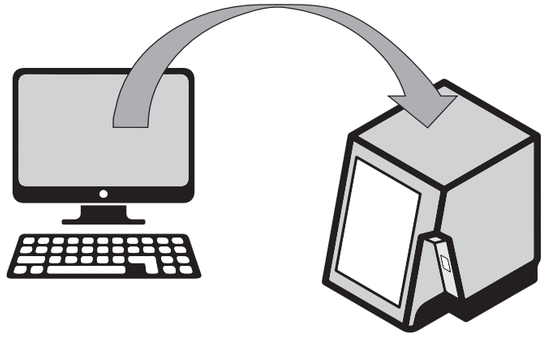
Autosampler Art.-No.: **HE0350**
suitable for Hemolyzer® 5 NG (closed); 50 positions



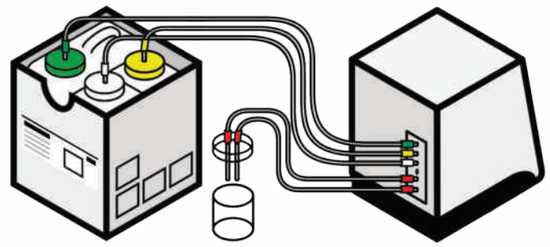
Hemolyzer® 5 NG (open mode) Art.-No.: **HE5200**

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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MP2023_en_61_001_01.01_20221024