MEDIST Grup
Soluții pentru sănătate

URS CERTIFICĂRI

Anexa 1 – Oferta tehnică

Digitally signed by Anghel Gabriela-Cristina
Date: 2021.12.27 09:23:47 EEST
Reason: MoldSign Signature
Location: Moldova

Specificatii tehnice solicitate	Specificatii tehnice ofertate
Analizator de urină automat care permite pînă la 100 teste/oră; Determinarea: Leu, Nit, Urobil, Prot, PH, Bl, SG, Ket, Bil, Cluc.	Analizor semi-automat de test de urină Tehnologie de măsurare: - Fotometru de reflexie cu 4 lungimi de undă discrete 505, 530, 620, 660 nm Parametrii: Sunt disponibile strip-uri cu număr diferit de parametri, funcție de nevoile utilizatorului: -11 Parametri: Bilirubină, Urobilinogen, Cetone, Acid ascorbic, Glucoză, Proteine (Albumină), Sânge (Hemoglobină), pH, Nitriți, Leucocite, Densitate specifică -7 Parametri: cetone, glucoză, proteine (albumină), sânge (hemoglobină), nitriți, leucocite, pH -5 Parametri: Glucoză, Proteine (Albumină), Sânge (Hemoglobină), Nitriți, Leucocite mALB/CREA: Albumină, Creatinină. Debit: Până la 50 de teste/oră (în modul normal) / Până la 120 de teste/oră (în modul rapid) Stocarea datelor: Baza de date pacient: 3.000 teste / baza de date QC: 1.000 teste Afișaj: LCD cu ecran tactil QVGA de 3,5 inchi Interfețe: Serial RS232, USB tip A, USB tip B, PS2 (tastatură externă, cititor de coduri de bare), suport card microSD, Ethernet Dimensiuni: 208 x 290 x 80 mm (LxPxA) Greutate: 1,2 kg Alimentare: 7,5 V DC / 3 A Mediul de operare: -Temperatura: + 15 ° C până la + 32 ° C -Umiditate relativă (fără condensare): 30% până la 80% -Presiune atmosferică: 70 kPa până la 106 kPa Imprimanta: termica incorporata Cititor de coduri de bare: extern Protocoale LIS2 (ASTM +), HL7, POCT1-A2 Caracteristici: -Asistentul de pornire la prima utilizare -Managementul operatorului cu opțiuni avansate de securitate a sistemului

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

	-Bandele de testare și managementul QC (trasabilitate completă prin LOT și intrarea de expirare) -Managementul datelor, managementul energiei -Pornire automată a măsurătorii (detecție automată a benzii) -Imprimare automată sau transfer de rezultat -Introducerea flexibilă a informațiilor avansate (de exemplu, culoarea probei și turbiditatea) Opțiuni avansate flexibile de testare și raportare (de exemplu, semnalizare de recomandare a sedimentelor)

Konformitätserklärung – Urin Diagnostik / Declaration of Conformity – Urine Diagnostics

Name und Adresse des Herstellers / *Name and address of the manufacturer:*

Analyticon Biotechnologies AG

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, da Bewertung in Eigenverantwortung *not applicable, lies in the responsibility of the manufacturer*

Ort, Datum / *Place, date*	Name und Funktion / *Name and function*
Lichtenfels, 03.09.2018	Dr. Jürgen Schmich (Sicherheitsbeauftragter gem. §30(2) MPG) *(safety officer for med. devices acc. §30(2) MDD)*

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

Analyticon Biotechnologies AG

Am Mühlenberg 10,
35104 Lichtenfels, Germany

Test strips

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® 11SYS	93100	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS	93150	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS	93050	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 10SL	93120	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 10SL	93120A	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 10SL	93120B	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5B	93134	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 3	93108	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 3	93108A	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® GAK	93107	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® GAK	93107A	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® GP	93104	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® GPK	93105	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS PLUS	94100	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS PLUS	94150	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS PLUS	95151	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11 Auto	95150	11.70.02.02	DE/CA30/HE-0033-10105-000
CombiScreen® 10SL PLUS	94120	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 9 PLUS	94115	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 9+Leuko PLUS	94250	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 9+Leuko PLUS	94200	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 7SYS PLUS	94110	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 7SYS PLUS	94110A	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5SYS PLUS	94109	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5+Leuko PLUS	94517	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5+Leuko PLUS	94117	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5+N PLUS	94535	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5+N PLUS	94135	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 3 PLUS	94508	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 3 PLUS	94108	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® Glu PLUS	94501	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® Nitrit PLUS	94506	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® mALB / CREA	94025	11.70.02.02	DE/CA30/56863/D/017/E

Instruments

Name	REF	EDMS-Code	Reg.-Nr.
Urilyzer® 100	UL0100	21.05.02	DE/CA30/HE-0033-10103-000
Urilyzer® 100 Pro	UL0100Pro	21.05.02	DE/CA30/HE-0033-10103-000
Urilyzer® 500 Pro	UL0500Pro	21.05.03	DE/CA30/56863/D/001/E
CombiScan® 100	A93009	21.05.02	DE/CA30/HE-0033-10004-000
CombiScan® 500	A93005	21.05.03	DE/CA30/HE-0033-10003-000
CombiScan® XL	A93007	21.05.04	DE/CA30/HE-0033-10007-000
Urilyzer® Auto	ULA240	21.05.04	DE/CA30/HE-0033-10106-001
Urilyzer® Auto	ULA240CN	21.05.04	DE/CA30/HE-0033-10106-001
Urilyzer® Sed	ULS120	21.05.04	DE/CA30/HE-0033-10109-000

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

Analyticon Biotechnologies AG

Am Mühlenberg 10,
35104 Lichtenfels, Germany

Accessory: Connection Unit for Urilyzer® Sed and Urilyzer® Auto

Name	REF	EDMS-Code	Reg.-Nr.
UriTrail	ULS001	26.02	DE/CA30/56863/D/000/E

Urine control

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® Control PN	93001	11.50.90.02.00	DE/CA30/56863/D/019/Ä
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
Urilyzer® Sed Control Set	ULS3100	11.70.02.10.00	DE/CA30/HE-0033-10107-000

Cleansers Urilyzer® Sed

Name	REF	EDMS-Code	Reg.-Nr.
Cleanser A	ULS2100	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Cleanser A	ULS2101	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Cleanser B	ULS2200	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Cleanser B	ULS2201	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Maintenance Cleanser	ULS2300	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Maintenance Cleanser	ULS2301	11.90.01.01.00	DE/CA30/56863/D/018/Ä

Traducere din limba germană

Document original bilingv: germană/engleză

Declarație de Conformitate – Diagnostic urină

Numele și adresa producătorului

Analyticon Biotechnologies AG

Am Mühlenberg 10,
35104 Lichtenfels, Germania

Declarăm, exclusiv pe propria noastră răspundere, că dispozitivele medicale pentru diagnosticarea in vitro

Denumirea și codul de dispozitivului: vezi anexa

clasificate după cum urmează, în conformitate cu directiva privind dispozitivele medicale de diagnostic in vitro 98/79 / CE

( ) Dispozitiv din Lista A, anexa II
( ) Dispozitiv din Lista B, anexa II
( ) Dispozitiv de auto-testare care nu este menționat în anexa II
(X) Alt dispozitiv

respectă toate dispozițiile directivei privind dispozitivele medicale de diagnostic in vitro 98/79 / CE care i se aplică

Procedura de evaluare a conformității	IVD 98/79/EG, Articol 9 (1) și anexa III
Codul EDMA și numărul de înregistrare	vezi anexa
Organismul de evaluare a conformității	nu este necesar, deoarece evaluarea se face pe proprie răspundere

Locul, data

Numele și funcția
Semnătură indescifrabilă

Lichtenfels, 03.09.2018

Dr. Jürgen Schmich
(Ofițer pt. siguranța dispoz. med.
conf. §30(2) MPG)

Anexa la declarația de conformitate – Diagnostic urină

Analyticon Biotechnologies AG

Am Mühlenberg 10,
35104 Lichtenfels, Germany

Benzi testare

Denumire	REF	Cod EDMS	Nr. Reg.
CombiScreen® 11SYS	93100	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS	93150	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS	93050	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 10SL	93120	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 10SL	93120A	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 10SL	93120B	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5B	93134	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 3	93108	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 3	93108A	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® GAK	93107	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® GAK	93107A	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® GP	93104	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® GPK	93105	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS PLUS	94100	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS PLUS	94150	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11SYS PLUS	95151	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 11 Auto	95150	11.70.02.02	DE/CA30/HE-0033-10105-000
CombiScreen® 10SL PLUS	94120	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 9 PLUS	94115	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 9+Leuko PLUS	94250	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 9+Leuko PLUS	94200	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 7SYS PLUS	94110	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 7SYS PLUS	94110A	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5SYS PLUS	94109	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5+Leuko PLUS	94517	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5+Leuko PLUS	94117	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5+N PLUS	94535	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 5+N PLUS	94135	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 3 PLUS	94508	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® 3 PLUS	94108	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® Glu PLUS	94501	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® Nitrit PLUS	94506	11.70.02.02	DE/CA30/HE-0033-10001-000
CombiScreen® mALB / CREA	94025	11.70.02.02	DE/CA30/56863/D/017/E

Instrumente

Denumire	REF.	Cod EDMS	Nr. Reg.
Urilyzer® 100	UL0100	21.05.02	DE/CA30/HE-0033-10103-000
Urilyzer® 100 Pro	UL0100Pro	21.05.02	DE/CA30/HE-0033-10103-000
Urilyzer® 500 Pro	UL0500Pro	21.05.03	DE/CA30/56863/D/001/E
CombiScan® 100	A93009	21.05.02	DE/CA30/HE-0033-10004-000
CombiScan® 500	A93005	21.05.03	DE/CA30/HE-0033-10003-000

CombiScan® XL	A93007	21.05.04	DE/CA30/HE-0033-10007-000
Urilyzer® Auto	ULA240	21.05.04	DE/CA30/HE-0033-10106-001
Urilyzer® Auto	ULA240CN	21.05.04	DE/CA30/HE-0033-10106-001
Urilyzer® Sed	ULS120	21.05.04	DE/CA30/HE-0033-10109-000

Anexa la declarația de conformitate – Diagnostic urină

Analyticon Biotechnologies AG

Am Mühlenberg 10,
35104 Lichtenfels, Germany

Accesorii: Unitate de conectare pentru Urilyzer® Sed și Urilyzer® Auto

Denumire	REF	Cod EDMS	Nr. reg.
UriTrail	ULS001	26.02	DE/CA30/56863/D/000/E

Control urină

Denumire	REF	Cod EDMS	Nr. reg.
CombiScreen® Control PN	93001	11.50.90.02.00	DE/CA30/56863/D/019/Ä
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
Urilyzer® Sed Control Set	ULS3100	11.70.02.10.00	DE/CA30/HE-0033-10107-000

Cleansers Urilyzer® Sed

Denumire	REF	Cod EDMS	Nr. reg.
Cleanser A	ULS2100	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Cleanser A	ULS2101	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Cleanser B	ULS2200	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Cleanser B	ULS2201	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Maintenance Cleanser	ULS2300	11.90.01.01.00	DE/CA30/56863/D/018/Ä
Maintenance Cleanser	ULS2301	11.90.01.01.00	DE/CA30/56863/D/018/Ä

Subsemnata, **CRISTESCU NATASA** traducător autorizat pentru limba Engleză, în temeiul autorizaţiei nr. 31443, eliberată de Ministerul Justiţiei, certific exactitatea traducerii efectuate din limba engleză în limba română, că textul prezentat a fost tradus în intregime şi că prin traducere, înscrisului nu i-au fost denaturate conţinutul şi sensul

CERTIFICATE

analyticon®

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Analyticon Biotechnologies AG

Scope of certification:

Development, production and distribution of in-vitro diagnostics from the field of urine diagnostics for professional and patient-oriented applications.
Distribution, service and installation of in-vitro-diagnostic analysis equipment from the fields of hematology, coagulation and urine diagnostics.
Distribution of in-vitro diagnostic devices from the field of coagulation and clinical chemistry.

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-Z1-00.

Certificate registration no.:	51519-14-00	Certificate valid from:	2020-11-16
		Certificate valid to:	2023-11-15

DEKRA Certification GmbH • Stuttgart • Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-11-16

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

Annex to the Certificate No. 51519-14-00

Revision status: 0

valid from 2020-11-16 to 2023-11-15

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Analyticon Biotechnologies AG	Am Mühlenberg 10 35104 Lichtenfels Germany	Development, production and distribution of in-vitro diagnostics from the field of urine diagnostics for professional and patient-oriented applications. Distribution, service and installation of in-vitro-diagnostic analysis equipment from the fields of hematology, coagulation and urine diagnostics. Distribution of in-vitro diagnostic devices from the field of coagulation and clinical chemistry.
	at the following locations / at the companies at the following locations		**Scope of certification**
1.	Analyticon Biotechnologies AG	Am Teichsberg 10 35104 Lichtenfels-Sachsenberg Germany	Storage of preliminary and final products in the field of in-vitro diagnostics.

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-11-16

CERTIFICAT

EN ISO 13485:2016

DEKRA Certification GmbH certifică prin prezentul document că societatea

Analyticon Biotechnologies AG

Domeniul certificării:

Dezvoltarea, fabricarea și distribuția produselor pentru diagnosticare *in vitro* în domeniul diagnosticării urinei pentru aplicații profesionale și orientate spre pacient.
Distribuția, întreținerea și instalarea echipamentelor de analiză pentru diagnosticare *in vitro* în domeniul diagnosticării hematologice, al coagulării și urinei.
Distribuția dispozitivelor de diagnosticare *in vitro* în domeniul coagulării și chimiei clinice.

Locație certificată:

Am Mühlenberg 10, 35104 Lichtenfels, Germania
(consultați anexa pentru alte locații)

a instituit și menține un sistem de management al calității conform standardului menționat mai sus. Conformitatea a fost acreditată prin raportul de audit nr. 51519-Z1-00.

Nr. de înregistrare certificat:	51519-14-00	Certificat valabil din:	16 noiembrie 2020
		Certificat valabil până la:	15 noiembrie 2023

ștampilă oficială
semnătură indescifrabilă

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-11-16

Anexă la Certificatul nr. 51519-14-00

Starea revizuirii: 0

valabil între 16.11.2020 și 15.11.2023

Următoarele locații/companii intră sub incidenţa certificatului de mai sus:

	Sediu	**Locație certificată**	**Domeniul certificării**
	Analyticon Biotechnologies AG	Am Mühlenberg 10 35104 Lichtenfels Germania	Dezvoltarea, fabricarea și distribuția produselor pentru diagnosticare *in vitro* în domeniul diagnosticării urinei pentru aplicații profesionale și orientate spre pacient. Distribuția, întreținerea și instalarea echipamentelor de analiză pentru diagnosticare *in vitro* în domeniul diagnosticării hematologice, al coagulării și urinei. Distribuția dispozitivelor de diagnosticare *in vitro* în domeniul coagulării și chimiei clinice.
	la următoarele locații/în cadrul companiilor din următoarele locații		**Domeniul certificării**
1.	Analyticon Biotechnologies AG	Am Teichsberg 10 35104 Lichtenfels-Sachsenberg Germania	Depozitarea produselor preliminare și finale în domeniul diagnosticării *in vitro*.

ștampilă oficială
semnătură indescifrabilă

Ruth Delbeck-Bayer

Ruth Delbeck-
DEKRA Certification GmbH, Stuttgart, 2020-11-16

Subsemnata **VERDES ELENA ALINA** traducător autorizat de Ministerul Justiţiei cu nr. 24515/2008, certific exactitatea traducerii cu textul înscrisului original din limba engleza în limba română.

Traducător / Traductrice / Translator

Urilyzer® 100 Pro

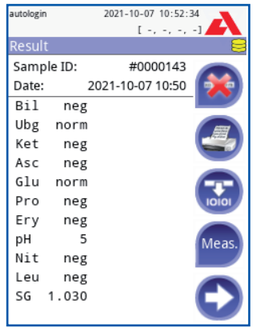
analyticon®

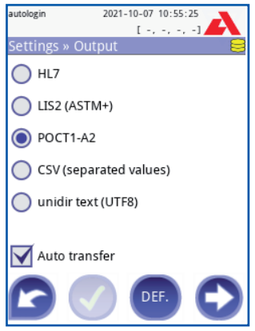
A new way in urinalysis

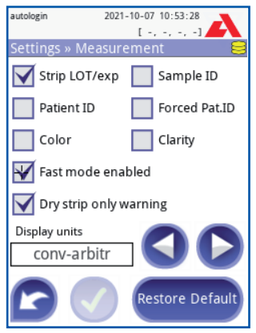
- Easy-to-use
- Smart and safe operation
- Extended connectivity capabilities
- POCT-features

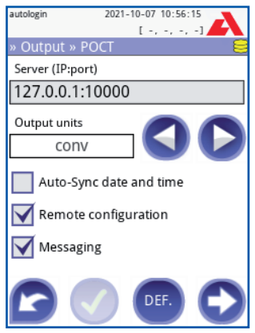
Easy-to-use

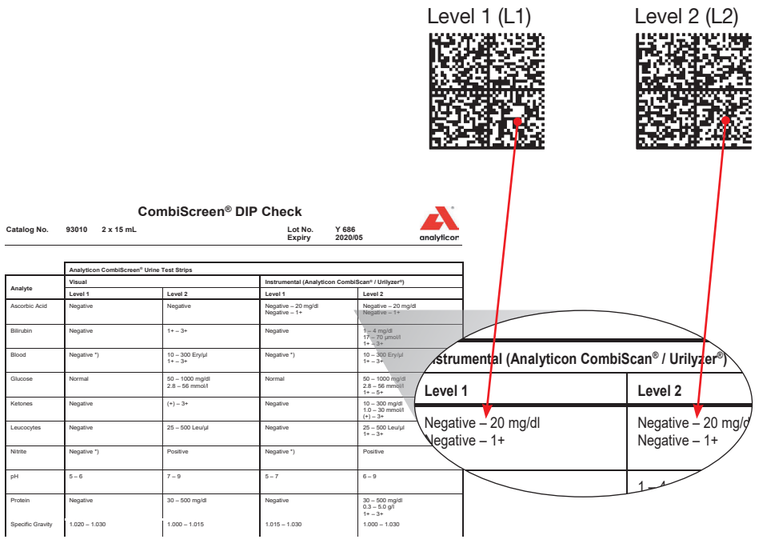
- A Start-Up Wizard leads the operator through the user-defined settings upon first start of the device.
- Automatic start of the measurement after placing the urine test strip allows hygienic and clean operation of the analyzer
- Positive results, reminders and warnings are shown in color (e.g. red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









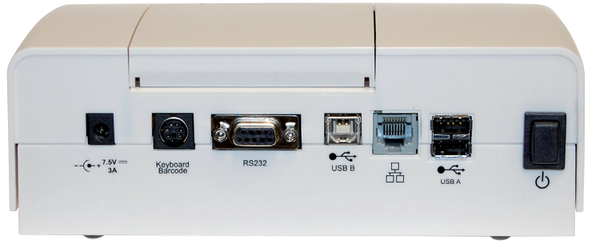


Smart and safe operation

- 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

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35104 Lichtenfels - Germany
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Not available for sale in the U.S.

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