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Vertretung und Repräsentanz

Certificate

Of Marketing Authorization of Medical Product

within Germany, the member states of the European Union
and the other states having a contractual agreement with the European Economic Area

Nr. **AR/IVD/XEMA LLC/01/2023**

Issued on the basis of the Declaration of conformity and registration taking into account account Article 11 of Regulation (EU) 2017/746 (IVDR) on In Vitro Diagnostic, and Medical Device Implementing Act (MPDG)

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der der Verordnung (EU) 2017/746 (IVDR) über In-vitro-Diagnostika und Medizinprodukterecht-Durchführungsgesetz (MPDG)

Manufacturer / Hersteller	**XEMA LLC** **SRN: UA-MF-000032959** UKRAINE, 03179 KYIV Akademika Yefremova St. 23 qa@xema.com.ua; www.xema.in.ua
Product name / Produkt	**See annex to the Certificate** Siehe Anhang zum Zertifikat
Product Classification: Produktklassifizierung	**In Vitro Diagnostic Medical Devices** In-vitro-Diagnostikum (IVD) Medizinprodukte
Category: Kategorie	**Common/ Other IVD** Sonstige IVD-Produkte
Conformity assessment procedure: Konformitatsbewertungsverfahren:	**EC DECLARATION OF CONFORMITY** **(Annex III, except point 6, Directive 98/79/EC)** **in connection with article 110(3) IVDR** **EU- KONFORMITATSERKLARUNG** (Anhang III, außer Nummer 6, Richtlinie 98/79 / EG) in Verbindung mit Artikel 110 (3) IVDR
State Competent Authority: Staatliche Zuständige Behörde	**BfArM** Federal Institute for Drugs and Medical Devices DMIDS (German Medical Device Information and Database System) **BfArM** Das Bundesinstitut für Arzneimittel und Medizinprodukte DMIDS (Deutsches Medizinprodukte-Informations- und Datenbanksystem)

Date of issue : **2023-03-07**
Das Ausstellungsdatum

Valid to : **2025-05-31**
Gültig bis

Represented in the EC by:

Polmed.de Beata Rozwadowska
Fichtenstr. 12A, 90763 Fürth, Germany
email: info@polmed.de
Tel: +49 911 93163967

Beata Rozwadowska * Polmed.de * Fichtenstr. 12A 90763 Fürth Germany

Polmed.de

SRN: DE-AR-000006947

Digitally signed by Monastîrschii Viorica
Date: 2023.12.29 10:24:28 EET
Reason: MoldSign Signature
Location: Moldova

Valid with the Extract from the database www.dimdi.de (German Medical Device Information and Database System (DMIDS))
Gilt nur mit :Auszug aus der Datenbank www.dimdi.de (Deutsches Medizinprodukte-Informations- und Datenbanksystem (DMIDS))

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Vertretung und Repräsentanz

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/XEMA LLC/01/2023

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
1.	ASPERGILLUS	K021	GalMAg EIA	**DE/CA64/00115824**
2.	HSV IgG	K104	HSV 1/2 IgG EIA	**DE/CA64/00115826**
3.	HSV IgM	K104M	HSV 1, 2 IgM EIA	**DE/CA64/00115833**
4.	HSV 2 IgG	K104B	HSV 2 IgG EIA	**DE/CA64/00115836**
5.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA	**DE/CA64/00115837**
6.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	anti-Treponema pallidum EIA	**DE/CA64/00115839**
7.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA	**DE/CA64/00115840**
8.	H. PYLORI ANTIBODY ASSAYS	K119G	Helicobacter pylori IgG EIA	**DE/CA64/00115850**
9.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA	**DE/CA64/00115851**
10.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA	**DE/CA64/00115852**
11.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA	**DE/CA64/00115853**
12.	MPO ANCA	K133	aMPO EIA	**DE/CA64/00115854**
13.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	anti-TGlu IgG EIA anti-TGlu IgA EIA	**DE/CA64/00115855**
14.	GIARDIA LAMBLIA	K171	anti-Giardia lamblia EIA	**DE/CA64/00115856**
15.	OTHER PARASITOLOGY	K174	Ascaris IgG EIA	**DE/CA64/00115857**
16.	ECHINOCOCCUS	K175	Echinococcus IgG EIA	**DE/CA64/00115858**
17.	DISTOMATOSIS	K176	Opisthorchis IgG EIA	**DE/CA64/00115859**
18.	GLIADIN ANTIBODIES	K180 K181	Gliadin IgG EIA Gliadin IgA EIA	**DE/CA64/00115860**
19.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA	**DE/CA64/00115861**
20.	THYROID STIMULATING HORMONE	K201	TSH EIA	**DE/CA64/00115863**
21.	LUTEINISING HORMONE	K202	LH EIA	**DE/CA64/00115864**
22.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA	**DE/CA64/00115865**
23.	HUMAN GROWTH HORMONE	K204	GH EIA	**DE/CA64/00115866**
24.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	hCG EIA	**DE/CA64/00115867**
25.	PROLACTIN	K206	Prolactin EIA	**DE/CA64/00115868**

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

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Vertretung und Repräsentanz

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/XEMA LLC/01/2023

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#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
26.	PROGESTERONE	K207	Progesterone EIA	**DE/CA64/00115869**
27.	ESTRADIOL	K208	Estradiol EIA	**DE/CA64/00115870**
28.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209	Testosterone EIA	**DE/CA64/00115871**
29.	CORTISOL	K210	Cortisol EIA	**DE/CA64/00115872**
30.	TRIIODOTHYRONINE	K211	T3 EIA	**DE/CA64/00115873**
31.	THYROXINE	K212	T4 EIA	**DE/CA64/00115874**
32.	FREE TRIIODOTHYRONINE	K213	fT3 EIA	**DE/CA64/00115875**
33.	FREE THYROXINE	K214	fT4 EIA	**DE/CA64/00115876**
34.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEAS EIA	**DE/CA64/00115877**
35.	17 OH PROGESTERONE	K217	17-OH-progesterone EIA	**DE/CA64/00115878**
36.	ESTRIOL	K218	free Estriol EIA	**DE/CA64/00115880**
37.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	free Testosterone EIA	**DE/CA64/00115881**
38.	CANCER ANTIGEN 125	K222	CA 125 EIA	**DE/CA64/00115882**
39.	CANCER ANTIGEN 19-9	K223	CA 19-9 EIA	**DE/CA64/00115883**
40.	CARCINOEMBRYONIC ANTIGEN	K224	CEA EIA	**DE/CA64/00115884**
41.	ALPHAFETOPROTEIN	K225	AFP EIA	**DE/CA64/00115885**
42.	CANCER ANTIGEN 15-3	K226	CA 15-3 (M12) EIA	**DE/CA64/00115886**
43.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA	**DE/CA64/00115887**
44.	ß HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	free β-HCG EIA	**DE/CA64/00115888**
45.	CYFRA 21-1	K236	CYFRA 21-1 EIA	**DE/CA64/00115889**
46.	SQUAMOUS CELL CARCINOMA ANTIGEN	K237	SCC (A) EIA	**DE/CA64/00115890**
47.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA	**DE/CA64/00115892**
48.	OTHER OTHER TUMOUR MARKERS	K239	HE4 EIA	**DE/CA64/00115893**
49.	CANCER ANTIGEN 242	K243	CA242 EIA	**DE/CA64/00115894**
50.	OTHER PREGNANCY TESTING HORMONES	K245	AMH EIA	**DE/CA64/00115896**

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

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Vertretung und Repräsentanz

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/XEMA LLC/01/2023

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
51.	HUMAN PLACENTAL LACTOGEN HPL	K246	Placental lactogen EIA	DE/CA64/00115897
52.	C-REACTIVE PROTEIN	K250	CRP EIA	DE/CA64/00115898
53.	C-PEPTIDE	K267C	C-peptide EIA	DE/CA64/00115900
54.	INSULIN	K267N	Insulin EIA	DE/CA64/00115901
55.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA	DE/CA64/00115902
56.	TROPONIN (T + I)	K291	Troponin I EIA	DE/CA64/00115903
57.	LYME ANTIBODY IGG	K118G	Borelia burgdorferi IgG EIA	DE/CA64/00115904
58.	LYME ANTIBODY IGM	K118M	Borelia burgdorferi IgM EIA	DE/CA64/00115905
59.	EBV ANTIBODIES	K108V K108VM K108N	Epstein-Barr virus VCA IgG EIA Epstein-Barr virus VCA IgM EIA Epstein-Barr virus EBNA IgG EIA	DE/CA64/00115906

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Represented in the EC by:

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email: info@polmed.de
Tel: +49 911 93163967

SRN: DE-AR-000006947

Beata Rozwadowska * Polmed.de * Fichtenstr. 12a, 90763 Fürth, Germany

Date: **March 07, 2023**

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Valid with the Extract from the database www.dimdi.de (German Medical Device Information and Database System (DMIDS))
Gilt nur mit :Auszug aus der Datenbank www.dimdi.de (Deutsches Medizinprodukte-Informations- und Datenbanksystem (DMIDS))

ТОВ «ХЕМА» код ЄДРПОУ 36038442
Адреса 03179, м. Київ, вул. Академіка Єфремова, 23
Для кореспонденції: 03179, а/с 49
З питань замовлення продукції: 050-422-62-16, 067-422-62-16
Тел.: +38 (095) 60-99-555 Факс: +38 (044) 422-62-16
e-mail:info@xema.com.ua
www.xema.in.ua

STATEMENT

We, XEMA LLC, as a manufacturer of in vitro diagnostic medical devices, having a registered office at Akademika Yefremova St. 23, Kyiv, Ukraine assign SRL SANMEDICO having a registered office at A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with legislative requirements of the Republic of Moldova.

We declare that the company mentioned above is authorized to register, notify, renew, or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement shall come into force on the date of its signing. The duration of this Statement is 3 years from the date of signing.

Date: 06.09.2023

Signature:

Director Xema LLC
Oleksandra Zavaliei

ТОВ «УКРМЕДСЕРТ»

СЕРТИФІКАТ

про відповідність системи управління якістю

Зареєстрований у Реєстрі
«29» червня 2022 р.
№ UA.SM.214-21
Дійсний до «03» серпня 2024 р.
Перше видання: «04» серпня 2021 р.

ЦИМ СЕРТИФІКАТОМ ВІДПОВІДНОСТІ ПОСВІДЧУЄТЬСЯ,
ЩО СИСТЕМА УПРАВЛІННЯ ЯКОСТІ СТОСОВНО

проектування та розроблення, виробництва та дистрибуції медичних виробів для діагностики in vitro

впроваджена:

ТОВ «ХЕМА»

за адресою: **вул. Академіка Єфремова, 23, м. Київ, 03179, Україна**

відповідає вимогам ISO 13485:2016;
ДСТУ EN ISO 13485:2018 (EN ISO 13485:2016, IDT; ISO 13485:2016, IDT).

Контроль відповідності сертифікованої системи управління якістю вимогам зазначеного стандарту здійснюється шляхом нагляду, періодичність і процедури якого регламентуються процедурами органу з оцінки відповідності.

Сертифікат видано Органом з оцінки відповідності ТОВ «УКРМЕДСЕРТ», акредитованим Національним агентством з акредитації України, атестат від 24.12.2019 № 8О047, адреса: вул. Драгоманова, будинок 1-А, оф. 2, м. Київ, 02059, Україна, тел./факс: +38-067-595-02-30, https://ukrmedcert.org.ua.

Директор **І.М. Хотенюк**

Чинність сертифіката відповідності можна перевірити в Реєстрі на сайті https://ukrmedcert.org.ua та за тел. +38-067-595-02-30

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

EKVITESTLAB LLC

Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150, tel. 0(800)31-89-87; +38 (044)334-89-87

e-mail: info@equitest.com.ua, web-site: www.equitest.com.ua

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

EQUI anti-Lamblia - ELISA kit for the qualitative detection of antibodies to *Giardia lamblia (intestinalis)*, REF EI-606

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **ISO 13485:2016 «Medical devices — Quality management systems — Requirements for regulatory purposes»**

Corporate Contact Information

EKVITESTLAB LLC
Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150
tel. 0(800)31-89-87; +38 (044)334-89-87
e-mail: info@equitest.com.ua
RESPONSIBLE PERSON'S name: Anna Yurchuk
Position: Director

SIGNATURE : 

Date : October 25, 2021
Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

EKVITESTLAB LLC

Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150, tel. 0(800)31-89-87; +38 (044)334-89-87

e-mail: info@equitest.com.ua, web-site: www.equitest.com.ua

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

EQUI Toxocara canis IgG - ELISA kit for the qualitative detection of IgG antibodies to *Toxocara canis*, REF EI-603

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

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- **ISO 13485:2016 «Medical devices — Quality management systems — Requirements for regulatory purposes»**

Corporate Contact Information

EKVITESTLAB LLC
Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150
tel. 0(800)31-89-87; +38 (044)334-89-87
e-mail: info@equitest.com.ua
RESPONSIBLE PERSON'S name: Anna Yurchuk
Position: Director

SIGNATURE : 

Date : October 25, 2021
Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

EKVITESTLAB LLC

Velyka Vasylkivska St. 114
03150 Kyiv, Ukraine
Tel. 0-800-31-89-87
e-mail: info@equitest.com.ua
www.equitest.com.ua

STATEMENT

We, EKVITESTLAB LLC, having a registered office at Velyka Vasylkivska street 114, Kyiv, 03150, Ukraine assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: 03 January 2023

Signature: _____

Director, Anna Yurchuk

ПРОМСТАНДАРТ ■ PROMSTANDART ■ ПРОМСТАНДАРТ ■ PROMSTANDART ■ ПРОМСТАНДАРТ

CERTIFICATE

MANAGEMENT SYSTEM CERTIFICATION BODY
«CONFORMITY ASSESSMENT BODY «PROMSTANDART», LLC
certifies that the enterprise

EKVITESTLAB
Limited Liability Company

registration code 38745936

legal address:
Ukraine, 03150, Kyiv, 114 Velyka Vasylkivska street,

manufacturer's address:
Ukraine, 04212, Kyiv, 60/2 Peremohy Avenue

has established and applies quality management system for
development, production, storage and sale of ELISA kits for in vitro diagnostic

Audit, № report 2020/015-20.2.1
confirmed that the requirements

ISO 13485:2016
«Medical devices — Quality management systems — Requirements for regulatory purposes»

are performed.

The control of conformity of the certified quality management system to the requirements of the specified standard is carried out by means of supervisory audit, the periodicity and procedures of which are regulated by the program.

Certificate registration number	№ UA.QMS.00014-21
Registered	06 April 2021
Valid until	05 April 2024

8O156
DSTU EN ISO/IEC 17021-1

Director of Certification Body
«CAB «PROMSTANDART», LLC

stamp (signature)

Sergiy Dubrovskyi

The validity of certificate can be verified by telephone: (056) 742-82-39
or on website of «CAB «PROMSTANDART», LLC: prom-standart.com.ua

210107

Vitrotest®
ELISA kits & components

ТОВ «ВІТРОТЕСТ БІОРЕАГЕНТ"
Адреса: 01103, м. Київ, вул. Бойчука, буд. 18-Б, кв. 56
Ідентифікаційний код: 42149820
ІПН: 421498226554

тел.: +380 67 329 84 25 +380 44 222 76 72
www.vitrotest.ua e-mail: info@vitrotest.ua

исх. № 16.02.2021/2
от 16.02.2021

Письмо об Авторизации

Настоящим письмом ООО «Витротест Биореагент», производитель иммуноферментных тест-систем под торговой маркой «Vitrotest®», подтверждает, что компания Sanmedico SRL является авторизированным дистрибьютором нашей компании на территории - Республики Молдова, обладающим правами по продаже продвижению и участию в тендерных торгах с нашей продукцией.

Директор ООО "Витротест Биореагент" **к.м.н. Николаенко И.В.**

СЕРТИФІКАТ

CERTIFICATE * CERTIFICAT * ZERTIFIKAT * СЕРТИФИКАТ * CERTIFICADO

ОРГАН СЕРТИФІКАЦІЇ СИСТЕМ УПРАВЛІННЯ
ДП «УКРМЕТРТЕСТСТАНДАРТ»
ЗАСВІДЧУЄ, ЩО

СИСТЕМА УПРАВЛІННЯ ЯКІСТЮ

ТОВАРИСТВА З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ «ВІТРОТЕСТ БІОРЕАГЕНТ»

Юридична адреса: вул. Бойчука, 18-Б, кв. 56, м. Київ, 01103, Україна
Адреса виробництва: вул. Курортна, 11, м. Київ, 04075, Україна

код ЄДРПОУ 42149820

стосовно
розроблення та виробництва тест-систем імуноферментних

ВІДПОВІДАЄ ВИМОГАМ ДСТУ EN ISO 13485:2018 (EN ISO 13485:2016, IDT; ISO 13485:2016, IDT)

Сертифікат № UA.C.378–19 в Реєстрі Органу сертифікації
зареєстрований " 25 " листопада 2019 року
чинний до " 24 " листопада 2022 року

Заступник керівника Органу сертифікації **В.Д. Ример**

ДЕРЖАВНЕ ПІДПРИЄМСТВО «ВСЕУКРАЇНСЬКИЙ ДЕРЖАВНИЙ НАУКОВО-ВИРОБНИЧИЙ ЦЕНТР СТАНДАРТИЗАЦІЇ, МЕТРОЛОГІЇ, СЕРТИФІКАЦІЇ ТА ЗАХИСТУ ПРАВ СПОЖИВАЧІВ»
(ДП «УКРМЕТРТЕСТСТАНДАРТ»)
вул. Метрологічна, 4, м. Київ, 03143, Україна, тел./факс +38 044 452-67-38
Атестат акредитації НААУ № 8О020

№ 8О020
ДСТУ EN ISO/IEC 17021-1

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浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD

CE-DOC-OG286
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

One Step Microalbumin Test Cassette (Urine)	GIHSA-102a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: CMC Medical Devices & Drugs S.L

EC Representative's Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: March 10, 2022

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092305 0001 Rev. 01

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01

Report No.: SH2198802

Valid from: 2022-04-11
Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
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电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

One Step Microalbumin Test Cassette (Urine)

INTENDED USE

The One Step Microalbumin Test Cassette (Urine) is intended for the qualitative detection of human serum albumin (HSA) in human urine specimens, as a screening test and as an aid in the diagnosis of renal dysfunction. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

INTRODUCTION

Human serum albumin is the most abundant protein in human blood plasma. The protein is normally not present in urine due to glomerular barrier; however, when there is an abnormally high permeability for albumin in the renal glomerulus, small amounts of albumin are filtered into the urine, resulting in microalbuminuria, which is defined as a slight increase in urinary albumin (20 – 200 μg/ml). Microalbuminuria is frequently seen in patients who have renal dysfunction with established diabetes, hypertension, heart failure, cirrhosis and systemic lupus erythematosus (SLE) and other renal diseases. Thus, the measurement of albumin in urine is an indicator of renal dysfunction in such diseases.

PRINCIPLE

The One Step Microalbumin Test Cassette (Urine) has been designed to detect microalbumin through visual interpretation of color development in the internal strip. The membrane was immobilized with albumin coated on the test region, and the conjugate pad was pre-coated with colored anti-albumin monoclonal antibodies colloidal gold conjugates. After specimens were added, the gold-conjugates move along the membrane chromatographically by capillary action and antibodies get to the test region. If there is no microalbumin molecule or the concentration of microalbumin molecule is less than 20 μ g/ml in the urine, the antibody gold conjugate would attach to the albumin coated on the membrane to form a visible test line. Therefore, the formation of a visible precipitant in the test region occurs when the urine is negative for microalbumin. If microalbumins are present in the urine, the microalbumine antigen competes with the immobilized albumin coated on the test region for limited antibody sites. In case of sufficient concentration of the albumin, it fills the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the albumin coated on the test region. Therefore, absence of the colored band on the test region indicates a positive result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRODUCT CONTENTS

The One Step Microalbumin Test Cassette (Urine) containing Albumin monoclonal antibodies conjugated particles and Albumin coated on the membrane.

MATERIALS SUPPLIED

1. Test Cassettes 2. Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
3. This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
4. Read the entire procedure carefully prior to testing.
5. Do not eat, drink or smoke in any area where specimens and kits are handled.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded according to local regulations.
9. The used testing materials should be discarded in accordance with local, state and/or federal regulations.

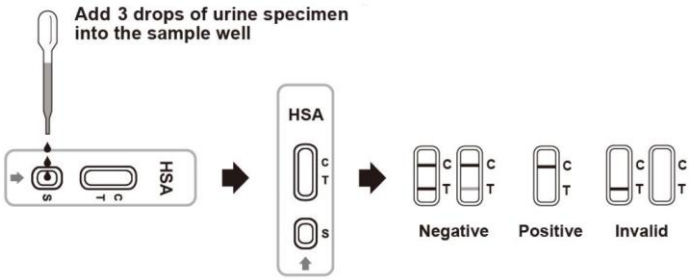
SPECIMEN COLLECTION AND PREPARATION

1. The One Step Microalbumin Test Cassette (Urine) is intended only for use with human urine specimens.
2. Though random urine specimens can be used, first morning urine specimens are preferable as they contain the highest concentration of microalbumin.
3. Collected urine specimens must be put in clear and dry containers. Ensure that a sufficient quantity of the specimen is collected to allow submerging the dipping area of the strip.
4. Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8° C for up to 48 hours. For long term storage, specimens should be kept below -20° C.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
6. Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.
7. Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) prior to testing.

1. Remove the test from its sealed pouch and use it as soon as possible. To obtain a best result, the assay should be performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
3. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not interpret results after 10 minutes. It is important that the background is clear before the result is read.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

Positive: One colored line appears in the control line region(C). No line appears in the test line region (T).

Negative: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The One Step Microalbumin Test Cassette (Urine) is for professional in vitro diagnostic use, and should be used for the qualitative detection of microalbumin only.
2. The One Step Microalbumin Test Cassette (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result.
3. A positive result with the test indicates the presence of albumin only, and does not indicate a diabetic nephropathy.
4. A negative result may not necessarily indicate microalbumin-free urine. Negative results can be obtained when microalbumin is present but below the cut-off level of the test (20μg/mL).
5. There is a possibility that technical or procedural errors as well as other substances and factors not listed may interfere with the test and cause false results.
6. The test is designed for use with human urine only. Due to absence of ions and other components in pure water the usage or pure water for test could lead to false or invalid results.
7. Although the test demonstrates superior accuracy in detecting HSA, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1.Clinical Sensitivity, Specificity and Accuracy

The One Step Microalbumin Test Cassette (Urine) was evaluated in comparison to a commercially available immunoassay at a cut-off of 20μg/mL. 120 urine samples, collected from volunteers, have been tested by both procedures with >99% agreement.

T**able 1: The** One Step Microalbumin Test **vs Commercial Microalbumin Rapid Test**

Method		Commercial Rapid Test		Total Results
Microalbumin Rapid Test Cassette	Results	Positive	Negative	
	Positive	64	1	65
	Negative	0	55	55
Total Results		64	56	120

Relative Sensitivity: 100%
Relative Specificity: 98.2%
Accuracy: 99.2%

2. Analytical Sensitivity

The One Step Microalbumin Test Cassette (Urine) has a sensitivity of 20μg/mL urine.

3. Interfering Substances

The specificity for the One Step Microalbumin Test Cassette (Urine) was tested by adding various compounds that are likely to be present in urine. All compounds were prepared in normal human urine with low amounts of albumin.

The following compounds produced positive results when tested at levels equal to or greater than the concentrations listed below.

Alfa-Fetoprotein (AFP) 1000μg/mL

The following compounds were found not to cross - react when tested at concentrations up to 1000 μg/ml.

Acetaminophen	Acetone	Amitriptyline
Ampicillin	Aspartame	Aspirin
Atropine	Benzocaine	Bilirubin
Caffeine	Chloroquine	(+)-Chlorpheniramine
Glucose	Guaiacol Glyceryl	Ether Hemoglobin, Imipramine

Thioridazine Trifluorperazine Vitamin C

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1. Hasslacher C, Danne T, Sawicki PT, Walter H.Frühdiagnose der diabetischen Nephropathie. Dtsch Arztebl 1999; 96(1-2): A-51 / B-47 / C-47.
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3. Lurbe et al: Increase in Nocturnal Blood Pressure and Progression to Microalbuminuria in Type 1 Diabetes. NEJM 2002; 347: 797 - 805
4. Perkins BA, Ficociello LH, Silva KH, Finkelstein DM, Warram JH, Krolewski AS. Regression of microalbuminuria in type 1 diabetes. N Engl J Med. 2003 Jun 5; 348(23): 2285-93.