KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

Doc#200/08-2022

Hersteller / Manufacturer:	**TECO Medical Instruments Production + Trading GmbH**
Adresse / Address:	**Dieselstrasse 1, 84088 Neufahrn, Germany**
Marktakteur / Actor ID SRN:	**DE-MF-000022642** https://ec.europa.eu

Wir erklären hier für die im Anhang A (Seite 2 – 23 IVD Produkte) spezifizierten Produkte dass sie gemäß der Richtlinie für In-vitro-Diagnostika Medizinprodukte 98/79/EC klassifiziert sind als allgemeine IVD.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers i.V.m. Artikel 110 Abs.3 und Abs.4 der Verordnung (EU) 2017/746 und des § 8 Abs.1 des Medizinprodukte-Durchführungsgesetzes, in der jeweils geltenden Fassung, ausgestellt.

Im Falle eigenmächtiger Veränderungen am Produkt oder der nicht bestimmungsgemäßen Verwendung verliert diese Erklärung ihre Gültigkeit.

We declare herewith for the products specified in Annex A (page 2 - 23 IVD products) that they are classified as general IVD according to the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of the manufacturer in according to article 110 para.3 and para.4 of Regulation (EU) 217/746 and section 8 para.1 of the Medical Device Law Implementing Act.

In case of unauthorised modifications to the products or un-intended use, this declaration loses its validity.

Sie entsprechen den anwendbaren Anforderungen der Richtlinie:	They meet applicable requirements of:
Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert gemäß Artikel 9 als "alle anderen Produkte"	Directive 98/79/EC on in-vitro-diagnostic medical devices classified according to article 9 as „all other products"
Die Qualitätssicherung entspricht den Anforderungen der Richtlinie 98/79/EG über In-vitro-Diagnostika für diese Art von Produkten.	The Quality Assurance is in accordance with the requirements of Directive 98/79/EC on in-vitro-diagnostic medical devices for those kind of products.
Der implementierte QM-Prozess entspricht der EN ISO 13485:2021	The implemented QM Process complies with EN ISO 13485:2021
Die vorstehende Konformitätserklärung ist gültig für alle Chargen dieser Produkte, die nach dem Datum der Unterzeichnung in Verkehr gebracht wurden.	The above mentioned declaration of conformity is valid for all lots of this product, which are distributed after the date of signature.
Das Konformitätsbewertungsverfahren entspricht Anhang III der Richtlinie 98/79/EG über In-vitro-Diagnostika für diese Art von Produkten.	The conformity assessment procedure complies with Annex III of Directive 98/79/EC on in-vitro-diagnostic medical devices for those kind of products.

Ort und Datum der Unterzeichnung: Neufahrn, 2022-08-31
Place and date of issue:

Medical Instruments TECO Production+Trading GmbH

Digitally signed by Monastîrschii Viorica
Date: 2024.01.25 12:21:56 EET
Reason: MoldSign Signature
Location: Moldova

Christian Hötzl
Verantwortliche Person / PRRC

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Doc#200/08-2022

KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Directive 98/79/EC Annex A
Übrige Produkte – Reagenzien für In-vitro-Diagnostika
Other products – Reagents for in vitro diagnostic – general IVD

Pos.	Article No	Tradename	Unit	Generic Device Term	EMDN / GMDN Code EUDAMED DI
1	A0230-040	TEClot PT-S (Quick)	10x4ml PT-S	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-040X7
2	A0230-100	TEClot PT-S (Quick)	10x10ml PT-S	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-100WY
3	A0260-050	TEClot PT-B (Owren)	5x10ml PT-B	Prothrombin time (quick test)	W0103020199 / 55986 B-PTB-A0260-050G2
4	A0320-050	TEClot APTT-S	10x5ml APTT-S	Activated partial thromboplastin time	W0103020102 / 55982 B-APTTS-A0320-050AM
5	A0401-020	TEClot TT	10x2ml TT	Thrombin time / reptilase / batroxbin time	W0103020103 / 55988 B-TT-A0401-0207P
6	A0511-020	TEClot FIB	10x2ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-020N2
7	A0511-050	TEClot FIB	10x5ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-050NB
8	C1010-020	TEChrom AT	6x6ml reagent FXa 3x3 ml substrate	Antithrombin	W0103020602 / 56156 B-AT-C1010-020HL
9	D2010-012	Red D-Dimer	3x4ml latex 3x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2010-0126W
10	D2020-005	Blue D-Dimer LC	1x5ml latex LC 1x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2020-0057E
11	P8001-010	TECal N	10x1ml	Calibration plasma for haemostasis	W0103020701 / 45786 B-CAL-P8001-005X8
12	P8200-005	TECal DD	5x1ml	Calibration plasma for haemostasis	W0103020701 / 47348 B-CAL-P8200-005XX
13	P6001-010	TEControl N	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6001-010H7
14	P6101-010	TEControl A	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6101-010HQ
15	P6201-010	TEControl A Plus	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6201-010J9
16	P5001-010	TEClot Factor II	10x1ml	Coagulation factor ii (prothrombin)	W0103020202 / 30542 B-FAC-II-P5001-010ML
17	P5101-010	TEClot Factor V	10x1ml	Coagulation factor v	W0103020204 / 30544 B-FAC-V-P5101-010AN
18	P5201-010	TEClot Factor VII	10x1ml	Coagulation factor vii	W0103020205 / 30545 B-FAC-VII-P5201-0107B
19	P5301-010	TEClot Factor VIII	10x1ml	Coagulation factor viii	W0103020207 / 30547 B-FAC-VIII-P5301-01097
20	P5401-010	TEClot Factor IX	10x1ml	Coagulation factor ix	W0103020208 / 30548 B-FAC-IX-P5401-0106C
21	P5501-010	TEClot Factor X	10x1ml	Coagulation factor x	W0103020209 / 30549 B-FAC-X-P5501-010EQ
22	P5601-010	TEClot Factor XI	10x1ml	Coagulation factor xi	W0103020210 / 30551 B-FAC-XI-P5601-010A8
23	P5701-010	TEClot Factor XII	10x1ml	Coagulation factor xii	W0103020211 / 30552 B-FAC-XII-P5701-010CJ

(Recital 23 of Directive 98/79/EC on In Vitro Diagnostics Medical Devices) - Annex A - general IVD

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KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

Doc#001-01/06-2022

Hersteller / Manufacturer: **TECO Medical Instruments Production and Trading GmbH**

Adresse / Address: **Dieselstrasse 1, 84088 Neufahrn, Germany**

Marktakteur / Actor ID SRN: **DE-MF-000022642** https://ec.europa.eu

Die hier benannten Produkte der generischen Produktgruppe erfüllen die Anforderungen der aufgeführten Verordnungen, Richtlinien und Normen. Im Falle eigenmächtiger Veränderungen am Produkt oder der nicht bestimmungsgemäßen Verwendung verliert diese Erklärung ihre Gültigkeit.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.

BASIS UDI-DI 426018278CMX81152

IVD - halb-automatische Blutgerinnungsmessgeräte - Handelsbezeichnung, Typ, Kat.-Nr.
IVD - semi-automated Coagulation Systems - trade name, type, model, Cat.-No.

Coatron X Eco / Coatron X Pro / Coatron X Top

81 101 10 **81 101 20** **81 101 40**

The products of the generic product group named here fulfil the requirements of listed regulations, directives and standards. In the case of unauthorised modifications to the product or use not in accordance with the intended purpose, this declaration becomes invalid.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Verordnung (EU) 2017/746
für in-vitro Diagnostika-IVDR
und dem harmonisierten Standard am 2022-05-12:

Risikoklassifizierung gemäß Artikel 47–Anhang VIII
Regel 5 b – „Klasse A "

Konformitätsbewertungsverfahren gemäß:
(EU) 2017/746 Artikel 17 (Anhang II+III)

Angewandte Normen zur Sicherstellung der grundlegenden Anforderungen an Leistung und Sicherheit:

EN ISO 18113-3:2011
DIN EN 62304:2018
DIN EN 62366-1
DIN EN 62366-1:2017
DIN EN 61326-1:2013
DIN EN 55011:2009 + A1:2010
IEC 61010-1:2010, AMD1:2016
IEC 61010-2-101:2015
IEC 61010-1:2010

Richtlinie 2011/65/EU RoHS III
(incl. (EU) 2015/863) - DIN EN IEC 63000

QM-System gemäß (EU) 2017/746 Art.10(8)
angewandter Standard: EN ISO 13485:2021

Regulation (EU) 2017/746
for In-vitro diagnostic medical devices
and it's harmonized standard at 2022-05-12:

Risk classified according to article 47 annex VIII
Rule 5 b – "Class A"

Conformity assessment procedure in accordance with:
(EU) 2017/746 Article 17 (annex II+III)

Standards applied to ensure the essential requirements for performance and safety:

EN ISO 18113-3:2011
DIN EN 62304:2018
DIN EN 62366-1
DIN EN 62366-1:2017
DIN EN 61326-1:2013
DIN EN 55011:2009 + A1:2010
IEC 61010-1:2010, AMD1:2016
IEC 61010-2-101:2015
IEC 61010-1:2010

Directive 2011/65/EU RoHS III
(incl. (EU) 2015/863 - DIN EN IEC 63000

QM-Systems in accordance with (EU) 2017/746 art.10(8)
Applied standard procedure: EN ISO 13485:2021

Ort und Datum der Unterzeichnung:
Place and date of issue: Neufahrn, 2022-06-21

Matthias Dieckmann
General Manager

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#100/07-2021

Wir / *We*

TECO Medical Instruments Production and Trading GmbH
Name des Herstellers / Manufacturer's *name*
Dieselstrasse 1, 84088 Neufahrn, Germany
Anschrift / *Address*

erklären in alleiniger Verantwortung, dass die unten gelisteten IVD Zubehör Produkte:
declare under our own responsibility, that the IVD accessories products, listed below:

Doppelküvette / *Double cuvette*	Ref. 19 000 02
Einzelküvette / *Single cuvette*	Ref. 20 000 02, 24 100 00
4-fach Küvette / *Cuvette 4 pos/ea*	Ref. 80 521 10
6-fach Küvette / *Cuvette 6 pos/ea*	Ref. 80 560 00
6-fach Küvette (micro) / *Cuvette 6 pos/ea (micro)*	Ref. 80 570 00

allen anwendbaren Anforderungen folgender Richtlinien entsprechen:

meet all applicable requirements of:

1. Richtlinie 98/79/EG über In-vitro Diagnostika und ihrem Zubehör, klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"- im Sinne von Zubehör zu In vitro Diagnostika gemäß Artikel 1.

1. Directive 98/79/EC on In-vitro diagnostic medical devices and their accessories, classified according to article 9 as: "all other products" – and in term of accessories for in vitro diagnostics according to artivel 1.

2. Richtlinie 2011/65/EU (RoHS III)

2. Directive 2011/65/EU (RoHS III)

Das QM-System des Herstellers ist zertifiziert nach:

The QM-system of the manufacturer is certified for:

EN ISO 13485:2016

EN ISO 13485:2016

Konformitätsbewertungsverfahren gemäß:

Conformity assessment procedure according to:

Gemäß Anhang III der Richtlinie 98/79/EG

According to Annex III of Directive 98/79/EC

Ort und Datum der Unterzeichnung:
Place and date of issue:

Neufahrn, 27.07.2021
Neufahrn, July 27, 2021

Medical Instruments TECO Production+Trading GmbH

Matthias Dieckmann
General Manager

TECO
MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH
Dieselstraße 1
D-84088 Neufahrn N.B.
fon: +49-8773/707 80-0
fax: +49-8773/707 80-29

Neufahrn, 26/04/2018

TO WHOM IT MAY CONCERN

We confirm that the instruments Coatron X Eco, Coatron X Pro and Coatron X Top have a closed cuvette system. Cuvettes have to be purchased with voucher identification code from TECO GmbH.

Medical Instruments
TECO
Production+Trading GmbH

Christian Hoetzl
General Manager
TECO Germany

TECO
MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH
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fax: +49-8773/707 80-29

TO WHOM IT MAY CONCERN
To any governmental departments,
registration and/or trade offices in MOLDOVA

Distribution Authorisation Letter

This letter confirms that **Sanmedico**
Mun. Chisinau
Str. Petricani 88/1 of. 10
Republica MOLDOVA

is the **legal, exclusive and sole** representative of **TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1, 84088 Neufahrn NB, Germany,** for the territory of **MOLDOVA** only for all TECO products listed below. **Sanmedico** may participate in public and private tenders, providing sales to all TECO customers in the territory. We as manufacturer certify that our warranty is duly passed to the purchaser through **Sanmedico** for the price, delivery schedules and the specifications of the published literature, catalogues and fully covering the commodities offered.

Sanmedico will provide the following information to TECO GmbH when so required in relation to its market surveillance activities:
Reporting of incidents to TECO must take place within 3 working days
Serial number of the device, exact location of the device and the user.

Validity: January 1st, 2023 to December 31st, 2024

Termination: Confirmation ends automatically on Dec. 31st of 2024 and must be then renewed.

Products:

- Coatron M1 — Semi-automated 1-channel Coagulometer (out of production)
- Coatron M2 — Semi-automated 2-channel Coagulometer (out of production)
- Coatron X Eco — Semi-automated 1-channel Coagulometer
- Coatron X Pro — Semi-automated 2-channel Coagulometer
- Coatron X Top — Semi-automated 4-channel Coagulometer
- Coatron A4 — Fully automated Coagulometer, 4 optic channels
- Coatron A6 — Fully automated Coagulometer, 6 optic channels
- Coatron A6 plus — Fully automated Coagulometer, 6 optic channels

all instruments with complete accessory, consumables and spare parts

- Hemostasis Reagents — Complete product line

This document is signed in Neufahrn, Germany, on January 18th, 2023

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl

Medical Instruments TECO Production+Trading GmbH

Certificate -Bescheinigung

TECO
Medical Instruments
Production+Trading GmbH
web: www.teco-gmbh.com
mail: info@teco-gmbh.com

Dieselstrasse 1
D-84088 Neufahrn/NB
fon: +49 8773 70780 00
fax: +49 8773 70780 29

CERTIFICATE OF TRAINING

Vitalie Goreacii
General manager of
Sanmedico
Chisinau
Republic of Moldava

have participated with success at the training session supervised by TECO GmbH, Germany for following instruments:

Coatron A series

- **Installation**
- **Application**
- **General use, also in combination with TECAM**
- **Maintenance**
- **Troubleshooting**
- **After Sales Service**

Training details:

Supervisor:	Chr. Baumgartner, Director RD of TECO
Device	Coatron A4 + A6, Inhouse Master Device
Place:	Laboratories of TECO
Date:	May 5th 2023

TECO
Dipl.-Ing. Univ.
Christian Baumgartner

Dipl.-Ing. Univ. (TUM)
Christian Baumgartner
Director R&D

Current issue date:	10 November 2022	Original approval(s):
Expiry date:	9 November 2025	ISO 13485 - 10 November 2022
Certificate identity number:	10479697	

Certificate of Approval

This is to certify that the Management System of:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00038268

The scope of this approval is applicable to:

Design, development, manufacturing, storage and sales of coagulation instruments and in-vitro-diagnostic reagents used in the hemostaseology and coagulation.

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited

UKAS MANAGEMENT SYSTEMS 0001

Atlas Medical

Declaration Ref No: DC21-0249

Date: 15.10.2021

CE Declaration of Conformity

Name and address of Manufacturer	**Atlas Medical GmbH** Ludwig-Erhard-Ring 3, 15827 Blankenefelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com

Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.17.003.0300	Atlas Periodic Acid Schiff (PAS) Stain Kit, 3x100ml	43587
8.17.004.0300	Atlas Iron Stain Kit, 3x100ml	43587
8.17.009.1000	Atlas Gram Stain Kit	43733
8.17.010.0750	Atlas ZN (Kinyoun) stain pack , 3x250ml	43587
8.15.144.0250	Atlas ZN Decolouriser, 250 ml /Bottle	43587
8.17.015.0500	Atlas Diff-3 Stain.	43587
8.17.016.1000	Atlas Papanicolau Stain Pack.	43587
8.17.110.0250	Atlas Papanicolau Stain EA35, 250 ml /Bottle.	43587
8.17.111.0250	Atlas Papanicolau Stain EA36, 250 ml /Bottle	43587
8.17.112.0250	Atlas Papanicolau Stain EA65, 250 ml /Bottle.	43587
8.17.114.0250	Atlas Papanicolau Stain EA50, 250 ml /Bottle.	43587
8.17.115.0250	Atlas Papanicolau Stain OG6, 250 ml /Bottle.	43587
8.17.014.1000	Atlas Reticulocytes stain (Methylene Blue) , 1000 ml /Bottle	43587
8.15.037.0250	Atlas Eosin Y (1%) Stain, 250 ml/Bottle	43587
8.15.038.0250	Atlas Eosin Y (5%) Stain, 250 ml/Bottle.	43587
8.15.041.0250	Atlas Field Stain (Solution A), 250ml/Bottle	43587
8.15.042.0250	Atlas Field Stain (Solution B), 250ml/Bottle	43587
8.15.043.0750	Atlas Field Stain Kit 3x250ml (250ml Fixing Reagent , 250ml Eosin Reagent, 250ml Methylene Blue Reagent).	43587
8.15.047.0250	Atlas Giemsa Stain, 250 ml/Bottle.	43587
8.15.059.0250	Atlas Haematoxylin Harris Stain , 250 ml/Bottle	43587
8.15.069.0250	Atlas Leishman Stain , 250 ml/Bottle.	43587
8.15.069.1000	Atlas Leishman Stain , 1000 ml/Bottle.	43587
8.15.074.0250	Atlas Lugol's Iodine, 250 ml/Bottle.	43587
8.15.078.0250	Atlas May Grunwald Stain, 250 ml/Bottle.	43587
8.15.105.0250	Atlas New Methylene Blue for Reticulocytes, 250 ml/Bottle.	43587
8.15.143.0250	Atlas Wright's Stain, 250 ml/Bottle.	43587
8.15.146.0100	Atlas Immersion oil, 100 Bottle/Box	43587

Atlas Medical

Declaration Ref No: DC21-0249

Date: 15.10.2021

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And
EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	15. October.2021
Place	Atlas Medical GmbH
Signed by: **Position :**	Amani AL-Habahbeh Regulatory Affairs Manager

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

CE Declaration of Conformity

We,

Atlas Medical GmbH
Head office: Ludwig-Erhard-Ring 3
15827 Blankenefelde-Mahlow Germany
Tel: +49(0)33708355030
Email: info@atlas-site.com

Middle East Site: : Sahab Industrial Zone Area, King Abdullah II Industrial City
Amman 11512, Jordan
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

Blood Grouping Reagents:

(Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent , Anti-AB Monoclonal Reagent and Anti-D IgG/IgG blend Reagent)

see the attached list of variants

That are classified as Annex II, list A

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,
EN 13612:2002, EN 13641:2002 , EN 13975:2003,
EN ISO 13485:2016, EN 62366-1:2020

And

Intended for In-Vitro Professional use only.

Conformity Assessment Route:

Annex IV.3 –Approval full Quality Assurance System.
Annex IV.4-EC Design Examination (of the product)

Notified Body:

G-MED	CE	0459

GMED, Laboratoire national de métrologie et d'essais
1 rue Gaston Boissier 75015 Paris
Tél. : 01 40 43 37 00 , TVA:FR 28 839 022 522

EC Certificates No.:

- **CE Certificate of Approval full Quality Assurance System: 33540 rev4.**
- **CE Certificate Of EC Design Examination: 33544 rev3.**

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)	Amani	

Atlas Medical

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

Product Code	Product Name	GMDN Code
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/Carton Box	52532
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 10 vials / Plastic Pack	52532
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 18 vials / Carton Box	52532
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, / Carton Box	52538
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials / Plastic Pack	52538
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials / Carton Box	52538
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/ Carton Box	46442
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials/Plastic Pack	46442
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials/Carton Box	46442
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 1 vial/ Carton Box	52647
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 10 vials / Plastic Pack	52647
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 18 vials / Carton Box	52647
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1 Vial/Carton Box	52532
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials / Plastic Pack	52532
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	52538
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials /Plastic Pack	52538
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)),3x10ml / plastic Pack	45308
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256), 2x10ml /Plastic Pack	52695
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	46442
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,10 vials /Plastic Pack	46442
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,18 vials / Carton Box	45308
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 1Vial/ Carton Box	52647
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 10 vials / Plastic Pack	52647

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)		

Atlas Medical
Quality Diagnostic Products

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128)),3x10ml/Plastic Pack	45308
8.02.47.1.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Carton Box.	45308
8.02.47.3.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Plastic Pack	45308
8.02.47.5.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/128)), 3x10ml/Plastic Pack	45308
8.02.49.0.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64)), 4x10ml/Carton Box	45308
8.02.49.2.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/128)), 4 x 10ml, 4 vials/Plastic Pack	45308
8.02.53.0.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml/Plastic Pack	45308
8.02.53.1.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml, 4vials/Plastic Pack	45308
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box	52532
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1/1024) , 10 ml/vial ,1Vial/ Carton Box	52538
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1/1024) , 10 ml/vial , 1Vial/ Carton Box	45308
8.02.85.0.0010	Anti-D IgG/IgM Blend Reagent , Titer 1/256, 10ml/vial, 1Vial/ Carton Box	52647

Atlas Medical
Quality Diagnostic Products

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)		

Atlas Medical

Date: 05/Jan/2023

STATEMENT

We, Atlas Medical having a registered office at Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL Sanmedico having a registered office at A. Corobceanu Street 7A, apt.9, Chisinau 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.

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature: _____

Date: 05.01.2023

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

Atlas Medical: Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany,
Tel:+4933708355030

Regulatory Office: William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom
Tel: +44 (0) 1223 858 910

Middle East Site: P.O Box 204, King Abdullah II Industrial Estate, Amman, 11512, Jordan
Tel: +962 6 4026468

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.2

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2023 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2026 (included)**
Etabli le */ Issued on :* **October 9th, 2023**

DocuSigned by:
Béatrice LYS
EF33BDA9BA...
GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 36655–2
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

2 sites / *2 sites*

DocuSigned by:
Beatrice Lys
FF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical CE 0459

Blood Grouping Reagents: Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent, Anti-AB Monoclonal Reagent, Anti-D IgG/IgM blend Reagent, & Their variants SLIDE AND TUBE TESTS

IVD **For *In-Vitro* and professional use only**

Store at 2- 8°C

INTENDED USE

The blood grouping reagents are used to detect the presence or absence of A, B or Rhesus Antigens on the surface of human red blood cells based on hemaglutination using slide or tube test techniques in whole blood samples or anticoagulant blood samples collected in EDTA , citrate or heparin tubes.

INTRODUCTION & PRINCIPLES

Blood grouping reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines. The reagents are diluted with phosphate buffer containing sodium chloride, EDTA and bovine albumin to give reagents that are optimized for use in tube and slide procedures. **Anti-A monoclonal reagent is colored with acid blue (patent blue) dye, Anti-B monoclonal reagent is colored with acid yellow (tartrazine) dye, and Anti-AB monoclonal reagent is not colored.** The test procedure is based on hemaglutination principle, where red cells possessing the antigen agglutinate in the presence of the corresponding antibody indicating that the result is positive. The test is considered negative when no agglutination appears.

Anti-D IgG/IgM blend reagent is prepared from carefully blended human monoclonal IgM and IgG. Anti-D IgG/IgM blend reagent is suitable for slide and tube test procedures. The reagent will directly agglutinate Rh D positive cells, including majority of variants (but not D^{VI}) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D^{VI} and low grade weak D (D^{u}) phenotypes by the indirect anti-globulin techniques.

Anti-D IgG/IgM blend reagent is diluted with a sodium chloride solution, sodium phosphate solution and bovine albumin (sodium caprylate free). Anti-D IgG/IgM blend reagent is not colored. The procedure is based on hemaglutination principle, where red cells' possessing the antigen agglutinates in the presence of the corresponding antibody in the reagent indicating that the result is positive. The test is considered negative when no agglutination appears.

MATERIALS

MATERIALS PROVIDED

Blood Grouping Reagents:

- Anti-A monoclonal reagent (10 ml/vial), Clone: (9113D10).
- Anti-B monoclonal reagent (10 ml/vial), Clone: (9621A8).
- Anti-AB monoclonal reagent (10ml/vial), Clone: (152D12+9113D10).
- Anti-D IgG/IgM Blend reagent (10 ml/vial), Clone: (P3X61 + P3X21223B10 + P3X290 + P3X35).

MATERIALS NEEDED BUT NOT PROVIDED

- Plastic test tube or glass.
- Isotonic saline solution (% 0.9) NaCl).
- Applicator sticks.
- Centrifuge (100-1200 (g) for tube test).
- Timer.
- Incubator
- Anti-Human Globulin Reagent (can be ordered from Atlas Medical).
- White or transparent glass slide.

PRECAUTIONS

- The reagents are intended for in vitro diagnostic use only.
- The test is for well trained professional healthy user not for lay user.
- These reagents are derived from animal and human sources, thus, appropriate care must be taken in the use and disposal of these reagents, as there are no known test methods that can guarantee absence of infectious agents.
- Do not use reagents if it is turbid or contain particles as this may indicate reagent deterioration or contamination.
- Protective clothing should be worn when handling the reagents.
- **The reagents contain (0.1-0.2%) Sodium Azide and 0.02% sodium arseniate which is toxic and can be absorbed through the skin. When drained, the drains should be thoroughly flushed with water.**
- The reagents should be used as supplied and in accordance to the procedure mentioned below. Don't use beyond expiration date.
- Avoid cross contamination of reagents or specimens.
- Visible signs of microbial growth in any reagent may indicate degradation and the use of such reagent should be discontinued.
- Don't use these reagents if the label is not available or damaged.
- Do not use dark glass slide.
- Don't use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and the test table top with water and soap once the testing is done.
- Heamolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well let area with very good visibility.
- Failure to follow the procedure in this package insert may give false results or safety hazard.
- Close the vial tightly after each test.
- The reagent is considered toxic, so don't drink or eat beside it.
- If spillage of reagent occurs clean with disinfectant (disinfectant used could be irritable so handle with care).

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 - 8°C.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

REAGENT PREPRATION

- The reagents are intended for use as supplied, no prior preparation or dilution of the reagent is required.
- All reagents should be brought to room temperature before use.

SPECIMEN COLLECTION AND PREPARATION

- Blood collected with or without anticoagulant (EDTA, Heparin or Citrate) can be used for Antigen typing.

Note: Blood collected without anticoagulant should be tested immediately.

- The specimens should be tested as soon as possible after collection. If testing is delayed, the specimens should be stored at 2- 8 ºC, Sample must be retained to room temperature prior to analysis. (Testing should be carried out within five days of collections).
- Insure that there is no sign of hemolysis.
- At the time of the test, centrifuge the blood sample at 1200 RCF for 3 minutes.
- Blood collection is to be done with great care.

PROCEDURES

A. DIRECT TUBE METHOD AT ROOM TEMPERATURE

1. Prepare a 5% suspension of red blood cells in isotonic solution.
2. Using the vial dropper, transfer a drop (40±10µl) of each reagent into a separate and appropriately marked tube.
3. Add 50 µl of red blood cell suspension prepared in step 1.
4. Shake to homogenize the mixture, then centrifuge at 500g for **1 minute.**
5. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
6. Read the reaction immediately.
7. For Anti-D tube, if the reaction is weak or negative, shake the tubes and incubate at 37°C for **15 minutes.**
8. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
9. Add one drop (50µl) of the AHG reagent into the tube. Mix and centrifuge at 120g for **1 minute.**
10. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
11. Read the reaction immediately.

B. ANTIGLOBULIN INDIRECT METHOD for ANTI-D

1. After immediately centrifuging and reading as above, if the reaction is weak or negative, shake the tubes and incubate at 37°C for 15 minutes.
2. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
3. Add one drop (40 µl ± 10 µl) of ANTI-HUMAN GLOBULIN to the tube. Mix and centrifuge at 120 (g) for **1 minute**.
4. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
5. Read the reaction immediately.

C. DIRECT SLIDE METHOD AT ROOM TEMPERATURE

1. Bring reagents and samples to room temperature (18-25°C).
2. Using the wax pen divide the slide into appropriate numbers of divisions.
3. Using the provided dropper, place one drop (40 µl ± 10 µl) of each reagent onto its correspondent division on the slide.
4. Add 25µl of the precipitated cells next to each drop of reagents.
5. Mix the reagent and the cells using a clean stirring stick over an area with a diameter of approximately 20-40mm.
6. Incubate the slide at room temperature (18-25°C) without stirring for **30 seconds**.
7. Hold the slide and gently rock the slide for **3 minutes** and observe macroscopically for any agglutination.
8. Read the reaction immediately.

READING THE RESULT

POSITIVE: If Agglutination appears.

NEGATIVE: If no agglutination is observed.

Use the below table to determine the blood group:

Result of each reaction				ABO Group
Anti-A monoclonal reagent	Anti-B monoclonal reagent	Anti-AB monoclonal reagent	Anti-D IgG/IgM blend reagent	
+	-	+	+	**A+**
+	-	+	-	**A-**
-	+	+	+	**B+**
-	+	+	-	**B-**
+	+	+	+	**AB+**
+	+	+	-	**AB-**
-	-	-	+	**O+**
-	-	-	-	**O-**

STABILITY OF THE REACTIONS

- ABO Blood Grouping Tube tests should be read immediately following centrifugation.
- Slide tests should be interpreted within three minutes to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of reagents.
- Delay in reading and interpreting results may result in weekly positive or falsely negative reactions. Slide tests should be interpreted at the end of the three minutes.

PROCEDURE LIMITATION

1. False positive/ negative results may occur due to:
   - Contamination from test materials.
   - Improper storage, cells concentration, incubation time or temperature.
   - Improper or excessive centrifugation.
   - Deviation from the recommended technique.
   - Blood samples of weak A or B subgroups may give rise to false negative results or weak reactions when tested using slide test method. It is advisable to re-test weak subgroups using tube test method.
2. Weaker reactions may be observed with stored blood than with fresh blood.
3. ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
4. ABO blood grouping interpretation on individuals greater than 6 months old should be confirmed by testing serum or plasma of the individual against group A and group B red cells (reverse grouping). If the results obtained with the serum do not correlate with the red cell test, further investigation is required.
5. Return the kit to the agent if it does not function properly.
6. Anti-D IgG/IgM blend Reagent tests conducted on particular weak-D phenotypes, while satisfactory, cannot ensure recognition of all weak variants, due to the variability of antigen patterns.

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

The following tables compare the results in slide and tube techniques of 3 lots of Atlas Medical reagents and the results of a CE marked device.

Slide Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
232	232	232	232	100%
Tube Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
212	212	212	212	100%

Slide Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%
Tube Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%

Slide Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
241	241	241	241	100%
Tube Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
243	243	243	243	100%

Slide Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
33	33	33	33	100%
Tube Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
24	24	24	24	100%

No inversion in diagnosis has been shown: from a qualitative point of view we have observed 100% compliance in direct group testing in slide and tube techniques for determination of A, B, AB and O groups for the three lots of Atlas Medical.

QUALITY CONTROL

The reactivity of all blood grouping reagents should be confirmed by testing known positive and negative red blood cells on each day of use.

To confirm the specificity and sensitivity, Blood grouping reagents should be tested with antigen-positive and antigen-negative red blood cells.

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4. Messeter L. et. al. Mouse monoclonal antibodies with anti-A, anti-B and anti-A,B specificities, some superior to human polyclonal ABO reagents, Vox Sang 46, 185-194, 1984
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8. Widmann F.K.ed Technical Manual, 9th Ed., Wahington D.C.: AABB 1985:9.

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Website: www.atlas-medical.com

PPI861A01
Rev.L (19.02.2022)

CE 0459

LIST OF VARIENTS:

Product Code	Product Name
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/Carton Box
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial. 10 vials / Plastic Pack
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial. 18 vials / Carton Box
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, / Carton Box
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials / Plastic Pack
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials / Carton Box
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/ Carton Box
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials/Plastic Pack
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials/Carton Box
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 1 vial/ Carton Box
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 10 vials / Plastic Pack
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 18 vials / Carton Box
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1 Vial/Carton Box
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials / Plastic Pack
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials /Plastic Pack
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1 /256), Anti-D (1/64)),3x10ml / plastic Pack
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1 /256), 2x10ml /Plastic Pack
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,10 vials /Plastic Pack
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,18 vials / Carton Box
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 1Vial/ Carton Box
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 10 vials / Plastic Pack
8.02.47.0.0030	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-D (1 /128)),3x10ml/Plastic Pack
8.02.47.1.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Carton Box.
8.02.47.3.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Plastic Pack
8.02.47.5.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /128)), 3x10ml/Plastic Pack
8.02.49.0.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /64)), 4x10ml/Carton Box
8.02.49.2.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /128)), 4 x 10ml, 4 vials/Plastic Pack
8.02.53.0.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml/Plastic Pack
8.02.53.1.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml, 4vials/Plastic Pack
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial ,1Vial/ Carton Box
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial , 1Vial/ Carton Box
8.02.85.0.0010	Anti-D IgG/IgM Blend reagent (Titer 1 /256), 10ml/vial, 1Vial/ Carton Box

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

GRAM STAIN PACK

IVD **For *in -vitro* diagnostic and professional use only**

15°C 30°C **Store at Room Temperature**

INTENDED USE

Gram Stain used for differentiate between gram positive and gram-negative bacteria.

INTRODUCTION

Gram staining is used to differentiate bacterial species into two large groups (Gram-positive and Gram-negative) based on the physical properties of their cell walls.

PRINCIPLE

Gram-positive bacteria have a thick mesh-like cell wall made of peptidoglycan (50-90% of cell wall), which stains Blue while gram-negative bacteria have a thinner layer (10% of cell wall), which stains pink. Gram-negative bacteria also have an additional outer membrane which contains lipids, and is separated from the cell wall by the periplasmic space. There are four basic steps of the Gram stain, which include applying a primary stain (crystal violet) to a heat-fixed smear of a bacterial culture, followed by the addition of a trapping agent (Gram's iodine), rapid decolorization with alcohol or acetone, and *counterstaining* with safranin or basic fuchsin.

Crystal violet (CV) dissociates in aqueous solutions into CV^+ and chloride (Cl^-) ions. These ions penetrate through the cell wall and cell membrane of both gram-positive and gram-negative cells. The CV^+ ion interacts with negatively charged components of bacterial cells and stains the cells Blue.

Iodine (I^- or I_3^-) interacts with CV^+ and forms large complexes of crystal violet and iodine (CV–I) within the inner and outer layers of the cell. Iodine is often referred to as a mordant, but is a trapping agent that prevents the removal of the CV-I complex and therefore color from the cell.

When a decolorizer such as alcohol or acetone is added, it interacts with the lipids of the cell membrane. A gram-negative cell will lose its outer membrane and the lipopolysaccharide layer is left exposed. The

CV–I complexes are washed from the gram-negative cell along with the outer membrane. In contrast, a gram-positive cell becomes dehydrated from an ethanol treatment. The large CV–I complexes become trapped within the gram-positive cell due to the multilayered nature of its peptidoglycan. The decolorization step is critical and must be timed correctly; the crystal violet stain will be removed from both gram-positive and negative cells if the decolorizing agent is left on too long (a matter of seconds).

After decolorization, the gram-positive cell remains Blue. and the gram-negative cell loses its Blue. color. Counterstain, which is usually positively charged safranin or basic fuchsin, is applied last to give decolorized gram-negative bacteria a pink or red color.

MATERIALS

MATERIALS PROVIDED

- Crystal Violet.
- Gram Iodine.
- Gram Decolouriser.
- Counterstain – Safranin O.

Note: This package insert is also used for individually packed reagent.

Storage and stability

- Store at room temperature.
- Stain Solution is stable up to the printed expiry date.
- Keep the bottles tightly closed to prevent air oxidation.

Precautions

- The reagent may cause eye, skin and respiratory tract irritation; so protective clothing should be worn when handling this reagent.
- The reagent is intended for in vitro diagnostic use only.
- Do not use this reagent if the label is not available or damaged.
- Test materials and samples should be discarded properly in biohazards container.
- This reagent is considered toxic, so do not drink or eat beside it.
- Wash hands and test table top with water and soap once the testing is done.

PROCEDURE

1. immerse the heat fixed smears with Crystal Violet and allow to stain for up to 1 minute.
2. Wash with tap water.
3. Flood the smear with Gram Iodine for 2 minutes.
4. Wash with tap water.
5. Decolorize the smear for few second only.
6. Wash thoroughly with tap water.
7. Counterstain with Safranin O for up to 2 minutes.
8. Wash and allow to dry.
9. Examine under microscope using oil immersion objective

RESULTS

- Gram positive organisms (Blue).
- Gram negative organisms (Red).

ATLAS Medical
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

PPI2112A01
Rev B (08.10.2020)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
	Flammable		

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

CE-DOC-OG027
Version 5.0

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)

Alpha-Fetoprotein Rapid Test Cassette (Whole blood/Serum/Plasma)	GEAFP-402a

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: QARAD BV

EC Representative's Address: Cipalstraat 3, 2440 Geel, BELGIUM

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 4, 2022

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

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

CE-DOC-OG034
Version 5.0

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)

See attachment

Classification: *List B*
Conformity assessment route: *Annex IV (Full Quality Assurance)*

Notified Body' Name: TÜV SÜD Product Service GmbH
Notified Body Address: Ridlerstraße 65 80339 München Germany
Notified Body ID: 0123
EC Certificate Registration number:V1 092305 0002 Rev.01
Expiry date of EC certificate: 2025-04-07

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: QARAD B.V.

EC Representative's Address: Cipalstraat 3, 2440 Geel BELGIUM

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: May 12, 2022

Joyce Pang

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

Attachment to CE-DOC-OG034 Version 5.0

Prostate Specific Antigen (PSA) Rapid Test Cassette (Whole Blood/Serum/Plasma)	GEPSA-402a
Prostate Specific Antigen (PSA) Rapid Test Strip (Whole Blood/Serum/Plasma)	GEPSA-401a
Prostate Specific Antigen (PSA) Rapid Test Cassette (Serum/Plasma)	GEPSA-302a
Prostate Specific Antigen (PSA) Rapid Test Strip (Serum/Plasma)	GEPSA-301a

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

CE-DOC-OG038
Version 2.0

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)

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402a
Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402b

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: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

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: August 11, 2020

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

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

CE-DOC-OG060
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)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

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: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

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: November 28, 2017

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

TÜV®

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

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

.

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

TÜV®

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
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

Toxicology Urine Test

Product Description	Format	Cut-off Value	Qualification
Acetaminophen (ACE) Test	Strip/Cassette/Dip Card/Cup	5000 ng/mL	CE
Amphetamine (AMP) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Barbiturates (BAR) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/200 ng/mL	CE 510(k)
Benzodiazepines (BZO) Test	Strip/Cassette/Dip Card/Cup	600/400/300/200/100 ng/mL	CE 510(k)
Buprenorphine (BUP) Test	Strip/Cassette/Dip Card/Cup	10/5 ng/mL	CE 510(k)
Caffeine (CAF) Test	Strip/Cassette/Dip Card/Cup	6000 ng/mL	/
Carisoprodol (SOMA) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	CE
Clonazepam (CLO) Test	Strip/Cassette/Dip Card/Cup	500/100 ng/mL	CE
Cocaine (COC) Test	Strip/Cassette/Dip Card/Cup	600/300/150/100 ng/mL	CE 510(k)
Codeine (COD) Test	Strip/Cassette/Dip Card/Cup	2000 ng/mL	CE
Cotinine (COT) Test	Strip/Cassette/Dip Card/Cup	400/300/200/100/50 ng/mL	CE
Ecstasy (MDMA) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250/150 ng/mL	CE 510(k)
Ethyl Glucuronide (EtG) Test	Strip/Cassette/Dip Card/Cup	500/300ng/mL	CE
Fentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	300/200/100/50 ng/mL	CE
Norfentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	200/50/20/10/5 ng/mL	CE
Gabapentin (GAB) Test	Strip/Cassette/Dip Card/Cup	3750/2000/1000 ng/mL	CE
Hydrocodone (HCD) Test	Strip/Cassette/Dip Card/Cup	300/10 ng/mL	CE
Hydromorphone (HMO) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
Ketamine (KET) Test	Strip/Cassette/Dip Card/Cup	3000/2000/1000/500/100 ng/mL	CE
Kratom (KRA) Test	Strip/Cassette/Dip Card/Cup	250/150/100 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Strip/Cassette/Dip Card/Cup	20 ng/mL	CE
Marijuana (THC) Test	Strip/Cassette/Dip Card/Cup	600/300/200/150/100/50/40/25/20/18/15 ng/mL	CE 510(k)
Methadone Metabolite (EDDP) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Methadone (MTD) Test	Strip/Cassette/Dip Card/Cup	1000/600/300/200/50 ng/mL	CE 510(k)
Methamphetamine (MET) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Methaqualone (MQL) Test	Strip/Cassette/Dip Card/Cup	300/1000 ng/mL	CE
Methcathinone (MTC) Test	Strip/Cassette/Dip Card/Cup	500/300 ng/mL	CE
3,4-Methylenedioxypyrovalerone (MDPV) Test	Strip/Cassette/Dip Card/Cup	1000/500/50 ng/mL	CE
Methylphenidate (MPD) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
6-Monoacetylmorphine (6-MAM) Test	Strip/Cassette/Dip Card/Cup	20/10 ng/mL	CE
Morphine (MOP) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/150/100 ng/mL	CE 510(k)
Opiate (OPI) Test	Strip/Cassette/Dip Card/Cup	2000/300/100 ng/mL	CE 510(k)
Oxycodone (OXY) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Phencyclidine (PCP) Test	Strip/Cassette/Dip Card/Cup	50/25 ng/mL	CE 510(k)
Pinaca Ab (K3) Test	Strip/Cassette/Dip Card/Cup	10 ng/mL	CE
Pregabalin (PGB) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500 ng/mL	CE
Propoxyphene (PPX) Test	Strip/Cassette/Dip Card/Cup	600/300 ng/mL	CE 510(k)
Synthetic Marijuana (K2) Test	Strip/Cassette/Dip Card/Cup	75/50/25/20/10 ng/mL	CE
Tramadol (TRA) Test	Strip/Cassette/Dip Card/Cup	200/100 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Strip/Cassette/Dip Card/Cup	1000/300 ng/mL	CE 510(k)
UR-144 Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	CE
Zolpidem (ZOL) Test New	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test New	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Alcohol (ALC) Test	Strip/Cassette/Dip Card/Cup	0.04%	CE

Toxicology Saliva Test

Product Description	Format	Cut-off Value	Qualification
7-Aminonclnozepam (ACL) Test New	Device	100 ng/mL	/
Amphetamine (AMP) Test	Device	50/40 ng/mL	CE
Barbiturates (BAR) Test	Device	300/50/40 ng/mL	CE
Benzodiazepines (BZO) Test	Device	50/20/10 ng/mL	CE
Buprenorphine (BUP) Test	Device	10/5 ng/mL	CE
Carisoprodol (SOMA) Test	Device	300 ng/mL	/
Cocaine (COC) Test	Device	50/20 ng/mL	CE
Codeine (COD) Test	Device	10 ng/mL	CE
Cotinine (COT) Test	Device	50/30/10 ng/mL	CE
Diphenhydramine (DIP) Test New	Device	150/100 ng/mL	/
Ecstasy (MDMA) Test	Device	60/50 ng/mL	CE
Ethyl Glucuronide (EtG) Test New	Device	150/100 ng/mL	/
Fentanyl (FEN) Test	Device	10 ng/mL	CE
Hydrocodone (HCD) Test New	Device	10 ng/mL	/
Hydromorphone (HMO) Test New	Device	300/150 ng/mL	/
Ketamine (KET) Test	Device	100/50 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Device	25/10 ng/mL	CE
Marijuana (THC) Test	Device	50/40/30/25/15/12/10/5/4/3 ng/mL	CE
Methadone Metabolite (EDDP) Test	Device	20 ng/mL	CE
Mephedrone (MEP) Test New	Device	50 ng/mL	/
Methadone (MTD) Test	Device	75/50/30 ng/mL	CE
Methamphetamine (MET) Test	Device	50 ng/mL	CE
Methaqualone (MQL) Test	Device	150/100 ng/mL	CE
Methcathinone (MTC) Test	Device	50 ng/mL	/
3,4-Methylenedioxypyrovalerone (MDPV) Test	Device	200/100/50 ng/mL	CE
Methylphenidate (MPD) Test	Device	50 ng/mL	/
6-Monoacetylmorphine (6-MAM) Test	Device	25/15/10/5/4 ng/mL	CE
Morphine (MOP) Test	Device	15 ng/mL	CE
Opiate (OPI) Test	Device	50/40 ng/mL	CE
Oxycodone (OXY) Test	Device	50/40/20 ng/mL	CE
Phencyclidine (PCP) Test	Device	10 ng/mL	CE
Phenytoin (PHEN) Test New	Device	150/100 ng/mL	/
Pinaca Ab (K3) Test New	Device	10 ng/mL	/
Pregabalin (PGB) Test New	Device	100 ng/mL	/
Propoxyphene (PPX) Test	Device	50/20 ng/mL	CE
Synthetic Marijuana (K2) Test	Device	25/10/5 ng/mL	CE
Tramadol (TRA) Test	Device	100/50 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Device	1000/500/300/150 ng/mL	CE
XLR-11 Test New	Device	100 ng/mL	/
Zolpidem (ZOL) Test New	Device	25 ng/mL	/
Zopiclone (ZOP) Test New	Device	25 ng/mL	/
Alcohol (ALC) Test	Device	0.05 ng/mL	CE

Toxicology Hair Test

Product Description	Format	Label	Cut-off Value	Qualification
Amphetamine (AMP) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5 ng/mg	/
Benzodiazepines (BZO) Test	Cassette	Fluorescence	0.2 ng/mg	/
		Gold	1 ng/mg	/
Cocaine (COC) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2 ng/mg	CE
Ecstasy (MDMA) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5 ng/mg	/
2-Fluorodeschloroketamin (FKE) Test	Cassette	Fluorescence	0.2 ng/mg	/
Ketamine (KET) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2/1.0.5 ng/mg	CE
Marijuana (THC) Test	Cassette	Fluorescence	0.05 ng/mg	CE
		Gold	2/1.5 ng/mg	CE
Methamphetamine (MET) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2/1 ng/mg	CE
Methcathinone (MTC) Test	Cassette	Fluorescence	0.2 ng/mg	CE
6-Monoacetylmorphine (6-MAM) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2 ng/mg	CE
Morphine (MOP) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5/2.0.5 ng/mg	CE
Oxycodone (OXY) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	4 ng/mg	/
Phencyclidine (PCP) Test	Cassette	Fluorescence	0.3 ng/mg	CE
		Gold	1 ng/mg	CE
Pinaca Ab (K3) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	0.5 ng/mg	/
Synthetic Marijuana (K2) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	1 ng/mg	/
Tramadol (TRA) Test	Cassette	Fluorescence	0.2 ng/mg	/
UR-144 Test	Cassette	Fluorescence	0.05 ng/mg	/

Infectious Disease

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Adenovirus Antigen Test	Swab	GCADE-502a/	Cassette	/	20 Tests/Kit
Adenovirus Test	Feces	GCADE-602a/	Cassette	/	20 Tests/Kit
Brucella Antibody Test	WB/S/P	GCBRU-402a/	Cassette	/	25 Tests/Kit
Candida albicans Test	Vaginal Secretion	GCCA-502a/	Cassette	10⁵ CFU/mL	20 Tests/Kit
Chagas Antibody Test	S/P	GCCHA-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHA-402a/	Cassette	/	25 Tests/Kit
Clostridium difficile GDH Test	Feces	GCCD(GDH)-602a/	Cassette	2 ng/mL	20 Tests/Kit
Clostridium difficile Toxin A/B Test	Feces	GCCD(Toxin A/B)-602a/	Cassette	Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Clostridium difficile GDH & Toxin A/B Combo Test	Feces	GCCD-625a/	Cassette	GDH: 2 ng/mL Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Chikungunya IgM Test	S/P	GCCHK(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHK(IgM)-402a/	Cassette	/	25 Tests/Kit
Chlamydia Test	Swab/Urine	GCCHL-502a/	Cassette	4.8×10⁵ IFU/mL	20 Tests/Kit
CMV IgG Test	S/P	GCCMV(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG)-402a	Cassette	/	25 Tests/Kit
CMV IgM Test	S/P	GCCMV(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgM)-402a	Cassette	/	25 Tests/Kit
CMV IgG/IgM Test	S/P	GCCMV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
COVID-19 IgM/IgG Test	WB/S/P	GCCOV-402a/	Cassette	/	25 Tests/Kit
COVID-19 Neutralizing Antibody Test	WB/S/P	GCCOV(NAb)-402b/	Cassette	/	25 Tests/Kit
COVID-19 Antigen Test	Nasopharyngeal Swab	GCCOV-502a/	Cassette	/	20 Tests/Kit
		GCCOV-502Ca/	Cassette	/	20 Tests/Kit
		GCCOV-501a/ New	Strip	/	20 Tests/Kit
	Nasal Swab	GCCOV-502a-NA/	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
		GCCOV-503a/ New	Device	/	1/2/5/10 Tests/Kit
	NA & NP Swab	GCCOV-502a-NN/	Cassette	/	20 Tests/Kit
	Oral Fluid	GCCOV-702a/	Cassette	/	20 Tests/Kit
COVID-19 Antigen Self-Test	Nasal Swab	GCCOV-502a-Hxx/	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
		GCCOV-502a-HxxOGE/	Cassette	/	1/2/3/5/7/8/10/15/20 Tests/Kit
	Oral Fluid	GCCOV-702a-Hxx/ New	Cassette	/	1/2/3/5/7/10/15/20 Tests/Kit
Digital COVID-19 Antigen Test	Nasal Swab	GCCOV-D503a/ New	Reader	/	1/2/3/5/7/10/15/20 Tests/Kit
COVID-19 Antigen & B.1.1.7 Mutant Strain Combo Test	Nasal Swab	GCCOV(B1117)-525a/	Cassette	/	20 Tests/Kit
COVID-19/Flu A&B /RSV Antigen Combo Test	Nasal Swab	GCFCR-7525a/ New	Cassette	/	20 Tests/Kit
SARS-CoV-2 Delta-series Mutant Strain Antigen Test	Nasal Swab	GCCOV(Del)-T502a/	Cassette	/	20 Tests/Kit
SARS-CoV-2 Ag Fluorescence Rapid Test	Nasal Swab	FCCOV-502a/ New	Cassette	/	20 Tests/Kit
Dengue IgG/IgM Antibody Test	WB/S/P	GCDEN(abi-402c/	Cassette	/	25 Tests/Kit
Dengue NS 1 Antigen Test	WB/S/P	GCDEN(NS1-402c/	Cassette	/	25 Tests/Kit
Dengue NS1 & IgG/IgM Combo Test	WB/S/P	GCDEN-425a/	Cassette	/	20 Tests/Kit
EV71 IgM Test	S/P	GCEV71(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCEV71(IgM)-402a/	Cassette	/	25 Tests/Kit
Giardia lamblia Test	Feces	GCGIA-602a/	Cassette	/	20 Tests/Kit
Gonorrhoeae Test	Swab	GCGON-502b	Cassette	1.0E+7	20 Tests/Kit
HAV IgM Test	S/P	GCHAV(IgM)-302Ba/	Cassette	/	25 Tests/Kit
HAV IgG/IgM Test	WB/S/P	GCHAV(IgG/IgM)-402a/	Cassette	/	25 Tests/Kit
HAV AntigenTest	Feces	GCHAV-602a/	Cassette	/	25 Tests/Kit
HBcAb Hepatitis B Core Antibody Test	S/P	GCHBcb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBcb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBcb-402a	Cassette	2 NCU	25 Tests/Kit
HBeAb Hepatitis B Envelope Antibody Test	S/P	GCHBeb-302a	Cassette	2 NCU	25 Tests/Kit
		GCHBeb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCHBeb-402a	Cassette	2 NCU	25 Tests/Kit
HBeAg Hepatitis B Envelope Antigen Test	S/P	GCHBeg-302a	Cassette	0.5 NCU	25 Tests/Kit
	WB/S/P	GCHBeg-402a	Cassette	0.5 NCU	25 Tests/Kit
HBsAb Hepatitis B Surface Antibody Test	S/P	GCHBsb-301a	Strip	30 mIU/mL	50 Tests/Kit
		GCHBsb-302a	Cassette	30 mIU/mL	25 Tests/Kit
		GCHBsb-401a	Strip	30 mIU/mL	50 Tests/Kit
	WB/S/P	GCHBsb-402a	Cassette	20 mIU/mL	25 Tests/Kit
		GCHBsb-402b	Cassette	20 mIU/mL	25 Tests/Kit
HBsAg Hepatitis B Surface Antigen Rapid Test	S/P	GCHBsg-301a	Strip	1 ng/mL	50 Tests/Kit
		GCHBsg-302a	Cassette	1 ng/mL	25 Tests/Kit
	WB/S/P	GCHBsg-401a	Strip	1 ng/mL	50 Tests/Kit
		GCHBsg-402a	Cassette	1 ng/mL	25 Tests/Kit
HBsAg/HCV Combo Test	WB/S/P	GCHBC-402a	Cassette	/	25 Tests/Kit
HBsAg/HCV/HIV/Syphilis Combo Test	S/P	GCHBCISY-345a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBCISY-445a	Cassette	/	20 Tests/Kit
HBV HBcAb/HBeAb/HBeAg/HBsAb /HBsAg Combo Test	S/P	GCHBV-355a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBV-455a	Cassette	/	20 Tests/Kit
HCV Hepatitis C Virus Test	S/P	GCHCV-301a	Strip	/	50 Tests/Kit
		GCHCV-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHCV-401a	Strip	/	50 Tests/Kit
		GCHCV-402a/	Cassette	/	25 Tests/Kit
HCV/HIV Combo Test	WB/S/P	GCHCI-402a	Cassette	/	25 Tests/Kit
HEV Hepatitis E Virus IgM Test	S/P	GCHEV-302a/	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Test	S/P	GCHIV-301a	Strip	/	50 Tests/Kit
		GCHIV-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHIV-401a	Strip	/	50 Tests/Kit
		GCHIV-402a/	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Tri-line Test	WB/S/P	GCHIV-GT402a	Cassette	/	25 Tests/Kit
HIV 1/2/O Antibody Test	S/P	GCHIV-T302b	Cassette	/	25 Tests/Kit
	WB/S/P	GCHIV-T402a	Cassette	/	25 Tests/Kit
HIV Antigen/Antibody Combo Test	WB/S/P	GCHIV(Ag/Ab)-402a	Cassette	/	25 Tests/Kit
HSV IgG Test	S/P	GCHSV(IgG)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG)-402a/	Cassette	/	25 Tests/Kit
HSV IgM Test	S/P	GCHSV(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgM)-402a/	Cassette	/	25 Tests/Kit
HSV IgG/IgM Test	S/P	GCHSV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
H. pylori Antibody Test	S/P	GCHP-301a/	Strip	/	50 Tests/Kit
		GCHP-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCHP-401a/	Strip	/	50 Tests/Kit
		GCHP-402a/	Cassette	/	25 Tests/Kit
H. pylori Antigen Test	Feces	GCHP-601a/	Strip	/	25 Tests/Kit
		GCHP-601Ca/	Strip	/	25 Tests/Kit
		GCHP-602a/	Cassette	/	20 Tests/Kit
		GCHP-602Ca/	Cassette	/	20 Tests/Kit
Influenza A Antigen Test	Nasal/Throat Swabs	GCFLU(A)-501a/	Strip	1.5 x 10⁵ TCID$_{50}$	25 Tests/Kit
		GCFLU(A)-502a/	Cassette	1.5 x 10⁵ TCID$_{50}$	20 Tests/Kit
Influenza A/B Antigen Test	Nasal/Throat Swabs	GCFLU(A/B)-501a/	Strip	1.5x 10⁵ TCID$_{50}$ / 1.5 x 10⁵ TCID$_{50}$	25 Tests/Kit
		GCFLU(A/B)-502a/	Cassette	1.5x 10⁵ TCID$_{50}$ / 1.5 x 10⁵ TCID$_{50}$	20 Tests/Kit
		GCFLU(A/B)-502Ca/	Cassette	1.5x 10⁵ TCID$_{50}$ / 1.5 x 10⁵ TCID$_{50}$	20 Tests/Kit
Influenza & COVID-19 Antigen Combo Test	Nasopharyngeal Swab	GCFC-525a/	Cassette	/	20 Tests/Kit
	NA & NP Swab	GCFC-525a-NN/	Cassette	/	20 Tests/Kit
		GCFC-525a-NA/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFC-T502a/ New	Cassette	/	1/5/20 Tests/Kit
		GCFC-T503a/ New	Device	/	1/2/5/10 Tests/Kit
Flu, COVID-19, RSV & Adeno Antigen Combo Test	Nasopharyngeal Swab	GCFCRA-545a/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFCRA-T525a/ New	Cassette	/	20 Tests/Kit
Leishmania Antibody Test	S/P	GCKal-301a	Strip	/	50 Tests/Kit
		GCKal-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCKal-401a/	Strip	/	50 Tests/Kit
		GCKal-402a	Cassette	/	25 Tests/Kit
		GCKal-T402a/	Cassette	/	25 Tests/Kit
Malaria Pan Antigen Test	Whole Blood	GCMAL(pan)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f. Antigen Test	Whole Blood	GCMAL(pf)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./Pan Antigen Test	Whole Blood	GCMAL(pf/pan)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antigen Test	Whole Blood	GCMAL(pf/pv)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antibody Test	S/P	GCMAL(pf/pv Ab)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCMAL(pf/pv Ab)-402a/	Cassette	/	25 Tests/Kit
Monkeypox IgG/IgM Antibody Test	WB/S/P	GCMKP-402a/ New	Cassette	/	25 Tests/Kit
Monkeypox Antigen Test	WB/S/P or Throat swab	GCMKP-502a/ New	Cassette	/	25 Tests/Kit
Mononucleosis Test	S/P	GCMON-325a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCMON-402a/	Cassette	/	25 Tests/Kit
		GCMON-425a/	Cassette	/	25 Tests/Kit
M. pneumonia IgM Test	S/P	GCMP(IgM)-302a/	Cassette	/	25 Tests/Kit
Respiratory Syncytial Virus Antigen Test	Swab	GCRSV-502a/	Cassette	/	20 Tests/Kit
Rotavirus Test	Feces	GCROA-602a/	Cassette	/	25 Tests/Kit
Rotavirus/Adenovirus Test		GCROA/ADE-602a/	Cassette	/	25 Tests/Kit
Rubella IgG Test	S/P	GCRUB(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG)-402a	Cassette	/	25 Tests/Kit
Rubella IgM Test	S/P	GCRUB(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgM)-402a	Cassette	/	25 Tests/Kit
Rubella IgG/IgM Test	S/P	GCRUB(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
		GCRUB(IgG/IgM)-T402a	Cassette	/	25 Tests/Kit
Strep A Test	Throat Swab	GCSTR-501a/	Strip	/	25 Tests/Kit
		GCSTR-501Ca/†	Strip	/	25 Tests/Kit
		GCSTR-502a/	Cassette	/	20 Tests/Kit
		GCSTR-502Ca/	Cassette	/	20 Tests/Kit
Syphilis Test	S/P	GCSYP-301a/	Strip	/	50 Tests/Kit
		GCSYP-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCSYP-401a/	Strip	/	50 Tests/Kit
		GCSYP-402a/	Cassette	/	25 Tests/Kit
S. typhi Antigen Test	S/P/Feces	GCSAL(ST)-602a/	Cassette	/	20 Tests/Kit
TOXO IgG Test	S/P	GCTOXO(IgG)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOXO(IgG)-402a	Cassette	/	25 Tests/Kit
TOXO IgM Test	S/P	GCTOXO(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOXO(IgM)-402a	Cassette	/	25 Tests/Kit
Toxo IgG/IgM Test	S/P	GCTOX-302b	Cassette	/	25 Tests/Kit
		GCTOX(IgG/IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX-402b	Cassette	/	25 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgG Combo Test	S/P	GCTOG-345a	Cassette	/	20 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgM Combo Test	S/P	GCTOM-345a	Cassette	/	20 Tests/Kit
Trichomonas vaginalis Test	Vaginal Swab	GCTV-502a/	Cassette	/	20 Tests/Kit
Tuberculosis IgG/IgM Test	S/P	GCTB-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTB-402a/	Cassette	/	25 Tests/Kit
Typhoid IgG/IgM Test	S/P	GCTYP-301a	Strip	/	50 Tests/Kit
		GCTYP-302a/	Cassette	/	25 Tests/Kit
V. cholerae O1 Antigen Test	Feces	GCVCHO(O1)-602a/	Cassette	/	25 Tests/Kit
V. cholerae O1/O139 Antigen Test	Feces	GCVCHO(O1/O0)-602a/	Cassette	/	25 Tests/Kit
ZIKA IgM Test	WB/S/P	GCZIK(IgM)-402a	Cassette	/	25 Tests/Kit
ZIKA IgG Test	WB/S/P	GCZIK(IgG)-402a	Cassette	/	25 Tests/Kit
ZIKA NS1 Test	WB/S/P	GCZIK(NS1)-402a	Cassette	/	25 Tests/Kit

√CE Marked †Cleared for US 510(k) **In Specimen column: WB: Whole Blood S: Serum P: Plasma**

Fertility


Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
hCG Pregnancy Test	Urine	GAHCG-101a/†	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-101b/	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-101d/	Strip	20 mIU/mL	100 Tests/Kit
		GAHCG-102a/†	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-102b/	Cassette	10 mIU/mL	25 Tests/Kit
		GAHCG-102d/	Cassette	20 mIU/mL	25 Tests/Kit
		GAHCG-103a/†	Midstream	25 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103b/	Midstream	10 mIU/mL	1/2 Test(s)/Kit
		GAHCG-103d/	Midstream	20 mIU/mL	1/2 Test(s)/Kit
	Urine/Serum	GAHCG-105a	Panel	25 mIU/mL	25 Tests/Kit
		GAHCG-201a/	Strip	25 mIU/mL	100 Tests/Kit
		GAHCG-201b/	Strip	10 mIU/mL	100 Tests/Kit
		GAHCG-202a/	Cassette	25 mIU/mL	25 Tests/Kit
		GAHCG-202b/	Cassette	10 mIU/mL	25 Tests/Kit
Digital Pregnancy Test	Urine	GAHCG-D103a/	Midstream	25 mIU/mL	1/2 Test(s)/Kit
LH Ovulation Test	Urine	GALH-101a/	Strip	25 mIU/mL	100 Tests/Kit
		GALH-101b/	Strip	40 mIU/mL	100 Tests/Kit
		GALH-101d	Strip	30 mIU/mL	100 Tests/Kit
		GALH-102a/	Cassette	25 mIU/mL	25 Tests/Kit
		GALH-102b/	Cassette	40 mIU/mL	25 Tests/Kit
		GALH-103a/	Midstream	25 mIU/mL	1/5 Test(s)/Kit
		GALH-103b/	Midstream	40 mIU/mL	1/5 Test(s)/Kit
		GALH-103d	Midstream	30 mIU/mL	1/5 Test(s)/Kit
FSH Menopause Test	Urine	GAFSH-101a/	Strip	25 mIU/mL	100 Tests/Kit
		GAFSH-102a/	Cassette	25 mIU/mL	25 Tests/Kit
IGFBP-1 PROM Test	Cervical Secretion	GAIGF1-501a/	Strip	25 ng/mL	25 Tests/Kit
		GAIGF1-502a/	Cassette	25 ng/mL	20 Tests/Kit
Male Fertility Test	Semen	GASPE-902a/	Cassette	15M/mL	1 Test/Kit

Cardiac Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
CK-MB Test	S/P	GDCKM-302a/	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GDCKM-402a/	Cassette	5 ng/mL	25 Tests/Kit
CRP C-Reactive Protein Semi -Quantitative Test	WB/S/P	GDCRP-402a/	Cassette	1–3–10 mg/L	25 Tests/Kit
		GDCRP-T402b/	Cassette	10–40–80 mg/L	25 Tests/Kit
D-dimer Test	WB/P	GDDDI-402b/	Cassette	500 ng/mL	25 Tests/Kit
Myoglobin Test	WB/S/P	GDMYO-402a/	Cassette	50 ng/mL	25 Tests/Kit
Procalcitonin Test	WB/S/P	GDPCT-T402a/	Cassette	0.5–2–10 ng/mL	25 Tests/Kit
Troponin I Test	S/P	GDTRO-302a/	Cassette	0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDTRO-402a/	Cassette	0.5 ng/mL	25 Tests/Kit
		GDTRO-402b/	Cassette	0.5 ng/mL	25 Tests/Kit
Cardiac Myoglobin/CK - MB/cTnI Combo Test	S/P	GDCAR-335a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDCAR-435a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
		GDCAR-W435a/	Cassette	50/5/0.5 ng/mL	20 Tests/Kit

Urinalysis


Product Description	Specimen	Format	Cut-off Value	Kit Size
Ascorbate√†	Urine	Strip	0.5-0.6 mmol/L	100 Tests/Canister
Bilirubin√†	Urine	Strip	8.6-17 μmol/L	100 Tests/Canister
Blood√†	Urine	Strip	5-15 Ery/μL	100 Tests/Canister
Ca√	Urine	Strip	2.5 mmol/L	100 Tests/Canister
Creatinine√	Urine	Strip	50 mg/dL	100 Tests/Canister
Glucose√†	Urine	Strip	2.8–5.5 mmol/L	100 Tests/Canister
Ketone√†	Urine	Strip	0.5–1.0 mmol/L	100 Tests/Canister
Leukocytes√†	Urine	Strip	5-15 Leuko/μL	100 Tests/Canister
Micro Albumin√	Urine	Strip	0.08-0.15 mg/dL	100 Tests/Canister
Nitrite√†	Urine	Strip	13–22 μmol/L	100 Tests/Canister
pH√†	Urine	Strip	0.5	100 Tests/Canister
Protein√†	Urine	Strip	0.15–0.3 g/L	100 Tests/Canister
Specific Gravity√†	Urine	Strip	0.005	100 Tests/Canister
Urobilinogen√†	Urine	Strip	3.3-16 μmol/L	100 Tests/Canister
Urinary Tract Infection Test Strip	Urine	Strip	LEU: 10-15 Leuko/μL NIT: 13–22 μmol/L	3 Tests/Kit

Tumor Marker

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
AFP Alpha Fetal Protein Test	S/P	GEAFP-301a/	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-302a/	Cassette	20 ng/mL	25 Tests/Kit
	WB/S/P	GEAFP-401a/	Strip	20 ng/mL	50 Tests/Kit
		GEAFP-402a/	Cassette	20 ng/mL	25 Tests/Kit
CEA Carcinoembryonic Antigen Test	S/P	GECEA-301a	Strip	5 ng/mL	50 Tests/Kit
		GECEA-302a	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GECEA-401a/	Strip	5 ng/mL	50 Tests/Kit
		GECEA-402a/	Cassette	5 ng/mL	25 Tests/Kit
FOB Fecal Occult Blood Test	Feces	GEFOB-601b/†	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601Cb/	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601c/	Strip	100 ng/mL	25 Tests/Kit
		GEFOB-601d	Strip	200 ng/mL	25 Tests/Kit
		GEFOB-602b/†	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602Cb/	Cassette	50 ng/mL	20 Tests/Kit
		GEFOB-602c/	Cassette	100 ng/mL	20 Tests/Kit
		GEFOB-602d	Cassette	200 ng/mL	20 Tests/Kit
		GEFOB-602h	Cassette	150 ng/mL	20 Tests/Kit
		GEFOB-602j/	Cassette	10 ng/mL	20 Tests/Kit
FOB /Transferrin Combo Test	Feces	GEFOB/TF-602a/	Cassette	50/10 ng/mL	20 Tests/Kit
Nuclear Matrix Protein 22 Test	Urine	GENMP22-102a/ New	Cassette	10 U/mL	25 Tests/Kit
PSA Prostate Specific Antigen Test	S/P	GEPSA-301a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-302a/	Cassette	4 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-401a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-402a/	Cassette	4 ng/mL	25 Tests/Kit
PSA Prostate Specific Antigen Semi-QuantitativeTest	S/P	GEPSA-302b	Cassette	4 ng/mL, 10 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-402b	Cassette	4 ng/mL, 10 ng/mL	25 Tests/Kit
Transferrin Test	Feces	GETF-601a/	Strip	10 ng/mL	25 Tests/Kit
		GETF-602a/	Cassette	10 ng/mL	20 Tests/Kit

Veterinary

Product Description	Specimen	Catalog No.	Format	Label	Cut-off Value	Kit Size
Canine Adenovirus (CAV) Antigen Test	Secretions	GFCAV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Coronavirus (CCV) Antigen Test	Feces	GFCCV-802a	Cassette	Gold	/	10 Tests/Kit
		FFCCV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Coronavirus (CCV) & Parvovirus (CPV) Antigen Combo Test	Feces	GFCCP-T602a	Cassette	Gold	/	10 Tests/Kit
		FFCCP-T602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine C-Reactive Protein (cCRP) Test	WB/S/P	FFCCR-402a	Cassette	Fluorescence	10 mg/L	10 Tests/Kit
Canine Distemper Virus (CDV) Antigen Test	Secretions	GFCDV-502a	Cassette	Gold	/	10 Tests/Kit
		FFCDV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Distemper Virus (CDV), Influenza Virus (CIV) & Adenovirus (CAV) Antigen Combo Test	Secretions	GFCDIA-532a	Cassette	Gold	/	10 Tests/Kit
Canine Influenza Virus (CIV) Antigen Test	Secretions	GFCIV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Parvovirus (CPV) Antigen Test	Feces	GFCPV-602a	Cassette	Gold	/	10 Tests/Kit
		FFCPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Canine Progesterone (cProg) Test	WB/S/P	FFCPR-402a	Cassette	Fluorescence	15 ng/mL	10 Tests/Kit
Feline Calicivirus (FCV) Antigen Test	Secretions	GFFCV-502a	Cassette	Gold	/	10 Tests/Kit
		FFFCV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Coronavirus (FCoV) Antigen Test	Feces	GFFCO-602a	Cassette	Gold	/	10 Tests/Kit
Feline Herpes Virus (FHV) Antigen Test	Secretions	GFFHV-502a	Cassette	Gold	/	10 Tests/Kit
		FFFHV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) Antigen Test	Feces	GFFPV-602a	Cassette	Gold	/	10 Tests/Kit
		FFFPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) & Coronavirus (FCoV) Antigen Combo Test	Feces	GFFPC-622a	Cassette	Gold	/	10 Tests/Kit
Feline Serum Amyloid A (fSAA) Test	WB/S/P	FFFSA-402a	Cassette	Fluorescence	5 mg/L	10 Tests/Kit
Toxoplasma (Toxo) IgG/IgM Test	WB/S/P	GFTOX-402a	Cassette	Gold	/	10 Tests/Kit

Non-Infectious Disease

Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Micro-Albumin Test	Urine	GIHSA-101a/	Strip	20 μg/mL	100 Tests/Kit
		GIHSA-102a	Cassette	20 μg/mL	25 Tests/Kit
Vaginal pH Test	Vaginal Secretion	VPH-501a New	Strip	3.8-4.4	100 Tests/Canister

Autoimmunity

Product Description	Specimen	Catalog No.	Format	Kit Size
Rheumatoid Factor IgM Test	S/P	GCRFIgM-302a	Cassette	25 Tests/Kit
Total IgE Test	S/P	GCIGE-302a	Cassette	25 Tests/Kit

Instrument



Product Description	Model
Urine Analyzer	Healgen 500√
Urine Analyzer	Healgen 501√
Colloidal Gold Test Reader	OG-D180
Handheld Oral Fluid Drug Test Reader	OG-D200
Multi-Function Colloidal Gold Test Reader	OG-D600
Fluorescence Immunoassay Analyzer	OG-G200
Handheld Fluorescence Immunoassay Analyzer	OG-G300
Mini Immunofluorescence Analyzer	OG-H100√
Veterinary Fluorescence Immunoassay Analyzer	OG-V100

√CE Marked †Cleared for US 510(k) In Specimen column: WB: Whole Blood S: Serum P: Plasma

HEALGEN®

Zhejiang Orient Gene Biotech Co., Ltd was founded in December 2005 and listed on the SEE STAR Market on February 5, 2020 (securities code: 688298).
Orient Gene specializes in R&D, production and sales of in vitro diagnostic products, mainly covering infectious diseases (including COVID-19 test series), toxicology, tumor markers, cardiac markers and fertility testing, etc. Through 16 years of technology accumulation and continuous investment in R&D, the Company has independently developed hundreds of products. The company own more than 200 authorized patents, and has obtained more than 500 product medical device certifications at home and abroad. The Company's sales network covers more than 100 countries, products are mainly sold to Europe, America and other developed countries.

Healgen Scientific LLC, a wholly owned subsidiary of Zhejiang Orient Gene Biotech Co., Ltd develops, manufactures and commercializes in vitro diagnostic test systems worldwide. Our product portfolio spans multiple testing categories and analytes to meet various clinical and laboratory needs.

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PRODUCT CATALOG

Enhancing Global Health

HEALGEN®

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ООО «Агат-Мед»
105173, г. Москва, ул. Главная, 6-12
тел. (495) 777-41-92
agat@agat.ru www.agat.ru

ПАСПОРТ

Масло иммерсионное, тип А (классическое), 100 мл

Серия **454/16** Дата выпуска **01.2022** Годен до **01.2025**
Количество флаконов в серии **20000**

Наименование показателя	Требования по ГОСТ 13739-78	Результаты анализа
1. Внешний вид	Жидкость от бесцветного до светло-желтого цвета	соответствует
2. Технические характеристики		
2.1. Вязкость кинематическая (ν), при 20 °С, м2/с*10-4, не менее	6	13
2.2. Коэффициент пропускания (Т), при толщине слоя 1 мм, %		
при длине волны 635 нм, не менее	95	96
при длине волны 440 нм, не менее	92	98
2.3. Коэффициент преломления (n), при 20 °С	1,515 ± 0,001	1,515
2.4. Средняя дисперсия (nf-nc) , при 20 °С	0,0106 +/- 0,0003	0,0107

Заключение ОКК ООО «Агат-Мед»:
Набор серии **454/16** требованиям ГОСТ 13739-78 соответствует.

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.

« 01 » января 2022 г.

"Агат-Мед"

МП

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 мая 2019 года № РЗН 2019/8352

На медицинское изделие
Индикаторы химические для контроля процесса паровой и воздушной стерилизации по ТУ 20.59.52-001-35927791-2017

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Научно-Производственное Объединение "Маркер" (ООО "НПО "Маркер"), Россия, 117292, Москва, ул. Профсоюзная, д. 26/44

Производитель
Общество с ограниченной ответственностью "Научно-Производственное Объединение "Маркер" (ООО "НПО "Маркер"), Россия, 117292, Москва, ул. Профсоюзная, д. 26/44

Место производства медицинского изделия
ООО «НПО Маркер», Россия, 300013, г. Тула, Привокзальный р-н, ул. Болдина, д. 98а, лит. Е

Номер регистрационного досье **№ РД-25642/72833 от 30.01.2019**

Класс потенциального риска применения медицинского изделия **1**

Код Общероссийского классификатора продукции по видам экономической деятельности **32.50.50.000**

Настоящее регистрационное удостоверение имеет приложение на 2 листах

приказом Росздравнадзора от 07 мая 2019 года № 3413
допущено к обращению на территории Российской Федерации

Врио руководителя Федеральной службы по надзору в сфере здравоохранения **Д.В. Пархоменко**

0039607

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 мая 2019 года **№ РЗН 2019/8352**

На медицинское изделие
Индикаторы химические для контроля процесса паровой и воздушной стерилизации по ТУ 20.59.52-001-35927791-2017, в вариантах исполнения:
1. Индикаторы химические для контроля процесса паровой и воздушной стерилизации, в составе:
1.1. Интегрирующий индикатор «Маркер», 5 класс для контроля процесса паровой и воздушной стерилизации.
1.2. Многопеременный индикатор «ХимТест», 4 класс для контроля параметров паровой стерилизации для режимов: 121 °С /20 мин, 126 °С /10 мин, 134 °С /5 мин.
1.3. Многопеременный индикатор «ХимТест», 4 класс для контроля параметров воздушной стерилизации для режимов: 160 °С /150 мин, 180 °С /60 мин, 200 °С /30 мин.
1.4. Имитирующий индикатор «Маркер-Прион», 6 класс для контроля параметров паровой стерилизации для режима: 134 °С /18 мин.
2. Индикаторы химические для контроля процесса паровой и воздушной стерилизации лекарственных средств, в составе:
2.1. Многопеременный индикатор «Маркер-Фарм», 4 класс для контроля параметров паровой и воздушной стерилизации для режимов: 100 °С /30 мин, 110 °С /20 мин, 120 °С /15 мин, 180 °С /30 мин.
2.2. Многопеременный индикатор «ХимТест-Фарм-1», 4 класс для контроля параметров паровой стерилизации для режимов: 100 °С /15 мин, 110 °С /10 мин, 120 °С /8 мин.
2.3. Многопеременный индикатор «ХимТест-Фарм-2», 4 класс для контроля параметров паровой стерилизации для режимов: 110 °С /15 мин, 120 °С /12 мин.
2.4. Многопеременный индикатор «ХимТест-Фарм-3», 4 класс для контроля параметров паровой стерилизации для режимов: 100 °С /30 мин, 110 °С /20 мин, 120 °С /15 мин.
2.5. Многопеременный индикатор «ХимТест-Фарм-4», 4 класс для контроля параметров паровой стерилизации для режимов: 112 °С /20 мин, 121 °С /15 мин.
2.6. Многопеременный индикатор «ХимТест-Фарм-5», 4 класс для контроля параметров паровой стерилизации для режимов: 120 °С /30 мин, 121 °С /20 мин.
2.7. Многопеременный индикатор «ХимТест-Фарм-6», 4 класс для контроля параметров паровой стерилизации для режима: 120 °С /30 мин.
2.8. Многопеременный индикатор «ХимТест-Фарм-7», 4 класс для контроля

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.В. Пархоменко**

0055896

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 мая 2019 года **№ РЗН 2019/8352**

параметров воздушной стерилизации для режима: 180 °С /30 мин.
2.9. Многопеременный индикатор «ХимТест-Фарм-8», 4 класс для контроля параметров воздушной стерилизации для режима: 180 °С /45 мин.
3. Индикаторы химические для контроля процесса стерилизации (парового обеззараживания) медицинских отходов, в составе:
3.1. Многопеременный индикатор «ХимТест-О-1», для контроля параметров парового обеззараживания для режимов: 120 °С /90 мин, 126 °С /60 мин, 132 °С /45 мин, 134 °С /27 мин.
3.2. Многопеременный индикатор «ХимТест-О-2», для контроля параметров парового обеззараживания для режимов: 120 °С /120 мин, 126 °С /90 мин, 132 °С /60 мин, 134 °С /35 мин.
3.3. Многопеременный индикатор «ХимТест-О-3», для контроля параметров парового обеззараживания для режимов: 132 °С /90 мин, 134 °С /60 мин.

Врио руководителя Федеральной службы по надзору в сфере здравоохранения **Д.В. Пархоменко**

0055897

ООО «Научно-Производственное Объединение Маркер»
ИНН: 7728890217
КПП: 772801001
ОГРН: 5147746104182
117292. г. Москва, ул. Профсоюзная, д. 26/44
тел.: +7 (495) 178-02-08; e-mail: info@npomarker.ru

Индикаторы химические для контроля процесса паровой и воздушной стерилизации
ТУ 20.59.52-001-35927791-2017

ПАСПОРТ

03.03.2020

Индикаторы химические для контроля процесса паровой и воздушной стерилизации:
многопеременный индикатор «ХимТест», 4 класс для контроля параметров воздушной стерилизации для режимов: 160 °С /150 мин, 180 °С /60 мин, 200 °С /30 мин;

Партия № **2503/2**
Дата изготовления: **март 2020 г.**
Годен до: **март 2025 г.**
Вид исполнения: **листы с индикаторами**

Результаты приемосдаточных испытаний

Наименование испытаний (проверок)	№№ пунктов ТУ (технических требований)	Результат испытаний
Проверка соответствия комплекту документации	1.1.1	соответствует
Проверка исполнений, общего внешнего вида, конструкции, формы, материалов, основных размеров, массы	1.2.1-1.2.3	соответствует
Проверка условий достижения конечного состояния	1.2.4, 1.2.5	соответствует
Проверка условий не достижения конечного состояния	1.2.6	соответствует
Проверка комплектности, маркировки и упаковки	1.3, 1.4, 1.5	соответствует

Генеральный директор ООО «НПО Маркер» И.П. Антонова

SYNTESYS

ISO9011:2008
Cert. N.6574/0

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo R. & C.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea
or representing the authorized mandatary within the European Community

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

Denominazione/*Description*	**Padella per ammalati, urinali uomo e donna, speculum vaginali, tamponcini cotonati, tamponi sterili in provetta, tamponi sterili con terreno Amies e Stuart in provetta/ *Bed pan, Urinal's man and woman, Vaginal speculum, Cotton swab, Sterile swab in test tube, Sterile swab with medium Amies or Stuart in test tube***
Materiale/*Material*	**Polipropilene, Polietilene, Legno/ *Polypropylene, Polyethylene, Wood***

È conforme alle disposizioni della direttiva 93/42/CE e smi, concernente i dispositivi medici ed al Decreto Legislativo di recepimento con D.lgs. del 24/02/1997 n° 46/97 e soddisfa a tutti i requisiti specificati.
Il dispositivo è stato classificato appartenente alla classe I° secondo i criteri stabiliti in base a quanto previsto dall'Art. 9 ed allegato IX della direttiva sopra citata /*It meets the EC Directive 93/42 about Medical Device, specifications established by the Italian law n 46/97, dated 24th February 1997. The device was classified as belonging to the 1st class, according to the specifications of the established by the art.9, IX enclosure of the above mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/ *declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07.01.2016
Issued on January 7th 2016

SYNTESYS S.A.S.
Il legale rappresentante
Rinaldo Ruggero

SYNTESYS

ISO9001:2008
Cert. N.6574/0

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867

COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo Ruggero & C.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea or representing the authorized mandatary within the European Community

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

Denominazione degli articoli prodotti/*Description of Manufacturer*	**Contenitori per urina, contenitori per feci, contenitori universali, Pipette Pasteur, Piastre di Petri, Anse Sterili per batteriologia, Aste a "L", Puntali Eppendorf gialli e blue, cuvette per spettrofotometro, tazzine per campionamento siero, bacchette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi alettati per provette diam. 12 mm e 16mm, provette con granuli ed acceleratore, provette sottovuoto per prelievo, Sistema SEDIPLAST, Microprovette, Portavetrini, Vetrini precolorati, Portaprovette, supporti per microprovette, bottiglie per raccolta urine.** ***Urine container, faeces container, universal container, Pasteur pipette, Petri dishes, Sterile loops, Sterile loops open "L", Eppendorf tips yellow and blue, cuvettes for spectrophotometer, samples cups, Rod to detach clot, disposable forceps, Disposable plastic tubes, winged stoppers for tubes diam. 12mm & 16mm, Test tube with granules and clot activator, vacuum test tube, SEDIPLAST system, micro test tubes, Slides Mailer,"TESTSIMPLETS" slides rack for test tubes, rack for micro test tubes, Bottles for urine collection.***

SYNTESYS

ISO9001:2008
Cert. N.6574/0

SYNTESYS S.A.S. DI RINALDO R. & C.
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E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

Materiale/*Material*	**Polipropilene, Polistirolo, Polietilene e Polimetilmetacrilato** ***Polypropylene, Polystyrene, Polyethylene and Polymetilmetacrylate***

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnotic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/*declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07/01/2016
Issued on January 7th 2016

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero

SYNTESYS®

Cert. N.7111/2 Cert. N.6574/2

SYNTESYS S.R.L. UNIPERSONALE
VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD)
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C.F./P.I./N.REG.IMP. PADOVA 03573950288
REA PD-320123 - CAP.SOC. 20.700,00€
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT
PEC POSTA@PEC.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/*manufacturer*

SYNTESYS S.r.l.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea
or representing the authorized mandatary within the European Community

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

Denominazione/*Description*	**Microprovette tipo Eppendorf in polipr. coniche graduate 1,5 ml c/tappo /***Polypropylene microtubes Eppendorf type conical graduated with cap vol. 1,5 ml*	
Lotto/*Lot*	**21184378**	Data di scadenza/expiry date **06.2026**
Codice/*Code*	**318766**	
Materiale/*Material*	**Polipropilene/** *Polypropylene*	
Confezione/*Pack*	**10.000 pezzi/***10.000 pcs.*	

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnostic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/ *declares that all technical documents attached to this conformity statement are filed in our company and can be consulted by any authorized body on demand.*

Data 09.09.2021

SYNTESYS S.R.L.
UNIPERSONALE
Il Legale Rappresentante
Rinaldo Ruggero

COPAN S GR11.1 DOC 08 REV06 OF 12/10/2020	**CERTIFICATE OF STERILITY AND QUALITY ASSURANCE** *CERTIFICADO DE ESTERILIDAD Y GARANTIA DE CALIDAD*	**N° 21-CRT04720**

CODE */CÓDIGO*		LOT.N°*/NO. DE LOTE*	**EXP. DATE** */FECHA DE CADUCIDAD*
155C	155C	2113591	31/05/2024

DEVICE DESCRIPTION: *DESCRIPCIÓN DEL PRODUCTO*:	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED HISOPO SENCILLOS SECOS MANGO DE PLASTICO

Products labelled "STERILE R" have been gamma irradiated. Sterilisation procedure is validated in conformity with BS EN ISO 11137-1:2015 AND BS EN ISO 11137-2:2015 to guarantee SAL 10^{-6}.
Productos etiquetado "STERILE R"han sido irradiados gamma. El procedimiento de esterilización ha sido validado según la norma BS EN ISO 11137-1:2015 AND BS EN ISO 11137-2:2015 *para garantizar el nivel de esterilidad (SAL) 10^{-6}.*

Goods has been manufactured according to the EN ISO 13485:2016 system.
El material ha sido fabricado de acuerdo al sistema EN ISO 13485:2016.

Copan Italia SpA certifies that all product quality requirements have been met and that all information stated above is correct.
Copan Italia SpA certifica estar conforme con todos los requerimientos arriba mencionados y que toda la información es correcta.

16/06/2021
Certificate Date of Issue
Fecha de Expedición del Certificad

Chief Quality Officer
Copan Italia SpA
Via F.Perotti, 10 – 25125 Brescia (Italy)

LP ITALIANA SPA
Via C. Reale 15/4, 20157 Milano, ITALY
T +39 02 3933 06.1 - F +39 02 3931 3484
www.lpitaliana.com - info@lpitaliana.com

Capitale Sociale € 309.600,00
R.E.A. MI 882798
Reg. Imp. C.F. e P.I. MI 01794050151

CONFORMITY DECLARATION
Serological Pipettes

References: Invoice FV-22-02443 of OCT. 10, 2022

Product Code	Description	Lot n.
160110	PS STERILE 1 ML PIPETTE, SINGLE WRAP.	B0890BAA
		Expiry Date
		2027-07

LP ITALIANA declares that all quality qualifications of the products have been respected and that all information on these documents are correct.

Products are manufactured in accordance with quality system ISO 13485 and ISO 9001 ☑

Products passed visual and functional controls and are in accordance with our internal procedures. ☑

Irradiating process is validated and in accordance with ISO 11137 ☑

Products are irradiated by ionizing radiations at nominal dose of 18 kGy. Batch number 3172253 ☑

LP ITALIANA SPA
Massimiliano Capitanio
Quality Assurance Manager

(This certificate is electronically generated. Signature and check marks are in digital form)

SYNTESYS®

Cert. N.7111/2 Cert. N.6574/2

SYNTESYS S.R.L. UNIPERSONALE
VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
C.F./P.I./N.REG.IMP. PADOVA 03573950288
REA PD-320123 - CAP.SOC. 20.700,00€
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT
PEC POSTA@PEC.SYNTESYS.IT

AUTHORIZATION LETTER

We, **Syntesys S.R.L.** having a registered office at Via G. Galilei 10/3, 35037 Selve di Teolo - PD - Italy, assign **Sanmedico SRL** having a registered office at A.Corobceanu str., apt. 9, Chişinău MD-2012, Moldova, as authorized representative.

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 letter is valid till 28.08.2024

Teolo, 28.08.2023

SYNTESYS S.R.L.
UNIPERSONALE
Via G. Galilei, 10/3 - 35037 Z.I. Selve - Teolo (PD)
C.F./P.I./R.I. PD: 03573950288 - Cap. Soc. 20.700,00 €
Tel. 049 9903866 - Fax 049 9903867

Rinaldo Ruggero
CEO and Legal Representative
SYNTESYS S.R.L.

IQNET

Building trust together.

Certificate

CISQ/ICIM S.P.A. has issued an IQNet recognized certificate that the organization:

SYNTESYS S.R.L.

Head Office and Operative Unit

Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)

Operative Units

Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)

Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD)
Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a/an

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on:	**2022-06-05**
First issued on:	**2013-06-05**
Expires on:	**2025-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: **IT-83562**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

ICIM

CERTIFICATO N.
CERTIFICATE No. **6574/3**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

SYNTESYS S.R.L.

Sede e Unità Operativa

Via G. Galilei, 10/1-2-3 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia

Commercializzazione di prodotti per analisi di laboratorio. Produzione di prodotti per analisi di laboratorio e articoli sanitari. Progettazione e gestione della produzione di tamponi sterili per la raccolta e la conservazione di campioni biologici, anche in ambito chirurgico, con o senza terreno di trasporto.

Unità Operative

Via G. Galilei, 16/1 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia *
Via San Benedetto, 48/A - Zona Industriale - 35037 Selve di Teolo (PD) – Italia *
Via G. Galilei, 3 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia *
** Magazzino.*

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29 - 14

Commercializzazione di prodotti per analisi di laboratorio. Produzione di prodotti per analisi di laboratorio e articoli sanitari. Progettazione e gestione della produzione di tamponi sterili per la raccolta e la conservazione di campioni biologici, anche in ambito chirurgico, con o senza terreno di trasporto.

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
05/06/2013	05/06/2022	04/06/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.

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Certificate

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Head Office and Operative Unit

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ISO 13485:2016

Issued on:	**2022-06-05**
First issued on:	**2014-06-21**
Expires on:	**2025-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: **IT-93779**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

ICIM

CERTIFICATO n.
CERTIFICATE No. **7111/3**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

SYNTESYS S.R.L.

Sede e Unità Operativa

Via G. Galilei, 10/1-2-3 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia

Commercializzazione di prodotti per analisi di laboratorio. Produzione di prodotti per analisi di laboratorio e articoli sanitari. Progettazione e gestione della produzione di tamponi sterili per la raccolta e la conservazione di campioni biologici, anche in ambito chirurgico, con o senza terreno di trasporto.

Unità Operative

Via G. Galilei, 16/1 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia *
Via San Benedetto, 48/A - Zona Industriale - 35037 Selve di Teolo (PD) – Italia *
Via G. Galilei, 3 - Zona Industriale - 35037 Selve di Teolo (PD) – Italia *
** Magazzino.*

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Commercializzazione di prodotti per analisi di laboratorio. Produzione di prodotti per analisi di laboratorio e articoli sanitari. Progettazione e gestione della produzione di tamponi sterili per la raccolta e la conservazione di campioni biologici, anche in ambito chirurgico, con o senza terreno di trasporto.

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DATA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
21/06/2014	05/06/2022	04/06/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

CISQ

www.cisq.com

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0860CM_03_IT

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

Polmed.de

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

SRN: DE-AR-000006947

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

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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))

Polmed.de

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.:

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#	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:

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

Instruction for use
A solid-phase enzyme immunoassay kit
for the quantitative determination of
thyroid microsomal antibodies in human serum or plasma

aTPO EIA

Catalogue number REF **K131**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

XEMA LLC
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EC REP Authorized Representative in EU:
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tel.:+ 49 911 931 639 67
E-mail: info@polmed.de
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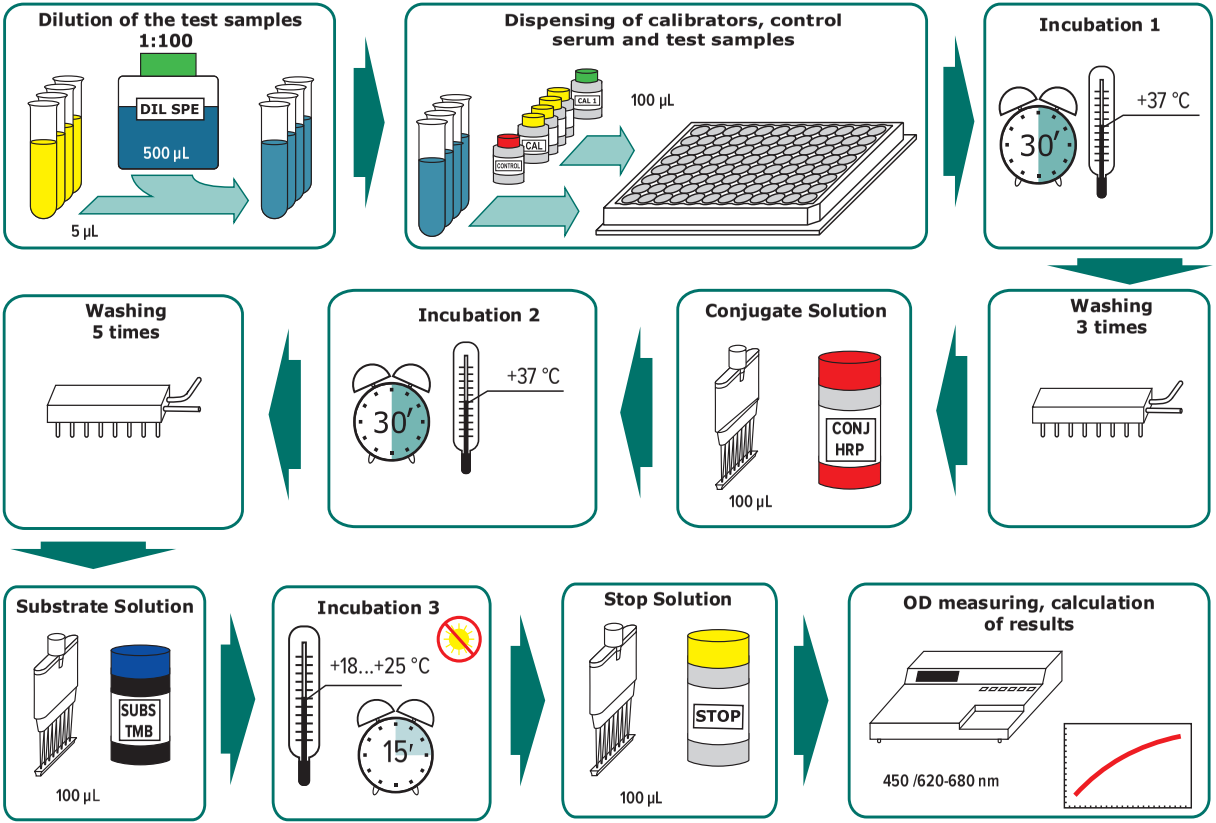
ASSAY PROCEDURE



K131

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of thyroid microsomal antibodies in human serum or plasma
aTPO EIA

1. INTENDED USE

The aTPO EIA kit is an enzyme immunoassay, intended for the quantitative determination of thyroid microsomal antibodies in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Anti-TPO antibodies (formerly – thyroid microsomal antibodies) are directed against a target protein – thyroid peroxidase (TPO) – located in the smooth endoplasmic reticulum of thyroid cells. The presence of anti-TPO antibodies in serum is associated with thyroid autoimmune diseases (Graves' disease and Hashimoto's thyroiditis). Anti-TPO antibodies mostly belong to the IgG class.

Low to moderate levels of serum anti-TPO antibodies can be found in some other autoimmune pathology (eg systemic lupus erythematosus or Sjogren syndrom) and, rarely, in apparently healthy subjects (especially elderly women). Anti-TPO antibodies are more sensitive in diagnosis of thyroid autoimmune diseases than anti-thyroglobulin (anti-TG) antibodies. However, in some cases anti-TG positive sera may be negative for anti-TPO. Therefore, combined determination of both types of anti-thyroid antibodies (anti-TPO + anti-TG) provides a more sensitive laboratory diagnostic tool for thyroid autoimmunity.

3. PRINCIPLE OF THE TEST

The determination of the anti-TPO antibodies (aTPO) is based on the indirect enzyme immunoassay principle. On the inner surface of the microplate wells are immobilized antigen TPO. Second antibodies – murine monoclonal anti-IgG antibodies conjugated to the horseradish peroxidase is used as enzyme conjugate. The analysis procedure includes three stages of incubation:

- during the first stage specific to antigen TPO antibodies from the specimen are bound by antigens coated onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated murine monoclonal antibodies bind to the antigen-antibody complexes, fixed in the formed at the previous stage complexes;
- during the third stage, the complexes formed due to the reaction with the chromogen 3,3',5,5'-tetramethylbenzidine are visualized.

After stopping the reaction with a stop solution, the intensity of the color of the microwells is measured. The optical density in the microwell is directly related to the quantity of the measured specific autoantibodies to thyroperoxidase in test specimen.

The concentration is determined according to the calibration graph of the dependence of the optical density on the content of anti-TPO antibodies in the calibration samples.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P131Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with antigen TPO; ready to use
C131Z	CAL 1	**Calibrator C1**	1.1 mL	1	Solution based on phosphate buffer (pH 7.2-7.4), free of anti-TPO antibodies, with preservative, ready to use (colourless liquid)
C131Z	CAL 2-5	**Calibrators**	1.1 mL	4	Solutions based on phosphate buffer (pH 7.2-7.4), containing 30; 100; 300 and 1000 IU/mL of anti-TPO antibodies, with preservative, ready to use (red liquids)
Q131Z	CONTROL	**Control Serum**	1.1 mL	1	Solution based on human serum, containing of known anti-TPO antibodies content, with preservative, ready to use (colourless liquid)
T131Z	CONJ HRP	**Conjugate Solution**	14 mL	1	Solution of murine monocnoclonal antibodies to IgG conjugated to the horseradish peroxidase; ready to use (red liquid)
SP131Z	DIL SPE	**EIA Buffer**	50 mL	1	Buffer solution with detergent and preservative, ready to use (blue liquid)
R055Z	SUBS TMB	**Substrate Solution**	14 mL	1	Tetramethylbenzidine (TMB) substrate solution; ready to use (colourless liquid)
S008Z	BUF WASH 26X	**26x Concentrate Washing Solution**	30 mL	1	Buffer solution with detergent, 26x concentrate (colourless liquid)
R050Z	STOP	**Stop Solution**	14 mL	1	5.0% solution of sulphuric acid; ready to use (colourless liquid)
The kit also includes instruction for use, quality control data sheet and plate sealing tape (3 pcs.)					

5. EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDED

- microplate photometer with 450 nm or 450\620-680 nm wavelength;
- dry thermostat for +37°C±2°C;
- automatic plate washer (optional);
- micropipettes with variable volume, range volume 5-1000 µL;
- graduated cylinder of 1000 mL capacity;
- distilled or deionized water;
- timer;
- vortex mixer;
- disposable gloves;
- absorbent paper.

6. WARNING AND PRECAUTIONS

In order to prevent incorrect results, strictly follow the recommended order and duration of the analysis procedure.

6.1. The kit is for *in vitro* diagnostic use only. For professional laboratory use.

6.2. Follow the rules mentioned below during the kit using:

- do not use kit beyond expire date;
- do not use the kit if its packaging is damaged;
- in order to avoid contamination, use new tips to pipette samples and reagents;
- use only verified equipment;
- close each vial with its own cap, after using the reagent;
- do not use components of other kits or reagents of other manufacturers;
- do not let wells dry after completing the rinsing step; immediately proceed to the next stage;
- avoid bubbles when adding reagents.

ATTENTION! The TMB substrate solution is light sensitive. Avoid prolonged exposure of the component to light.

6.3. Some kit components, such as stop solution, substrate solution, and washing solution, may cause toxic or irritant effects. If they get on the skin or mucosa, the affected area should be washed with plenty of running water.

6.4. All human products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guidelines or regulations.

6.5. The Calibrators and Control Serum included in the kit are negative for antibodies to HIV 1,2, hepatitis C virus and HBsAg, but the reagents should be considered as potentially infectious material and handled carefully.

6.6. Specimens must not contain any azide compounds, as they inhibit activity of peroxidase.

6.7. Wear protective gloves, protective clothing, eye protection, face protection.

6.8. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.

6.9. Safety Data Sheet for this product is available upon request directly from XEMA LLC.

6.10. Serious incidents related to the kit must be reported to the manufacturer, Authorized Representative, and to the Competent Authority of the EU member state(s) where the incident has occurred.

7. SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE OF SAMPLES

7.1. Blood sampling should be carried out from the cubital vein with a disposable needle using a vacuum blood sampling system. Serum or plasma specimens should be clearly labeled and identified. Serum must be separated from the clot as early as possible to avoid hemolysis of red blood cells. If there are any visible particles in the sample, they should be removed by centrifugation at 3000-5000 rpm for 20 minutes at room temperature or by filtration.

Don't use samples with high lipidemia, hemolysis as they may give false test results.

7.2. Specimen should be stored at +2…+8°C up to 3 days. Specimen held for a longer time, should be placed in a freezer at -15°C or below, do not refreeze/thaw samples.

7.3. For the transportation of samples, it is recommended to use triple packaging. The primary package is the labeled tube containing the sample. Secondary packaging is a polyethylene bag that is hermetically closed with a zip-lock. The outer packaging is a heat-insulating container, while the secondary packaging is placed in the outer packaging for transportation in the center of the thermal container. Frozen refrigerants are placed on the bottom, along the side walls of the thermal container, and cover the samples with them.

8. TRANSPORTATION AND STORAGE TERMS OF KIT, WASTE DISPOSAL

Information about the singularity storage conditions, transportation of the kit, and disposal of waste should be taken into account by all persons who participate in these processes.

8.1. Transportation

The aTPO EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25ºC for 5 days is acceptable.

8.2. Storage

The aTPO EIA kit should be stored in the manufacturer's packaging at +2...+8°C. Do not freeze.

The kit contains reagents sufficient for 96 determinations including Calibrators and Control Serum.

Once opened test-kit is stable for 2 months when stored properly as intended by manufacturer at 2-8°C.

In case of partial use of the kit, the components should be stored in the following way:

- strips that remain unused must be carefully sealed with the plate sealing tape and stored at +2...+8°C within 2 months;
- EIA Buffer, Substrate Solution, Stop Solution, and Washing Solution concentrate after opening the vial, can be stored tightly closed at +2...+8°C until the kit's shelf life;
- Conjugate Solution, Calibrators and Control Serum after opening the vial, can be stored tightly closed at +2...+8°C within 2 months
- diluted Washing Solution can be stored at room temperature (+18…+25°C) for up to 5 days or at +2…+8°C for up to 14 days.

Kits that were stored in violation of the storage condition cannot be used.

8.3. Disposal

Expired kit components, used reagents and materials, as well as residual samples must be inactivated and disposed of in accordance with legal requirements.

9. REAGENTS PREPARATION

9.1. All reagents (including microstrips) and test samples should be allowed to reach room temperature (+18…+25 °C) for at least 30 minutes before use.

9.2. Microplate preparation

Open the package with the microplate and install the required number of strips into the frame. Unused strips must be sealed with plate sealing tape to prevent moisture from affecting the plate's holes and placed back in the bag.

9.3. Washing solution preparation

Add the contents of the 30 mL washing solution concentrate vial to 750 mL of distilled or deionized water and mix thoroughly. In case of partial use of the kit, take the necessary amount of washing solution concentrate and dilute it 26 times with distilled or deionized water.

The spending of the components in case of partial use of the kit is given in the table:

Quantity of strips	1	2	3	4	5	6	7	8	9	10	11	12
Volume of the washing solution concentrate, mL	2.5	5	7.5	10	12.5	15	17.5	20	22.5	25	27.5	30
Volume of water, mL	62.5	125	187.5	250	312.5	375	437.5	500	562.5	625	687.5	750

9.4. Samples preparation

Dilute samples using EIA buffer 101 fold (for example, add to the vial 5 µL of the test sample + 500 µL EIA buffer).

If suggested analyte concentration in the sample exceeds the 1000 IU/mL, additionally dilute this sample accordingly, using EIA buffer. Use of other buffers or reagents for sample dilution may lead to incorrect measurement.

NOTE: in order to obtain reliable results, we recommend to use several successive dilutions of biological fluids.

Do not dilute Control Serum and Calibrators!

10. ASSAY PROCEDURE

10.1 Put the desired number of strips into the frame based on the number of test samples in 2 replicates and 12 wells for Calibrators and Control Serum (2 wells for each Calibrator (CAL 1-5) and 2 wells for Control Serum (Q)).

10.2 Dilute the test samples as described in 9.4.

10.3 Dispense **100 µL of Calibrators and Control Serum as well as 100 µL of diluted test serum/plasma samples** (SAMP) to the wells of the microplate according to the scheme below. The introduction of Calibrators, Control Serum and test samples should be carried out within 5 minutes to ensure equal incubation time for the first and last samples.

NOTE: during performing several independent series of tests, Calibrators, and Control Serum should be used each time.

Scheme of introduction of samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL1	CAL1	SAMP3	SAMP3	SAMP11	SAMP11						
B	CAL2	CAL2	SAMP4	SAMP4	SAMP12	SAMP12						
C	CAL3	CAL3	SAMP5	SAMP5	SAMP13	SAMP13						
D	CAL4	CAL4	SAMP6	SAMP6	SAMP14	SAMP14						
E	CAL5	CAL5	SAMP7	SAMP7	SAMP15	SAMP15						
F	Q	Q	SAMP8	SAMP8								
G	SAMP1	SAMP1	SAMP9	SAMP9								
H	SAMP2	SAMP2	SAMP10	SAMP10								

10.4 Carefully mix the contents of the microplate in a circular motion on a horizontal surface, cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.5 At the end of the incubation period, remove and discard the plate cover. Aspirate and wash each well 3 times using an automatic washer or an 8-channel dispenser. For each washing, add 300 µL of Washing Solution (see 9.3) to all wells, then remove the liquid by aspiration or decantation. The residual volume of the Washing Solution after each aspiration or decantation should be no more than 5µL. After washing, carefully remove the remaining liquid from the wells on the absorbent paper. For the automatic washer/analyzer, the Washing Solution volume can be increased to 350 µL.

10.6 Add **100 µL of Conjugate Solution** to all wells.

10.7 Cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.8 At the end of the incubation period, aspirate and wash each well 5 times as described in 10.5.

10.9 Add **100 µL of Substrate Solution** to all wells. The introduction of the Substrate Solution into the wells must be carried out within 2-3 minutes. Incubate the microplate in the dark **at room temperature (+18...+25°C) for 15 minutes**.

10.10 Add **100 µL of Stop Solution** to all wells in the same order as the Substrate Solution. After adding the Stop Solution, the contents of the wells turn yellow.

10.11 Read the optical density (OD) of the wells at 450nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution. Set photometer blank on CAL1.

10.12 Plot a calibration curve in linear coordinates: (x) is the concentration of aTPO IU/mL in the calibrators, (y) – OD versus aTPO concentration (OD 450 nm / 620–680 nm). Manual or computerized data reduction is applicable at this stage. Point-by-point or linear data reduction is recommended due to non-linear shape of curve.

10.13 Determine the corresponding concentration of aTPO in tested samples from the calibration curve. In the case of preliminary dilution of the test sample (see 9.4), the obtained result should be multiplied by the dilution factor.

10.14 The aTPO EIA kit can be used for screening. For this purpose, it is necessary to add 100 µL of Calibrator CAL1 to the wells of the microplate in duplicates, and 100 µL of Calibrator CAL2 30 IU/mL to other wells in duplicates, to the rest wells - 100 µL of diluted tested samples. Compare the value of OD of each tested serum (plasma) sample with the OD of calibrator CAL2 30 IU/ml (IU/ml) (ODC). If the OD value of the test sample is higher than the ODC value (+10%), then the result should be considered as POSITIVE (more than 30 IU/ml aTPO). If the OD value of the tested sample is lower than the ODC value (-10%), then the result should be considered as NEGATIVE. If the OD value of the tested sample is within ± 10%, then this result should be considered EQUIVOCAL.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is above 0.15, and the values of the Control Serum fall into the required range (see Quality control Data Sheet).

12. EXPECTED VALUES

Therapeutical consequences should not be based on results of IVD methods alone – all available clinical and laboratory findings should be used by a physician to elaborate therapeutically measures. Each laboratory should establish its own normal range for aTPO. Based on data obtained by XEMA, the following normal range is recommended (see below).

NOTE: values of aTPO concentrations in the tested samples that are below the LoD (2.5 IU/mL) and also exceed the value of the upper calibrator (1000 IU/mL) should be provided in the following form: «the aTPO concentration of tested sample X is «lower than 2.5 IU/mL» or «higher than 1000 IU/mL».

Sex, age	Units, IU/mL	
	Lower limit	Upper limit
Males	-	30
Females	-	30
Females >50 yrs	-	50

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1 Precision of Measurement

Repeatability (Intra assay repeatability) was determined by evaluation the coefficient of variation (CV) for 2 different samples during 1 day in 24 replicates on one series of ELISA kit.

Sample	Concentration, IU/mL	CV, %
1	322.4	6.74
2	175.2	5.62

Reproducibility (Inter assay reproducibility) was determined by evaluating the coefficients of variation for 2 samples during 5 days in 8-replicate determinations.

Sample	Concentration, IU/mL	CV, %
1	341.6	7.15
2	181.7	4.48

Reproducibility between lots was investigated by testing samples for one day on three lots. Each sample was run in 8 replicates.

Sample	Concentration1, IU/mL	Concentration2, IU/mL	Concentration3, IU/mL	CV, %
1	352.6	358.4	360.1	2.1
2	182.6	198.7	200.4	6.1

13.1.2 Trueness

The trueness of measurement is the degree of closeness of the average value obtained from a large number of measurement results to the true value. The bias of the measurement result (bias of measurements) is the difference between the mathematical expectation of the measurement result and the true value of the measurand. The bias was calculated for each sample and it was determined that it corresponds to the specified limits of ± 10%.

13.1.3 Linearity

Linearity was determined using sera samples with known aTPO concentration (low and high) and mixing them with each other and buffer solution in different proportions. According to the measurements, linear range of kit is 30-300 IU/mL ±10%.

13.1.4 Analytical sensitivity

Limit of detection (LoD) – the lowest aTPO concentration in the serum or plasma sample that is detected by the aTPO EIA kit is no lower than 2.5 IU/mL.

Limit of quantification (LoQ) – the lowest concentration of the analyte in the sample that is determined quantitatively with the declared trueness for aTPO EIA kit is 20 IU/mL.

13.1.5 Analytical specificity

For the analysis result is not affected by the presence in the sample of bilirubin in a concentration of up to 0.21 mg/mL and hemoglobin in a concentration of up to 10 mg/mL.

14. REFERENCES

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3. Bonnyns M., Van Haelts L., Bastenie P. – Asymptomatic atrophic thyroiditis. Horm. Res. 1982, 16:338.
4. Buchanan W., Alexander W., Crooks J., Koutras D., Wayne E., Anderson J.R., Goudie R. – Association of thyrotoxicosis and autoimmune thyroiditis. Brit.Med. J., 1961, 1:843.
5. Наказ МОЗ України №325 від 08.06.2015 «Про затвердження Державних санітарно-протиепідемічних правил і норм щодо поводження з медичними відходами».
6. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
7. НПАОП 85.14-1.09-81. Правила облаштування, техніки безпеки, виробничої санітарії, протиепідемічного режиму і особистої гігієни при роботі в лабораторіях (відділеннях, відділах) санітарноепідеміологічних установ системи Міністерства охорони здоров`я СРСР (НАОП 9.1.50-1.09-81)

SAMPLES IDENTIFICATION PLAN

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

LOT _____ DATE _____

SAMPLES IDENTIFICATION PLAN

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

LOT _____ DATE _____

	Manufacturer
	*In vitro* diagnistic medical device
	Catalogue number
	Use-by date
	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
	Authorized representative in the European Community/European Union
	CE Conformity Marking

For any issues related to operation of the kit and technical support, please contact by telefon number

+38 044 294-69-78

or write to:

qa@xema.com.ua

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Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of autoantibodies to thyroglobulin in human serum or plasma

aTG EIA

Catalogue number REF **K132**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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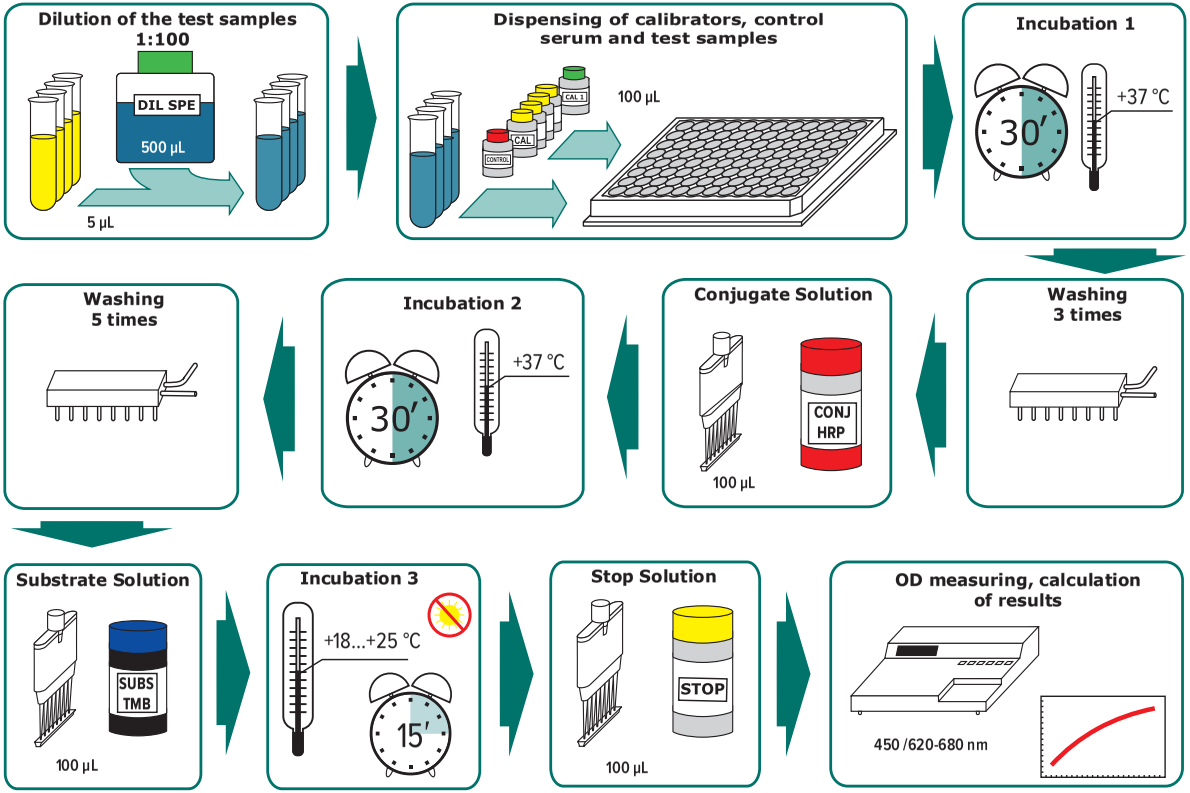
ASSAY PROCEDURE



K132

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of autoantibodies to thyroglobulin in human serum or plasma
aTG EIA

1. INTENDED USE

The aTG EIA kit is an enzyme immunoassay, intended for the quantitative determination of autoantibodies to thyroglobulin in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Thyroglobulin (TG) is a well known target for autoantibodies occurring in thyroid autoimmunity (Graves' disease and Hashimoto's thyroiditis). Anti-TG antibodies mostly belong to the IgG class. Low to moderate levels of anti-TG antibodies can be found in sera of other autoimmune patients (eg systemic lupus erythematosus or Sjogren syndrome).

In some cases anti-TG positive sera may show negativity for other type of anti-thyroid antibodies – anti-TPO. Therefore, combined determination of both types of anti-thyroid antibodies (anti-TPO + anti-TG) provides most sensitive laboratory diagnostic tool for thyroid autoimmunity. Separately from autoimmunity, anti-TG antibodies may develop in patients suffering from thyroid cancer. High level of anti-TG in such patients may interfere with correct determination of serum thyroglobulin which serves as tumour marker for therapy control in this group of patients.

3. PRINCIPLE OF THE TEST

The determination of the anti-TG antibodies (aTG) is based on the indirect enzyme immunoassay principle. On the inner surface of the microplate wells are immobilized antigen Thyroglobulin. Second antibodies – murine monoclonal anti-IgG antibodies conjugated to the horseradish peroxidase is used as enzyme conjugate. The analysis procedure includes three stages of incubation:

- during the first stage specific to antigen anti-TG antibodies from the specimen are bound by antigens coated onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated murine monoclonal antibodies bind to the antigen-antibody complexes, fixed in the formed at the previous stage complexes;
- during the third stage, the complexes formed due to the reaction with the chromogen 3,3',5,5'-tetramethylbenzidine are visualized.

After stopping the reaction with a stop solution, the intensity of the color of the microwells is measured. The optical density in the microwell is directly related to the quantity of the measured specific autoantibodies to thyroglobulin in test specimen.

The concentration is determined according to the calibration graph of the dependence of the optical density on the content of anti-TG antibodies in the calibration samples.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P132Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with antigen Thyroglobulin; ready to use
C132Z	CAL 1	**Calibrator C1**	1.1 mL	1	Solution based on phosphate buffer (pH 7.2-7.4), free of anti-TG antibodies, with preservative, ready to use (colourless liquid)
C132Z	CAL 2-5	**Calibrators**	1.1 mL	4	Solutions based on phosphate buffer (pH 7.2-7.4), containing 100; 300; 1000 and 3000 IU/mL of anti-TG antibodies, with preservative, ready to use (blue liquids)
Q132Z	CONTROL	**Control Serum**	1.1 mL	1	Solution based on human serum, containing of known anti-TG antibodies content, with preservative, ready to use (colourless liquid)
T132Z	CONJ HRP	**Conjugate Solution**	14 mL	1	Solution of murine monocnoclonal antibodies to IgG conjugated to the horseradish peroxidase; ready to use (magenta liquid)
S011Z3	DIL	**EIA Buffer**	50 mL	1	Buffer solution with detergent and preservative, ready to use (blue liquid)
R055Z	SUBS TMB	**Substrate Solution**	14 mL	1	Tetramethylbenzidine (TMB) substrate solution; ready to use (colourless liquid)
S008Z	BUF WASH 26X	**26x Concentrate Washing Solution**	22 mL	2	Buffer solution with detergent, 26x concentrate (colourless liquid)
R050Z	STOP	**Stop Solution**	14 mL	1	5.0% solution of sulphuric acid; ready to use (colourless liquid)
The kit also includes instruction for use, quality control data sheet and plate sealing tape (3 pcs.)					

5. EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDED

– microplate photometer with 450 nm or 450\620-680 nm wavelength;
– dry thermostat for +37°C±1°C;
– automatic plate washer (optional);
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– graduated cylinder of 1000 mL capacity;
– distilled or deionized water;
– timer;
– vortex mixer;
– disposable gloves;
– absorbent paper.

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In order to prevent incorrect results, strictly follow the recommended order and duration of the analysis procedure.

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ATTENTION! The TMB substrate solution is light sensitive. Avoid prolonged exposure of the component to light.

6.3. Some kit components, such as stop solution, substrate solution, and washing solution, may cause toxic or irritant effects. If they get on the skin or mucosa, the affected area should be washed with plenty of running water.

6.4. All human products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guidelines or regulations.

6.5. The Calibrators and Control Serum included in the kit are negative for antibodies to HIV 1,2, hepatitis C virus and HBsAg, but the reagents should be considered as potentially infectious material and handled carefully.

6.6. Specimens must not contain any azide compounds, as they inhibit activity of peroxidase.

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7.1. Blood sampling should be carried out from the cubital vein with a disposable needle using a vacuum blood sampling system. Serum or plasma specimens should be clearly labeled and identified. Serum must be separated from the clot as early as possible to avoid hemolysis of red blood cells. If there are any visible particles in the sample, they should be removed by centrifugation at 3000-5000 rpm for 20 minutes at room temperature or by filtration.

Don't use samples with high lipidemia, hemolysis as they may give false test results.

7.2. Specimen should be stored at +2…+8°C up to 3 days. Specimen held for a longer time, should be placed in a freezer at -15°C or below; do not refreeze/thaw samples.

7.3. For the transportation of samples, it is recommended to use triple packaging. The primary package is the labeled tube containing the sample. Secondary packaging is a polyethylene bag that is hermetically closed with a zip-lock. The outer packaging is a heat-insulating container, while the secondary packaging is placed in the outer packaging for transportation in the center of the thermal container. Frozen refrigerants are placed on the bottom, along the side walls of the thermal container, and cover the samples with them.

8. TRANSPORTATION AND STORAGE TERMS OF KIT, WASTE DISPOSAL

Information about the singularity storage conditions, transportation of the kit, and disposal of waste should be taken into account by all persons who participate in these processes.

8.1. Transportation

The aTG EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25ºC for 5 days is acceptable.

8.2. Storage

The aTG EIA kit should be stored in the manufacturer's packaging at +2...+8°C. Do not freeze.

The kit contains reagents sufficient for 96 determinations including Calibrators and Control Serum.

Once opened test-kit is stable for 2 months when stored properly as intended by manufacturer at 2-8°C.

In case of partial use of the kit, the components should be stored in the following way:

- strips that remain unused must be carefully sealed with the plate sealing tape and stored at +2...+8°C within 2 months;
- EIA Buffer, Substrate Solution, Stop Solution, and Washing Solution concentrate after opening the vial, can be stored tightly closed at +2...+8°C until the kit's shelf life;
- Conjugate Solution, Calibrators and Control Serum after opening the vial, can be stored tightly closed at +2...+8°C within 2 months
- diluted Washing Solution can be stored at room temperature (+18…+25°C) for up to 5 days or at +2…+8°C for up to 14 days.

Kits that were stored in violation of the storage condition cannot be used.

8.3. Disposal

Expired kit components, used reagents and materials, as well as residual samples must be inactivated and disposed of in accordance with legal requirements.

9. REAGENTS PREPARATION

9.1. All reagents (including microstrips) and test samples should be allowed to reach room temperature (+18…+25 °C) for at least 30 minutes before use.

9.2. Microplate preparation

Open the package with the microplate and install the required number of strips into the frame. Unused strips must be sealed with plate sealing tape to prevent moisture from affecting the plate's holes and placed back in the bag.

9.3. Washing solution preparation

Add the contents of the 22 mL washing solution concentrate vial to 550 mL of distilled or deionized water and mix thoroughly. In case of partial use of the kit, take the necessary amount of washing solution concentrate and dilute it 26 times with distilled or deionized water.

The spending of the components in case of partial use of the kit is given in the table:

Quantity of strips	1	2	3	4	5	6	7	8	9	10	11	12
Volume of the washing solution concentrate, mL	1.8	3.6	5.4	7.2	9	10.8	12.6	14.4	16.2	18	19.8	22
Volume of water, mL	45	90	135	180	225	270	315	360	405	450	495	550

9.4. Samples preparation

Dilute samples using EIA buffer 101 fold (for example, add to the vial 5 µL of the test sample + 500 µL EIA buffer).

If suggested analyte concentration in the sample exceeds the 3000 IU/mL, additionally dilute this sample accordingly, using EIA buffer. Use of other buffers or reagents for sample dilution may lead to incorrect measurement.

NOTE: in order to obtain reliable results, we recommend to use several successive dilutions of biological fluids.

Do not dilute Control Serum and Calibrators!

10. ASSAY PROCEDURE

10.1 Put the desired number of strips into the frame based on the number of test samples in 2 replicates and 12 wells for Calibrators and Control Serum (2 wells for each Calibrator (CAL 1-5) and 2 wells for Control Serum (Q)).

10.2 Dilute the test samples as described in 9.4.

10.3 Dispense **100 µL of Calibrators and Control Serum as well as 100 µL of diluted test serum/plasma samples** (SAMP) to the wells of the microplate according to the scheme below. The introduction of Calibrators, Control Serum and test samples should be carried out within 5 minutes to ensure equal incubation time for the first and last samples.

NOTE: during performing several independent series of tests, Calibrators, and Control Serum should be used each time.

Scheme of introduction of samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL1	CAL1	SAMP3	SAMP3	SAMP11	SAMP11						
B	CAL2	CAL2	SAMP4	SAMP4	SAMP12	SAMP12						
C	CAL3	CAL3	SAMP5	SAMP5	SAMP13	SAMP13						
D	CAL4	CAL4	SAMP6	SAMP6	SAMP14	SAMP14						
E	CAL5	CAL5	SAMP7	SAMP7	SAMP15	SAMP15						
F	Q	Q	SAMP8	SAMP8								
G	SAMP1	SAMP1	SAMP9	SAMP9								
H	SAMP2	SAMP2	SAMP10	SAMP10								

10.4 Carefully mix the contents of the microplate in a circular motion on a horizontal surface, cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.5 At the end of the incubation period, remove and discard the plate cover. Aspirate and wash each well 3 times using an automatic washer or an 8-channel dispenser. For each washing, add 300 µL of Washing Solution (see 9.3) to all wells, then remove the liquid by aspiration or decantation. The residual volume of the Washing Solution after each aspiration or decantation should be no more than 5µL. After washing, carefully remove the remaining liquid from the wells on the absorbent paper. For the automatic washer/analyzer, the Washing Solution volume can be increased to 350 µL.

10.6 Add **100 µL of Conjugate Solution** to all wells.

10.7 Cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.8 At the end of the incubation period, aspirate and wash each well 5 times as described in 10.5.

10.9 Add **100 µL of Substrate Solution** to all wells. The introduction of the Substrate Solution into the wells must be carried out within 2-3 minutes. Incubate the microplate in the dark **at room temperature (+18…+25°C) for 15 minutes**.

10.10 Add **100 µL of Stop Solution** to all wells in the same order as the Substrate Solution. After adding the Stop Solution, the contents of the wells turn yellow.

10.11 Read the optical density (OD) of the wells at 450nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution. Set photometer blank on CAL1.

10.12 Plot a calibration curve in linear coordinates: (x) is the concentration of aTG IU/mL in the calibrators, (y) – OD versus aTG concentration (OD 450 nm / 620–680 nm). Manual or computerized data reduction is applicable at this stage. Point-by-point or linear data reduction is recommended due to non-linear shape of curve.

10.13 Determine the corresponding concentration of aTG in tested samples from the calibration curve. In the case of preliminary dilution of the test sample (see 9.4), the obtained result should be multiplied by the dilution factor.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is above 0.15, and the values of the Control Serum fall into the required range (see Quality control Data Sheet).

12. EXPECTED VALUES

Therapeutical consequences should not be based on results of IVD methods alone – all available clinical and laboratory findings should be used by a physician to elaborate therapeutically measures. Each laboratory should establish its own normal range for aTG. Based on data obtained by XEMA, the following normal range is recommended (see below).

NOTE: values of aTG concentrations in the tested samples that are below the LoD (5.0 IU/mL) and also exceed the value of the upper calibrator (3000 IU/mL) should be provided in the following form: «the aTG concentration of tested sample X is «lower than 5.0 IU/mL» or «higher than 3000 IU/mL».

Sex, age	Units, IU/mL	
	Lower limit	Upper limit
Males	-	100
Females	-	100
Females >50 yrs	-	150

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1 Precision of Measurement

Repeatability (Intra assay repeatability) was determined by evaluation the coefficient of variation (CV) for 2 different samples during 1 day in 24 replicates on one series of ELISA kit.

Sample	Concentration, IU/mL	CV, %
1	1256.9	2.46
2	110.7	5.39

Reproducibility (Inter assay reproducibility) was determined by evaluating the coefficients of variation for 2 samples during 5 days in 8-replicate determinations.

Sample	Concentration, IU/mL	CV, %
1	1264.5	4.33
2	107.9	6.43

Reproducibility between lots was investigated by testing samples for one day on three lots. Each sample was run in 8 replicates.

Sample	Concentration1, IU/mL	Concentration2, IU/mL	Concentration3, IU/mL	CV, %
121	1270.5	1262.8	1276.6	0.54
433	109.4	114.5	118.5	4.00

13.1.2 Trueness

The trueness of measurement is the degree of closeness of the average value obtained from a large number of measurement results to the true value. The bias of the measurement result (bias of measurements) is the difference between the mathematical expectation of the measurement result and the true value of the measurand. The bias was calculated for each sample and it was determined that it corresponds to the specified limits of ± 10%.

13.1.3 Linearity

Linearity was determined using sera samples with known aTG concentration (low and high) and mixing them with each other and buffer solution in different proportions. According to the measurements, linear range of kit is 100-3000 IU/mL ±10%.

13.1.4 Analytical sensitivity

Limit of detection (LoD) – the lowest aTG concentration in the serum or plasma sample that is detected by the aTG EIA kit is no lower than 5 IU/mL.

Limit of quantification (LoQ) – the lowest concentration of the analyte in the sample that is determined quantitatively with the declared trueness for aTG EIA kit is 100 IU/mL.

13.1.5 Analytical specificity

For the analysis result is not affected by the presence in the sample of bilirubin in a concentration of up to 0.21 mg/mL and hemoglobin in a concentration of up to 10 mg/mL.

14. REFERENCES

1. U Feldt-Rasmussen – Analytical and clinical performance goals for testing autoantibodies to thyroperoxidase, thyroglobulin, and thyrotropin receptor. Clin. Chem., Jan 1996; 42: 160 – 163.
2. PW Ladenson – Optimal laboratory testing for diagnosis and monitoring of thyroid nodules, goiter, and thyroid cancer. Clin. Chem., Jan 1996; 42: 183 – 187.
3. Anthony P. Weetman – Graves' Disease. N. Engl. J. Med., Oct 2000; 343: 1236 – 1248.4. Buchanan W., Alexander W., Crooks J., Koutras D., Wayne E., Anderson J.R., Goudie R. – Association of thyrotoxicosis and autoimmune thyroiditis. Brit.Med. J., 1961, 1:843.
4. Наказ МОЗ України №325 від 08.06.2015 «Про затвердження Державних санітарно-протиепідемічних правил і норм щодо поводження з медичними відходами».
5. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
6. НПАОП 85.14-1.09-81. Правила облаштування, техніки безпеки, виробничої санітарії, протиепідемічного режиму і особистої гігієни при роботі в лабораторіях (відділеннях, відділах) санітарноепідеміологічних установ системи Міністерства охорони здоров`я СРСР (НАОП 9.1.50-1.09-81)

SAMPLES IDENTIFICATION PLAN

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

LOT _____ DATE _____

SAMPLES IDENTIFICATION PLAN

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

LOT _____ DATE _____

	Manufacturer
	*In vitro* diagnistic medical device
	Catalogue number
	Use-by date
	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
	Authorized representative in the European Community/European Union
	CE Conformity Marking

For any issues related to operation of the kit and technical support, please contact by telefon number

+38 044 294-69-78

or write to:

qa@xema.com.ua

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Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of thyroid stimulating hormone in human serum or plasma

TSH EIA

Catalogue number REF **K201**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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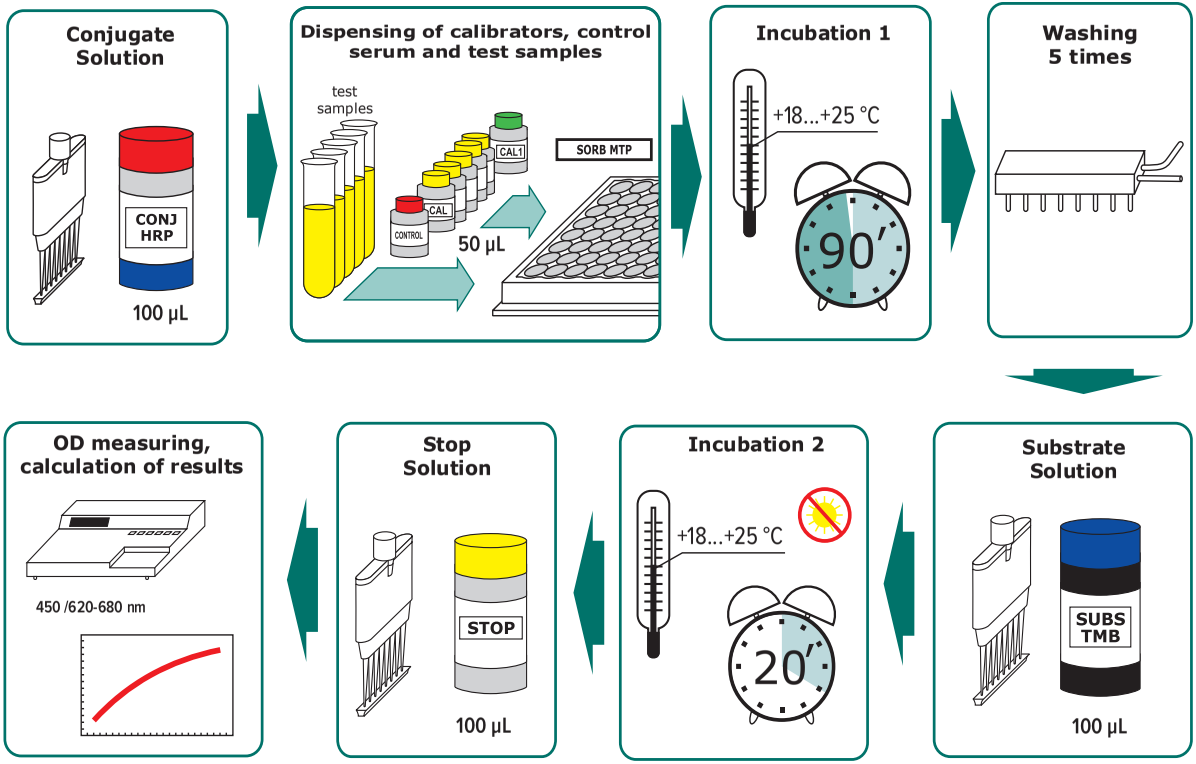
ASSAY PROCEDURE



K201

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of thyroid stimulating hormone in human serum or plasma
TSH EIA

1. INTENDED USE

The TSH EIA kit is an enzyme immunoassay, intended for the quantitative determination of thyroid stimulating hormone in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Thyroid stimulating hormone (TSH) is a glycoprotein with molecular weight ca.30 kDa which is secreted by hypophysis. A molecule of TSH consists of two noncovalently bound subunits: α and β. β-subunit determines biological activity and immunological specificity of TSH.

TSH stimulates thyroid gland to secrete thyroid hormones. When the concentration of these hormones in blood serum increases secretion of TSH is inhibited; on the contrary, when the level of thyroid hormones decreases, in the pituitary gland, the release of TSH increases, and therefore the production and release increases thyroid hormones.TSH secretion is subject to circadian rhythms with highest levels seen early in the morning (6 a.m.). Changes of TSH blood level during a day are not significant; nevertheless, if the results do not correspond with clinical status and other laboratory data, it is recommended to take and test another blood sample.

Determination of TSH level in serum is recommended in the following states and conditions:

1) diagnostics of dysfunction of the thyroid gland;

2) hypothyroidism (TSH level is increased. The diagnosis is confirmed by low concentrations of total and free T4 and T3. In mild subclinical forms when T4 and T3 levels are within normal ranges, determination of TSH concentration is critical);

3) hyperthyroidism (synthesis and secretion of TSH are inhibited); monitoring of replacement therapy;

4) screening for congenital hypothyroidism (on the fifth day of life, the level is determined TSH in a blood spot on filter paper or in blood serum). TSH level elevated at birth (up to 35 mIU/L), but after a few days it decreases to basal (both in boys and in girls).

Serum TSH level is elevated during pregnancy, after physical stress, in individuals with lowered blood pressure and lowered temperature. Secretion of TSH is inhibited by Cortisol and Growth hormone. Low TSH levels are often seen in elderly people, in patients with chronic renal insufficiency, liver cirrhosis, in retardation of sexual development, in secondary amenorrhea, Cushing syndrome, acromegaly.

3. PRINCIPLE OF THE TEST

The determination of TSH is based on the two-site sandwich enzyme immunoassay principle. On the inner surface of the microplate wells are immobilized specific murine monoclonal antibodies to β-chain of human TSH. Second antibodies – Fab 2 fragment of murine monoclonal antibodies to human TSH conjugated to the horseradish peroxidase is used as enzyme conjugate.

The analysis procedure includes two stages of incubation:

- during the first stage TSH from the specimen is captured by the antibodies coated onto the microwell surface, as well as horseradish peroxidase-conjugated monoclonal antibodies bind to free epitopes of immobilized TSH;
- during the second stage, the complexes formed due to the reaction with the chromogen 3,3',5,5'-tetramethylbenzidine are visualized.

After stopping the reaction with a stop solution, the intensity of the color of the microwells is measured. The optical density in the microwell is directly related to the quantity of the measured TSH in the serum specimen (plasma). The concentration is determined according to the calibration graph of the dependence of the optical density on the content of TSH in the calibration samples.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P201Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with murine monoclonal antibodies to β-chain of human TSH; ready to use
C201Z	CAL 1	**Calibrator C1**	2 mL	1	Solution based on phosphate buffer (pH 7.2-7.4), free of human TSH, with preservative, ready to use (yellow liquid)
C201Z	CAL 2-6	**Calibrators**	0.8 mL	5	Solution based on phosphate buffer (pH 7.2-7.4), containing 0,2; 1; 5; 10 and 20 mIU/L of human TSH, with preservative, ready to use (red liquids)
Q201Z	CONTROL	**Control Serum**	0.8 mL	1	Solution based on human serum, containing of known human TSH content, with preservative, ready to use (colourless liquid)
T201Z	CONJ HRP	**Conjugate Solution**	14 mL	1	Solution of Fab 2 fragment of murine monoclonal antibodies to human TSH conjugated to the horseradish peroxidase; ready to use (blue liquid)
R055Z	SUBS TMB	**Substrate Solution**	14 mL	1	Tetramethylbenzidine (TMB) substrate solution; ready to use (colourless liquid)
S008Z	BUF WASH 26X	**26x Concentrate Washing Solution**	22 mL	1	Buffer solution with detergent, 26x concentrate (colourless liquid)
R050Z	STOP	**Stop Solution**	14 mL	1	5.0% solution of sulphuric acid; ready to use (colourless liquid)
The kit also includes instruction for use, quality control data sheet and plate sealing tape (2 pcs.)					

5. EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDED

– microplate photometer with 450 nm wavelength or 450\620-680 nm;
– automatic plate washer (optional);
– micropipettes with variable volume, range volume 5-1000 µL;
– graduated cylinder of 1000 mL capacity;
– distilled or deionized water;
– timer;
– vortex mixer;
– disposable gloves;
– absorbent paper.

6. WARNING AND PRECAUTIONS

In order to prevent incorrect results, strictly follow the recommended order and duration of the analysis procedure.

6.1. The kit is for *in vitro* diagnostic use only. For professional laboratory use.

6.2. Follow the rules mentioned below during the kit using:

- do not use kit beyond expire date;
- do not use the kit if its packaging is damaged;
- in order to avoid contamination, use new tips to pipette samples and reagents;
- use only verified equipment;
- close each vial with its own cap, after using the reagent;
- do not use components of other kits or reagents of other manufacturers;
- do not let wells dry after completing the rinsing step; immediately proceed to the next stage;
- avoid bubbles when adding reagents.

ATTENTION! The TMB substrate solution is light sensitive. Avoid prolonged exposure of the component to light.

6.3. Some kit components, such as stop solution, substrate solution, and washing solution, may cause toxic or irritant effects. If they get on the skin or mucosa, the affected area should be washed with plenty of running water.

6.4. All human products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guidelines or regulations.

6.5. The Calibrators and Control Serum included in the kit are negative for antibodies to HIV 1,2, hepatitis C virus and HBsAg, but the reagents should be considered as potentially infectious material and handled carefully.

6.6. Specimens must not contain any azide compounds, as they inhibit activity of peroxidase.

6.7. Wear protective gloves, protective clothing, eye protection, face protection.

6.8. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.

6.9. Safety Data Sheet for this product is available upon request directly from XEMA LLC.

6.10. Serious incidents related to the kit must be reported to the manufacturer, Authorized Representative, and to the Competent Authority of the EU member state(s) where the incident has occurred.

7. SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE OF SAMPLES

7.1. Blood sampling should be carried out from the cubital vein with a disposable needle using a vacuum blood sampling system. Serum or plasma specimens should be clearly labeled and identified. Serum must be separated from the clot as early as possible to avoid hemolysis of red blood cells. If there are any visible particles in the sample, they should be removed by centrifugation at 3000-5000 rpm for 20 minutes at room temperature or by filtration.

Don't use samples with high lipidemia, hemolysis as they may give false test results.

7.2. Specimen should be stored at +2…+8°C up to 3 days. Specimen held for a longer time, should be placed in a freezer at -15°C or below, do not refreeze/thaw samples.

7.3. For the transportation of samples, it is recommended to use triple packaging. The primary package is the labeled tube containing the sample. Secondary packaging is a polyethylene bag that is hermetically closed with a zip-lock. The outer packaging is a heat-insulating container, while the secondary packaging is placed in the outer packaging for transportation in the center of the thermal container. Frozen refrigerants are placed on the bottom, along the side walls of the thermal container, and cover the samples with them.

8. TRANSPORTATION AND STORAGE TERMS OF KIT, WASTE DISPOSAL

Information about the singularity storage conditions, transportation of the kit, and disposal of waste should be taken into account by all persons who participate in these processes.

8.1. Transportation

The TSH EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25ºC for 5 days is acceptable.

8.2. Storage

The TSH EIA kit should be stored in the manufacturer's packaging at +2...+8°C. Do not freeze.

The kit contains reagents sufficient for 96 determinations including Calibrators and Control Serum.

Once opened test-kit is stable for 2 months when stored properly as intended by manufacturer at 2-8°C.

In case of partial use of the kit, the components should be stored in the following way:

- strips that remain unused must be carefully sealed with the plate sealing tape and stored at +2...+8°C within 2 months;
- Substrate Solution, Stop Solution, and Washing Solution concentrate after opening the vial, can be stored tightly closed at +2...+8°C until the kit's shelf life;
- Conjugate Solution, Calibrators and Control Serum after opening the vial, can be stored tightly closed at +2...+8°C within 2 months.

  NOTE: Single freezing of Calibrators and Control Serum in aliquots is allowed.
- diluted Washing Solution can be stored at room temperature (+18…+25°C) for up to 5 days or at +2…+8°C for up to 14 days.

  Kits that were stored in violation of the storage condition cannot be used.

8.3. Disposal

Expired kit components, used reagents and materials, as well as residual samples must be inactivated and disposed of in accordance with legal requirements.

9. REAGENTS PREPARATION

9.1. All reagents (including microstrips) and test samples should be allowed to reach room temperature (+18…+25 °C) for at least 30 minutes before use.

9.2. Microplate preparation

Open the package with the microplate and install the required number of strips into the frame. Unused strips must be sealed with plate sealing tape to prevent moisture from affecting the plate's holes and placed back in the bag.

9.3. Washing Solution preparation

Add the contents of the 22 mL Washing Solution concentrate vial to 550 mL of distilled or deionized water and mix thoroughly. In case of partial use of the kit, take the necessary amount of Washing Solution concentrate and dilute it 26 times with distilled or deionized water.

The spending of the components in case of partial use of the kit is given in the table:

Quantity of strips	1	2	3	4	5	6	7	8	9	10	11	12
Volume of the Washing Solution concentrate, mL	1.8	3.6	5.4	7.2	9	10.8	12.6	14.4	16.2	18	19.8	22
Volume of water, mL	45	90	135	180	225	270	315	360	405	450	495	550

9.4. Samples preparation

If suggested analyte concentration in the sample exceeds the 20 mIU/L, additionally dilute this sample accordingly, using (Calibrator C1). Use of other buffers or reagents for sample dilution may lead to incorrect measurement.

NOTE: in order to obtain reliable results, we recommend to use several successive dilutions of the blood serum (plasma) sample

Do not dilute Control Serum and Calibrators!

10. ПРОВЕДЕННЯ АНАЛІЗУ

10.1 Put the desired number of strips into the frame based on the number of test samples in 2 replicates and 14 wells for Calibrators and Control Serum (2 wells for each Calibrator (CAL 1-6) and 2 wells for Control Serum (Q)).

10.2 If necessary, dilute the test samples as described in 9.4.

10.3 Dispense **100 µL of Conjugate Solution** to all wells.

10.4 Dispense **50 µL of Calibrators and Control Serum as well as 50 µL of test serum/plasma samples** (SAMP) to the wells of the microplate according to the scheme below. The introduction of Calibrators, Control Serum and test samples should be carried out within 5 minutes to ensure equal incubation time for the first and last samples.

NOTE: during performing several independent series of tests, Calibrators, and Control Serum should be used each time.

Scheme of introduction of samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL1	CAL1	SAMP2	SAMP2	SAMP10	SAMP10						
B	CAL2	CAL2	SAMP3	SAMP3	SAMP11	SAMP11						
C	CAL3	CAL3	SAMP4	SAMP4	SAMP12	SAMP12						
D	CAL4	CAL4	SAMP5	SAMP5								
E	CAL5	CAL5	SAMP6	SAMP6								
F	CAL6	CAL6	SAMP7	SAMP7								
G	Q	Q	SAMP8	SAMP8								
H	SAMP1	SAMP1	SAMP9	SAMP9								

10.5 Carefully mix the contents of the microplate in a circular motion on a horizontal surface, cover strips with a plate sealing tape and incubate for **90 minutes at room temperature (+18...+25°C)**.

10.6 At the end of the incubation period, remove and discard the plate cover. Aspirate and wash each well 5 times using an automatic washer or an 8-channel dispenser. For each washing, add 300 µL of Washing Solution (see 9.3) to all wells, then remove the liquid by aspiration or decantation. The residual volume of the Washing Solution after each aspiration or decantation should be no more than 5µL. After washing, carefully remove the remaining liquid from the wells on the absorbent paper. For the automatic washer/analyzer, the wash solution volume can be increased to 350 µL.

10.7 Add **100 µL of Substrate Solution** to all wells. The introduction of the Substrate Solution into the wells must be carried out within 2-3 minutes. Incubate the microplate in the dark **at room temperature (+18...+25°C) for 20 minutes**.

10.8 Add **100 µL of Stop Solution** to all wells in the same order as the Substrate Solution. After adding the Stop Solution, the contents of the wells turn yellow.

10.9 Read the optical density (OD) of the wells at 450nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the Stop Solution. Set photometer blank on CAL1.

10.10 Plot a calibration curve in linear coordinates: (x) is the TSH concentration in the calibrators mIU/L, (y) – OD versus TSH concentration (OD 450 nm / 620–680 nm). Manual or computerized data reduction is applicable at this stage. Point-by-point or linear data reduction is recommended due to non-linear shape of curve.

10.11 Determine the corresponding concentration of TSH in tested samples from the calibration curve. In the case of preliminary dilution of the test sample (see 9.4), the obtained result should be multiplied by the dilution factor.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is above 0.15, and the values of the Control Serum fall into the required range (see Quality control Data Sheet).

12. EXPECTED VALUES

Therapeutical consequences should not be based on the results of IVD methods alone – all available clinical and laboratory findings should be used by a physician to elaborate therapeutically measures. Each laboratory should establish its own normal range for TSH. Based on data obtained by XEMA, the following normal range is recommended (see below).

NOTE: values of TSH concentrations in the tested samples that are below the LoD (0.04 mIU/L) and also exceed the value of the upper Calibrator (20 mIU/L) should be provided in the following form : «the TSH concentration of tested sample X is «lower than 0.04 mIU/L» or «higher than 20 mIU/L».

Sex, age	Units, mIU/L	
	Lower limit	Upper limit
Healthy donors	0.3	4.0

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1 Precision of Measurement

Repeatability (Intra assay repeatability) was determined by evaluation the coefficient of variation (CV) for 2 different samples during 1 day in 24 replicates on one series of ELISA kit.

Sample	Concentration, mIU/L	CV, %
1	2.12	7.2
2	3.64	3.8

Reproducibility (Inter assay reproducibility) was determined by evaluating the coefficients of variation for 2 samples during 5 days in 8-replicate determinations.

Sample	Concentration, mIU/L	CV, %
1	2.27	12.0
2	3.87	6.4

Reproducibility between lots was investigated by testing samples for one day on three lots. Each sample was run in 8 replicates.

Sample	Concentration1, mIU/L	Concentration2, mIU/L	Concentration3, mIU/L	CV, %
1	2.32	2.02	1.81	9.9
2	3.71	3.56	3.32	5.6

13.1.2 Trueness

The trueness of measurement is the degree of closeness of the average value obtained from a large number of measurement results to the true value. The bias of the measurement result (bias of measurements) is the difference between the mathematical expectation of the measurement result and the true value of the measurand. The bias was calculated for each sample and it was determined that it corresponds to the specified limits of ± 10%.

13.1.3 Linearity

Linearity was determined using sera samples with known TSH concentration (low and high) and mixing them with each other and buffer solution in different proportions. According to the measurements, linear range of kit is 0.2-10 mIU/L ±10%.

13.1.4 Analytical sensitivity

Limit of detection (LoD) – the lowest TSH concentration in the serum or plasma sample that is detected by the TSH EIA kit is no lower than 0.04 mIU/L.

Limit of quantification (LoQ) – the lowest concentration of the analyte in the sample that is determined quantitatively with the declared trueness for TSH EIA kit is 0,15 mIU/L.

13.1.5 Hook Effect

Hook effect is absent for all samples up to reasonably foreseen concentrations 20 mIU/L.

13.1.5 Analytical specificity

For the analysis result is not affected by the presence in the sample of bilirubin in a concentration of up to 0.21 mg/mL and hemoglobin in a concentration of up to 10 mg/mL.

The cross-reactivity of TSH with other analytes is shown in the table:

Analyte	Cross-reactivity, %
HCG	< 0.1
LH	< 0.1
FSH	< 0.1

14. REFERENCES

1. Ekins R. Methods for measurement of free thyroid hormones. In: Free thyroid hormones. Amsterdam: Expecta Medica; 1979; p. 72-92.
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7. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
8. НПАОП 85.14-1.09-81. Правила облаштування, техніки безпеки, виробничої санітарії, протиепідемічного режиму і особистої гігієни при роботі в лабораторіях (відділеннях, відділах) санітарноепідеміологічних установ системи Міністерства охорони здоров`я СРСР (НАОП 9.1.50-1.09-81)

SAMPLES IDENTIFICATION PLAN

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	Manufacturer
	*In vitro* diagnistic medical device
	Catalogue number
	Use-by date
	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
	Authorized representative in the European Community/European Union
	CE Conformity Marking

For any issues related to operation of the kit and technical support, please contact by telefon number

+38 044 294-69-78

or write to:

qa@xema.com.ua

XEMA LLC
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03179, Kyiv, Ukraine
tel.:+38 044 422-62-16
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E-mail: qa@xema.com.ua
www.xema.in.ua

Instruction for use
A solid-phase enzyme immunoassay kit
for the quantitative determination of
triiodothyronine in human serum or plasma

T3 EIA

Catalogue number REF **K211**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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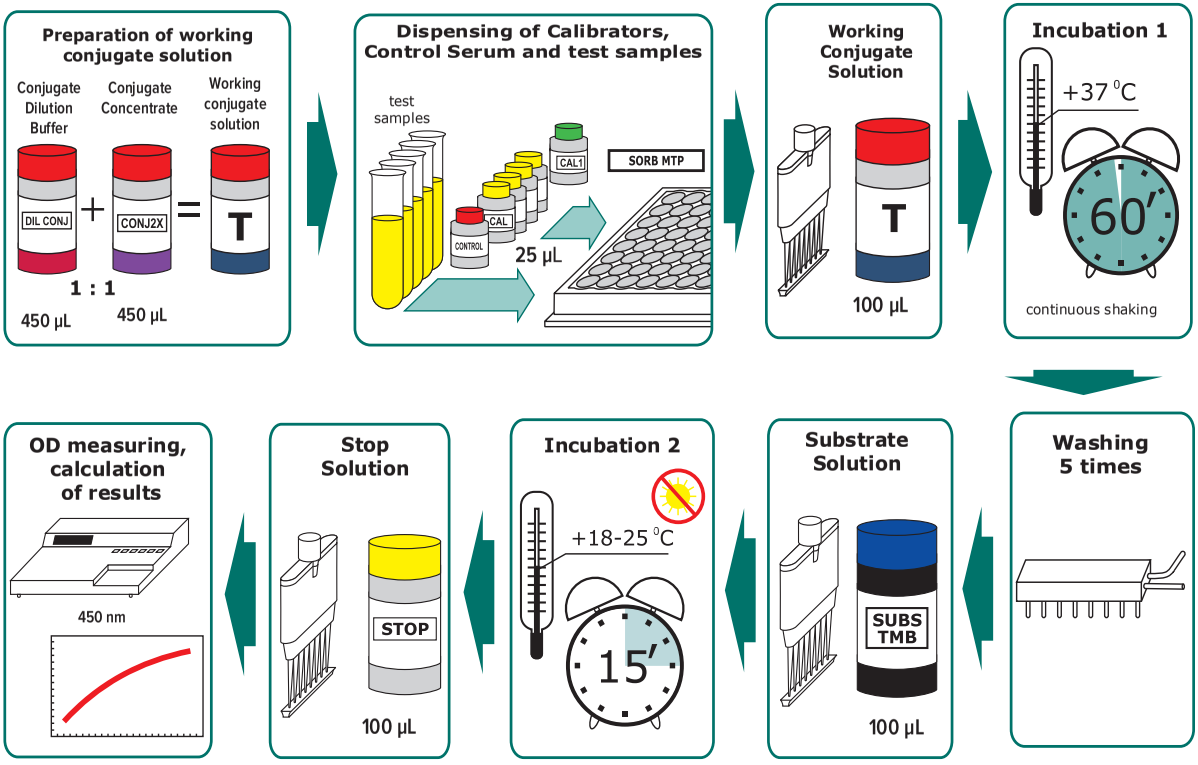
tel.:+ 49 911 931 639 67
E-mail: info@polmed.de
www.polmed.de

ASSAY PROCEDURE



K211

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of triiodothyronine in human serum or plasma
T3 EIA

1. INTENDED USE

The T3 EIA kit is an enzyme immunoassay, intended for the quantitative determination of triiodothyronine in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Triiodothyronine (T3) is a hormone with a molecular weight of 651 Da, 58% of which is iodine. Thyroid hormones thyroxin (T4) and 3,5,3′-triiodothyronine (T3) exert regulatory influences on growth, differentiation, cellular metabolism and development of skeletal and organ systems. T4 and T3 in blood are found both in free and bound form – mostly, they are bound to thyroxin binding globulin (TBG). Only free forms of T3 and T4 exert hormonal activity also their percentage is very low – 0.3% for T3 and 0.03% for T4.

The concentration of T3 is much less than that of T4 but its metabolic activity is about 3 times greater. About 80% of T3 is produced in peripheral tissues by deiodination of T4, and only 20% is secreted by thyroid gland. That is why in hypothyroid patients T3 level may for a long time remain on the lower limit of the normal range, because its loss may be compensated by enhanced conversion of T4 into T3.

Determination of T3 level is most useful in T3-hyperthyroidism because 5-10% of such patients do not show significant changes in T4 level while concentration of T3 is highly elevated. Elevated T3 levels are seen in early thyroid hypofunction, after intake of estrogens, oral contraceptives, heroin, methadone, during pregnancy.

Decreased concentrations of T3 are found in initial stage of hyperthyroidism, acute and subacute thyroiditis, after intake of androgens, dexamethasone, salycilates. Decreased concentrations of T3 are found in initial stage of hyperthyroidism, acute and subacute thyroiditis, after intake of androgens, dexamethasone, salycilates.

3. TEST PRINCIPLE

The determination of triiodothyronine is based on the competition principle of the enzyme immunoassay. On the inner surface of the microplate wells are immobilized specific rabbit polyclonal to T3 antibodies. T3 conjugated to the horseradish peroxidase is used as enzyme conjugate. The analysis procedure includes two stages of incubation:

- during the first stage T3 from the specimen competes with the conjugated T3 for coating antibodies. As a result, a complex bounded to the solid phase and containing peroxidase is formed.
- during the second stage, the complexes formed due to the reaction with the chromogen 3,3′,5,5′-tetramethylbenzidine are visualized.

After stopping the reaction with a stop solution, the intensity of the color of the microwells is measured. The optical density in the microwell is inversely related to the quantity of the measured T3 in the serum specimen (plasma).

The concentration is determined according to the calibration graph of the dependence of the optical density on the content of T3 in the calibration samples.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P211Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with rabbit polyclonal antibodies to T3, ready to use;
C211Z	CAL 1	**Calibrator C1**	0.5 mL	1	Solution based on tris buffer (pH 7.2-7.4), free of T3, with preservative, ready to use (yellow liquid)
C211Z	CAL 2-5	**Calibrators**	0.5 mL	4	Solutions based on tris buffer (pH 7.2-7.4), containing 0,75; 1,5; 7,5 and 15 nmol/L of T3, with preservative, ready to use (blue liquids)
Q211Z	CONTROL	**Control serum**	0.5 mL	1	Solution based on human plasma, containing of known T3 content, with preservative, ready to use (colourless liquid)
T211XZ	CONJ 2X	**Conjugate Concentrate**	7 mL	1	Solution of T3 conjugated to the horseradish peroxidase; 2x concentrate (purple liquid)
ST211Z	DIL CONJ	**Conjugate Dilution Buffer**	7 mL	1	Buffer solution with detergent ready to use (red liquid)
R055Z	SUBS TMB	**Substrate Solution**	14 ml (мл)	1	Tetramethylbenzidine (TMB) substrate solution; ready to use (colourless liquid)
S008Z	BUF WASH 26X	**26x Concentrate Washing Solution**	22 ml (мл)	1	Buffer solution with detergent, 26x concentrate (colourless liquid)
R050Z	STOP	**Stop Solution**	14 ml (мл)	1	5.0% solution of sulphuric acid; ready to use (colourless liquid)
The kit also includes instruction for use, quality control data sheet and plate sealing tape (2 pcs.)					

5. EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDED

- microplate photometer with 450 nm wavelength;
- shaker maintaining a speed of 500 rpm for +37 °C±2°C;
- automatic plate washer (optional);
- micropipettes with variable volume, range volume 5-1000 µL;
- graduated cylinder of 1000 mL capacity;
- distilled or deionized water;
- timer;
- vortex mixer;
- disposable gloves;
- absorbent paper.

6. WARNING AND PRECAUTIONS

In order to prevent incorrect results, strictly follow the recommended order and duration of the analysis procedure.

6.1. The kit is for *in vitro* diagnostic use only. For professional laboratory use.

6.2. Follow the rules mentioned below during the kit using:

- do not use kit beyond expire date;
- do not use the kit if its packaging is damaged;
- in order to avoid contamination, use new tips to pipette samples and reagents;
- use only verified equipment;
- close each vial with its own cap, after using the reagent;
- do not use components of other kits or reagents of other manufacturers;
- do not let wells dry after completing the rinsing step; immediately proceed to the next stage;
- avoid bubbles when adding reagents.

ATTENTION! The TMB substrate solution is light sensitive. Avoid prolonged exposure of the component to light.

6.3. Some kit components, such as stop solution, substrate solution, and washing solution, may cause toxic or irritant effects. If they get on the skin or mucosa, the affected area should be washed with plenty of running water.

6.4. All human products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guidelines or regulations.

6.5. The Calibrators and Control Serum included in the kit are negative for antibodies to HIV 1,2, hepatitis C virus and HBsAg, but the reagents should be considered as potentially infectious material and handled carefully.

6.6. Specimens must not contain any azide compounds, as they inhibit activity of peroxidase.

6.7. Wear protective gloves, protective clothing, eye protection, face protection.

6.8. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.

6.9. Safety Data Sheet for this product is available upon request directly from XEMA LLC.

6.10. Serious incidents related to the kit must be reported to the manufacturer, Authorized Representative, and to the Competent Authority of the EU member state(s) where the incident has occurred.

7. SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE OF SAMPLES

7.1. Blood sampling should be carried out from the cubital vein with a disposable needle using a vacuum blood sampling system. Serum or plasma specimens should be clearly labeled and identified. Serum must be separated from the clot as early as possible to avoid hemolysis of red blood cells. If there are any visible particles in the sample, they should be removed by centrifugation at 3000-5000 rpm for 20 minutes at room temperature or by filtration.

Don't use samples with high lipidemia, hemolysis as they may give false test results.

7.2. Specimen should be stored at +2…+8°C up to 3 days. Specimen held for a longer time, should be placed in a freezer at -15°C or below; do not refreeze/thaw samples.

7.3. For the transportation of samples, it is recommended to use triple packaging. The primary package is the labeled tube containing the sample. Secondary packaging is a polyethylene bag that is hermetically closed with a zip-lock. The outer packaging is a heat-insulating container, while the secondary packaging is placed in the outer packaging for transportation in the center of the thermal container. Frozen refrigerants are placed on the bottom, along the side walls of the thermal container, and cover the samples with them.

8. TRANSPORTATION AND STORAGE TERMS OF KIT, WASTE DISPOSAL

Information about the singularity storage conditions, transportation of the kit, and disposal of waste should be taken into account by all persons who participate in these processes.

8.1. Transportation

The T3 EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25ºC for 5 days is acceptable.

8.2. Storage

The T3 EIA kit should be stored in the manufacturer's packaging at +2...+8°C. Do not freeze.

The kit contains reagents sufficient for 96 determinations including Calibrators and Control Serum.

Once opened test-kit is stable for 2 months when stored properly as intended by manufacturer at 2-8°C.

In case of partial use of the kit, the components should be stored in the following way:

- strips that remain unused must be carefully sealed with the plate sealing tape and stored at +2...+8°C within 2 months;
- Substrate Solution, Stop Solution, and Washing Solution concentrate after opening the vial, can be stored tightly closed at +2...+8°C until the kit's shelf life;
- Conjugate Concentrate, Conjugate Dilution Buffer, Calibrators and Control Serum after opening the vial, can be stored tightly closed at +2...+8°C within 2 months;
- diluted Washing Solution can be stored at room temperature (+18…+25°C) for up to 5 days or at +2…+8°C for up to 14 days.

Kits that were stored in violation of the storage condition cannot be used.

8.3. Disposal

Expired kit components, used reagents and materials, as well as residual samples must be inactivated and disposed of in accordance with legal requirements.

9. REAGENTS PREPARATION

9.1. All reagents (including microstrips) and test samples should be allowed to reach room temperature (+18…+25 °C) for at least 30 minutes before use.

9.2. Microplate preparation

Open the package with the microplate and install the required number of strips into the frame. Unused strips must be sealed with plate sealing tape to prevent moisture from affecting the plate's holes and placed back in the bag.

9.3. Washing Solution preparation

Add the contents of the 22 mL Washing Solution concentrate vial to 550 mL of distilled or deionized water and mix thoroughly. In case of partial use of the kit, take the necessary amount of Washing Solution concentrate and dilute it 26 times with distilled or deionized water.

9.4. Working conjugate solution preparation

Prepare a working conjugate solution by 2 dilutions of Conjugate Concentrate in Conjugate Dilution Buffer (eg, 450 µL of concentrate + 450 µL of Conjugate Dilution Buffer). In the case of partial use of the kit, take the necessary amount of Conjugate Concentrate and dilute it 2 times with Conjugate Dilution Buffer, since the working conjugate solution in a diluted form is not stored for a long time.

The spending of the components in case of partial use of the kit is given in the table:

Quantity of strips	1	2	3	4	5	6	7	8	9	10	11	12
Volume of the Washing Solution concentrate, mL	1.8	3.6	5.4	7.2	9	10.8	12.6	14.4	16.2	18	19.8	22
Volume of water, mL	45	90	135	180	225	270	315	360	405	450	495	550
Volume of Conjugate Concentrate, mL	0.45	0.9	1.35	1.8	2.25	2.7	3.15	3.6	4.05	4.5	4.95	5.4
Volume of Conjugate Dilution Buffer, mL	0.45	0.9	1.35	1.8	2.25	2.7	3.15	3.6	4.05	4.5	4.95	5.4

10. ASSAY PROCEDURE

10.1 Put the desired number of strips into the frame based on the number of test samples in 2 replicates and 12 wells for Calibrators and Control Serum (2 wells for each calibrator (CAL 1-5) and 2 wells for control serum (Q)).

10.2 Prepare Working conjugate solution as described in 9.4.

10.3 Dispense **25 µL of Calibrators and Control Serum as well as 25 µL of test serum/plasma samples** (SAMP) to the wells of the microplate according to the scheme below. The introduction of Calibrators, Control Serum and test samples should be carried out within 5 minutes to ensure equal incubation time for the first and last samples.

Note: during performing several independent series of tests, Calibrators, and Control Sample should be used each time.

Scheme of introduction of samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL1	CAL1	SAMP3	SAMP3	SAMP11	SAMP11						
B	CAL2	CAL2	SAMP4	SAMP4	SAMP12	SAMP12						
C	CAL3	CAL3	SAMP5	SAMP5								
D	CAL4	CAL4	SAMP6	SAMP6								
E	CAL5	CAL5	SAMP7	SAMP7								
F	Q	Q	SAMP8	SAMP8								
G	SAMP1	SAMP1	SAMP9	SAMP9								
H	SAMP2	SAMP2	SAMP10	SAMP10								

10.4 Dispense **100 µL of Working conjugate solution** to all wells.

10.5 Carefully mix the contents of the microplate in a circular motion on a horizontal surface, cover strips with a plate sealing tape and incubate for **60 minutes at +37°C with continuous shaking 500 rpm**.

10.6 At the end of the incubation period, remove and discard the plate cover. Aspirate and wash each well 5 times using an automatic washer or an 8-channel dispenser. For each washing, add 300 µL of Washing Solution (see 9.3) to all wells, then remove the liquid by aspiration or decantation. The residual volume of the Washing Solution after each aspiration or decantation should be no more than 5µL. After washing, carefully remove the remaining liquid from the wells on the absorbent paper. For the automatic washer/analyzer, the Washing Solution volume can be increased to 350 µL.

10.7 Add **100 µL of Substrate Solution** to all wells. The introduction of the substrate solution into the wells must be carried out within 2-3 minutes. Incubate the microplate in the dark **at room temperature (+18...+25°C) for 15 minutes**.

10.8 Add **100 µL of Stop Solution** to all wells in the same order as the substrate solution. After adding the Stop Solution, the contents of the wells turn yellow.

10.9 Read the optical density (OD) of the wells at 450nm using a microplate photometer within 5 minutes of adding the Stop Solution.

10.10 Plot a calibration curve in semi-logarithmic coordinates: (x) is the decimal logarithm of the T3 concentration in the calibrators nmol/L, (y) – OD versus T3 concentration (OD 450 nm). Manual or computerized data reduction is applicable at this stage. Point-by-point or linear data reduction is recommended due to non-linear shape of curve. Adjust the concentration of CAL1 to an infinitesimally small value, for example, 0.001 nmol/L.

10.11 Determine the corresponding concentration of T3 in tested samples from the calibration curve.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is above 1.2, and the values of the Control Serum fall into the required range (see Quality control Data Sheet).

12. EXPECTED VALUES

Therapeutical consequences should not be based on results of IVD methods alone – all available clinical and laboratory findings should be used by a physician to elaborate therapeutically measures. Each laboratory should establish its own normal range for T3. Based on data obtained by XEMA, the following normal range is recommended (see below). NOTE: the patients that have received murine monoclonal antibodies for radioimaging or immunotherapy develop high titered anti-mouse antibodies (HAMA). The presence of these antibodies may cause false results in the present assay. Sera from HAMA positive patients should be treated with depleting adsorbents before assaying.

NOTE: values of T3 concentrations in the tested samples that are below the LoD (0.2 nmol/L) and also exceed the value of the upper calibrator (15 nmol/L) should be provided in the following form: «the T3 concentration of tested sample X is «lower than 0.2 nmol/L» or «higher than 15 nmol/L».

The concentration values of the T3 EIA kit calibrators are expressed in nmol/L. To convert the concentration in ng/mL it is necessary to multiply by 0.65 the obtained concentration value in nmol/L.

1 nmol/L = 0.65 ng/mL

Sex, age	Units, nmol/L		Units alternative, ng/mL	
	Lower limit	Upper limit	Lower limit	Upper limit
Healthy donors	1.2	3.2	0.8	2.1

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1 Precision of Measurement

Repeatability (Intra assay repeatability) was determined by evaluation the coefficient of variation (CV) for 2 different samples during 1 day in 24 replicates on one series of ELISA kit.

Sample	Concentration, nmol/L	CV, %
1	2.32	9.16
2	1.45	9.66

Reproducibility (Inter assay reproducibility) was determined by evaluating the coefficients of variation for 2 samples during 5 days in 8-replicate determinations.

Sample	Concentration, nmol/L	CV, %
1	1.38	9.89
2	1.75	8.41

Reproducibility between lots was investigated by testing samples for one day on three lots. Each sample was run in 8 replicates.

Sample	Concentration1, nmol/L	Concentration2, nmol/L	Concentration3, nmol/L	CV, %
1	2.12	2.02	2.27	13.9
2	1.56	1.44	1.81	15.6

13.1.2 Trueness

The trueness of measurement is the degree of closeness of the average value obtained from a large number of measurement results to the true value. The bias of the measurement result (bias of measurements) is the difference between the mathematical expectation of the measurement result and the true value of the measurand. The bias was calculated for each sample and it was determined that it corresponds to the specified limits of ± 10%.

13.1.3 Linearity

Linearity was determined using sera samples with known T3 concentration (low and high) and mixing them with each other and buffer solution in different proportions. According to the measurements, linear range of kit is 0.75 –15 nmol/L ±10%.

13.1.4 Analytical sensitivity

Limit of detection (LoD) – the lowest T3 concentration in the serum or plasma sample that is detected by the T3 EIA kit is no lower than 0.2 nmol/L.

Limit of quantification (LoQ) – the lowest concentration of the analyte in the sample that is determined quantitatively with the declared trueness for T3 EIA kit is 0.55 nmol/L.

3.1.5 Analytical specificity

For the analysis result is not affected by the presence in the sample of bilirubin in a concentration of up to 0.21 mg/mL and hemoglobin in a concentration of up to 10 mg/mL.

The cross-reactivity of T3 with other analytes is shown in the table:

Analyte	Cross-reactivity, %
L-Thyroxin	0.01
D-Thyroxin	0.04

14. REFERENCES

1. Physiology of thyroid hormones. IN: Division of Drugs and Toxicology, American Medical Association: Drug Evaluations Annual 1995. Amer Med Assn, Chicago, 1995, ch 47, pp 1039-1040.
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H												

LOT _____ DATE _____

	Manufacturer
	*In vitro* diagnistic medical device
	Catalogue number
	Use-by date
	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
	Authorized representative in the European Community/European Union
	CE Conformity Marking

For any issues related to operation of the kit and technical support, please contact by telefon number

+38 044 294-69-78

or write to:

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Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of thyroxin in human serum or plasma

T4 EIA

Catalogue number REF **K212**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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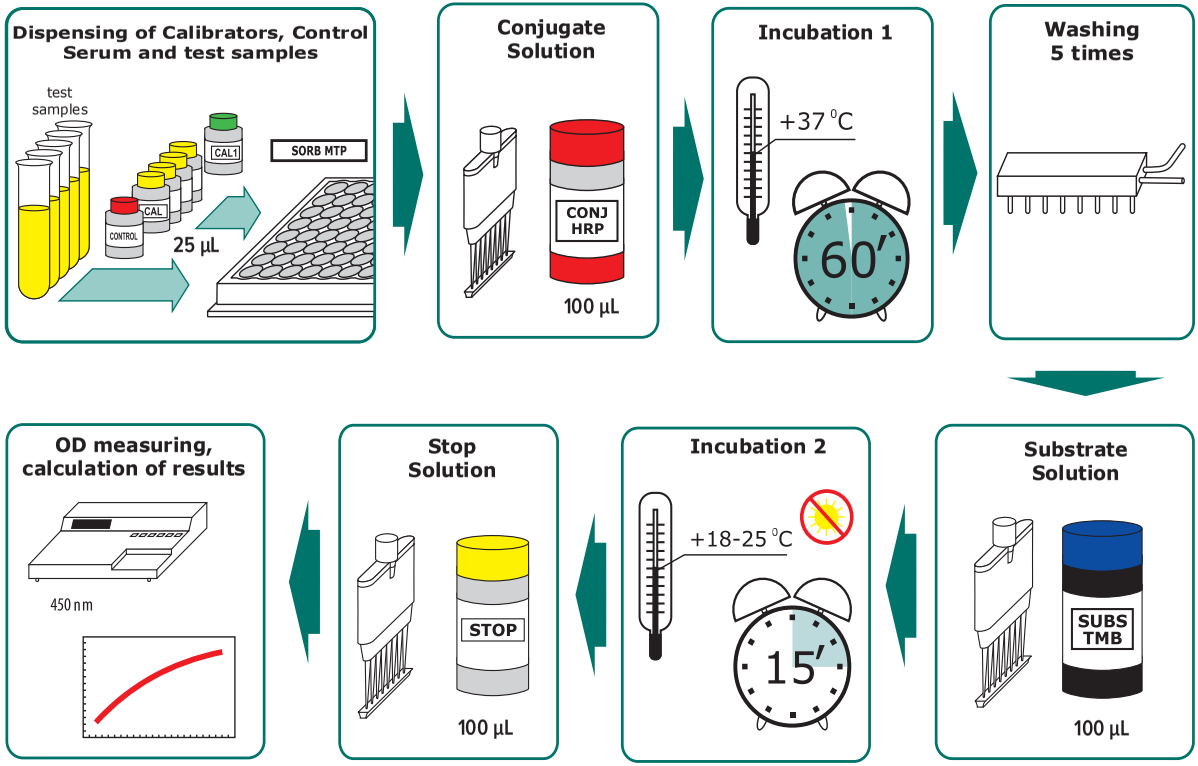
ASSAY PROCEDURE



K212

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of thyroxin in human serum or plasma
T4 EIA

1. INTENDED USE

The T4 EIA kit is an enzyme immunoassay, intended for the quantitative determination of thyroxin in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Thyroxine (T4) and triiodothyronine (T3) are hormones that are produced by the thyroid gland and circulate in the blood both free and bound - mainly with thyroxine-binding globulin (TBG). Only free T3 and T4 are characterized by Hormonal activity, but their share is very small: 0.03% of the total content for T4 and 0.3% - for T3. Concentration of T4 in serum blood is the most accepted indicator of thyroid gland function, which allows you to clearly distinguish between hyper-, hypo- and euthyroidism.

Increase of total T4 concentration is observed with hyperthyroidism, with pituitary tumors, with conditions with elevated TSH levels (pregnancy, acute or chronic active hepatitis, estrogen-secreting tumors or estrogen intake, genetically conditional increase), while taking oral contraceptives, heroin, methadone, thyroid drugs, TSH, thyroliberin.

Decrease of total T4 concentration is observed in hypothyroidism, panhypopituitarism, states of low levels of TSH (acromegaly, nephrotic syndrome, hypoproteinemia, chronic liver disease, androgen-secreting tumors, or androgens, genetically determined decrease), hemolysis, exercise, when taking amino salicylic and acetylsalicylic acids, glucocorticoids, sulfonamides, cholestyramine, reserpine, potassium iodide, triiodothyronine.

3. TEST PRINCIPLE

Determination of the thyroxine is based on competition principle of the enzyme immunoassay. Microwells plate is coated with specific murine monoclonal to thyroxine antibodies. Thyroxine conjugated to the horseradish peroxidase is used as enzyme conjugate. The analysis procedure includes two stages of incubation:

- during the first stage thyroxine from the specimen competes with the conjugated thyroxine for coating antibodies. As a result, a complex bounded to the solid phase and containing peroxidase is formed.
- during the second stage, the complexes formed due the reaction with the chromogen 3,3',5,5'-tetramethylbenzidine are visualized.

After stopping the reaction with a stop solution, the intensity of the color of the microwells is measured. Optical density in the microwell is inversely related to the quantity of the measured thyroxine in the specimen of the serum (plasma).

The concentration is determined according to the calibration graph of the dependence of the optical density on the content of thyroxine in the calibration samples.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P212Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with murine monoclonal antibodies to T4; ready to use
C212Z	CAL 1	**Calibrator C1**	0.5 mL	1	Solution based on human plasma, free of thyroxin, with preservative, ready to use (yellow liquid)
C212Z	CAL 2-5	**Calibrators**	0.5 mL	4	Solutions based on human plasma, containing 32; 64; 160 and 320 nmol/L of thyroxin, with preservative, ready to use (red liquids)
Q212Z	CONTROL	**Control Serum**	0.5 mL	1	Solution based on human plasma, containing of known thyroxin content, with preservative, ready to use (colourless liquid)
T212XZ	CONJ	**Conjugate Solution**	14 mL	1	Solution of thyroxin conjugated to the horseradish peroxidase; ready to use (red liquid)
R055Z	SUBS TMB	**Substrate Solution**	14 mL	1	Tetramethylbenzidine (TMB) substrate solution; ready to use (colourless liquid)
S008Z	BUF WASH 26X	**26x Concentrate Washing Solution**	22 mL	1	Buffer solution with detergent, 26x concentrate (colourless liquid)
R050Z	STOP	**Stop Solution**	14 mL	1	5.0% solution of sulphuric acid; ready to use (colourless liquid)
The kit also includes instruction for use, quality control data sheet and plate sealing tape (2 pcs.)					

5. EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDED

– microplate photometer with 450 nm wavelength;
– dry thermostat for +37°C±2°C;
– automatic plate washer (optional);
– micropipettes with variable volume, range volume 5-1000 µL;
– graduated cylinder of 1000 mL capacity;
– distilled or deionized water;
– timer;
– vortex mixer;
– disposable gloves;
– absorbent paper.

6. WARNING AND PRECAUTIONS

In order to prevent incorrect results, strictly follow the recommended order and duration of the analysis procedure.

6.1. The kit is for *in vitro* diagnostic use only. For professional laboratory use.

6.2. Follow the rules mentioned below during the kit using:

- do not use kit beyond expire date;
- do not use the kit if its packaging is damaged;
- in order to avoid contamination, use new tips to pipette samples and reagents;
- use only verified equipment;
- close each vial with its own cap, after using the reagent;
- do not use components of other kits or reagents of other manufacturers;
- do not let wells dry after completing the rinsing step; immediately proceed to the next stage;
- avoid bubbles when adding reagents.

ATTENTION! The TMB substrate solution is light sensitive. Avoid prolonged exposure of the component to light.

6.3. Some kit components, such as stop solution, substrate solution, and washing solution, may cause toxic or irritant effects. If they get on the skin or mucosa, the affected area should be washed with plenty of running water.

6.4. All human products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guidelines or regulations.

6.5. The Calibrators and Control Serum included in the kit are negative for antibodies to HIV 1,2, hepatitis C virus and HBsAg, but the reagents should be considered as potentially infectious material and handled carefully.

6.6. Specimens must not contain any azide compounds, as they inhibit activity of peroxidase.

6.7. Wear protective gloves, protective clothing, eye protection, face protection.

6.8. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.

6.9. Safety Data Sheet for this product is available upon request directly from XEMA LLC.

6.10. Serious incidents related to the kit must be reported to the manufacturer, Authorized Representative, and to the Competent Authority of the EU member state(s) where the incident has occurred.

7. SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE OF SAMPLES

7.1. Blood sampling should be carried out from the cubital vein with a disposable needle using a vacuum blood sampling system. Serum or plasma specimens should be clearly labeled and identified. Serum must be separated from the clot as early as possible to avoid hemolysis of red blood cells. If there are any visible particles in the sample, they should be removed by centrifugation at 3000-5000 rpm for 20 minutes at room temperature or by filtration.

Don't use samples with high lipidemia, hemolysis as they may give false test results.

7.2. Specimen should be stored at +2…+8°C up to 3 days. Specimen held for a longer time, should be placed in a freezer at -15°C or below, do not refreeze/thaw samples.

7.3. For the transportation of samples, it is recommended to use triple packaging. The primary package is the labeled tube containing the sample. Secondary packaging is a polyethylene bag that is hermetically closed with a zip-lock. The outer packaging is a heat-insulating container, while the secondary packaging is placed in the outer packaging for transportation in the center of the thermal container. Frozen refrigerants are placed on the bottom, along the side walls of the thermal container, and cover the samples with them.

8. TRANSPORTATION AND STORAGE TERMS OF KIT, WASTE DISPOSAL

Information about the singularity storage conditions, transportation of the kit, and disposal of waste should be taken into account by all persons who participate in these processes.

8.1. Transportation

The T4 EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25ºC for 5 days is acceptable.

8.2. Storage

The T4 EIA kit should be stored in the manufacturer's packaging at +2...+8°C. Do not freeze.

The kit contains reagents sufficient for 96 determinations including Calibrators and Control Serum.

Once opened test-kit is stable for 2 months when stored properly as intended by manufacturer at 2-8°C.

In case of partial use of the kit, the components should be stored in the following way:

- strips that remain unused must be carefully sealed with the plate sealing tape and stored at +2...+8°C within 2 months;
- Substrate Solution, Stop Solution, and Washing Solution concentrate after opening the vial, can be stored tightly closed at +2...+8°C until the kit's shelf life;
- Conjugate Solution, Calibrators and Control Serum after opening the vial, can be stored tightly closed at +2...+8°C within 2 months;

  NOTE: Single freezing of Calibrators and Control Serum in aliquots is allowed
- diluted washing solution can be stored at room temperature (+18…+25°C) for up to 5 days or at +2…+8°C for up to 14 days.

Kits that were stored in violation of the storage condition cannot be used.

8.3. Disposal

Expired kit components, used reagents and materials, as well as residual samples must be inactivated and disposed of in accordance with legal requirements.

9. REAGENTS PREPARATION

9.1. All reagents (including microstrips) and test samples should be allowed to reach room temperature (+18…+25 °C) for at least 30 minutes before use.

9.2. Microplate preparation

Open the package with the microplate and install the required number of strips into the frame. Unused strips must be sealed with plate sealing tape to prevent moisture from affecting the plate's holes and placed back in the bag.

9.3. Washing Solution preparation

Add the contents of the 22 mL Washing Solution concentrate vial to 550 mL of distilled or deionized water and mix thoroughly. In case of partial use of the kit, take the necessary amount of washing solution concentrate and dilute it 26 times with distilled or deionized water.

The spending of the components in case of partial use of the kit is given in the table:

Quantity of strips	1	2	3	4	5	6	7	8	9	10	11	12
Volume of the Washing Solution concentrate, mL	1.8	3.6	5.4	7.2	9	10.8	12.6	14.4	16.2	18	19.8	22
Volume of water, mL	45	90	135	180	225	270	315	360	405	450	495	550

10. ASSAY PROCEDURE

10.1 Put the desired number of strips into the frame based on the number of test samples in 2 replicates and 12 wells for Calibrators and Control Serum (2 wells for each calibrator (CAL 1-5) and 2 wells for control serum (Q)).

10.2 Dispense **25 µL of Calibrators and Control Serum as well as 25 µL of test serum/plasma samples** (SAMP) to the wells of the microplate according to the scheme below. The introduction of Calibrators, Control Serum and test samples should be carried out within 5 minutes to ensure equal incubation time for the first and last samples.

Note: during performing several independent series of tests, Calibrators, and Control Sample should be used each time.

Scheme of introduction of samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL1	CAL1	SAMP3	SAMP3	SAMP11	SAMP11						
B	CAL2	CAL2	SAMP4	SAMP4	SAMP12	SAMP12						
C	CAL3	CAL3	SAMP5	SAMP5								
D	CAL4	CAL4	SAMP6	SAMP6								
E	CAL5	CAL5	SAMP7	SAMP7								
F	Q	Q	SAMP8	SAMP8								
G	SAMP1	SAMP1	SAMP9	SAMP9								
H	SAMP2	SAMP2	SAMP10	SAMP10								

10.3 Add **100 µL of the Conjugate Solution** to all wells.

10.4 Carefully mix the contents of the microplate in a circular motion on a horizontal surface, cover strips with a plate sealing tape and incubate for **60 minutes at +37°C**.

10.5 At the end of the incubation period, remove and discard the plate cover. Aspirate and wash each well 5 times using an automatic washer or an 8-channel dispenser. For each washing, add 300 µL of Washing Solution (see 9.3) to all wells, then remove the liquid by aspiration or decantation. The residual volume of the Washing Solution after each aspiration or decantation should be no more than 5µL. After washing, carefully remove the remaining liquid from the wells on the absorbent paper. For the automatic washer/analyzer, the Washing Solution volume can be increased to 350 µL.

10.6 Add **100 µL of Substrate Solution** to all wells. The introduction of the substrate solution into the wells must be carried out within 2-3 minutes. Incubate the microplate in the dark **at room temperature (+18...+25°C) for 15 minutes**.

10.7 Add **100 µL of Stop Solution** to all wells in the same order as the substrate solution. After adding the Stop Solution, the contents of the wells turn yellow.

10.8 Read the optical density (OD) of the wells at 450nm using a microplate photometer within 5 minutes of adding the Stop Solution.

10.9 Plot a calibration curve in semi-logarithmic coordinates: (x) is the decimal logarithm of the T4 concentration in the calibrators nmol/L, (y) – OD versus T4 concentration (OD 450 nm). Manual or computerized data reduction is applicable at this stage. Point-by-point or linear data reduction is recommended due to non-linear shape of curve. Adjust the concentration of CAL1 to an infinitesimally small value, for example, 0.001 nmol/L.

10.10 Determine the corresponding concentration of T4 in tested samples from the calibration curve.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is above 1.2, and the values of the Control Serum fall into the required range (see Quality control Data Sheet).

12. EXPECTED VALUES

12.1. Therapeutical consequences should not be based on results of IVD methods alone – all available clinical and laboratory findings should be used by a physician to elaborate therapeutically measures. Each laboratory should establish its own normal range for T4. Based on data obtained by XEMA, the following normal range is recommended (see below). NOTE: the patients that have received murine monoclonal antibodies for radioimaging or immunotherapy develop high titered anti-mouse antibodies (HAMA). The presence of these antibodies may cause false results in the present assay. Sera from HAMA positive patients should be treated with depleting adsorbents before assaying

NOTE: values of T4 concentrations in the tested samples that are below the LoD (3.0 nmol/L) and also exceed the value of the upper calibrator (320 nmol/L) should be provided in the following form : «the T4 concentration of tested sample X is «lower than 3.0 nmol/L» or «higher than 320 nmol/L».

12.2. The calibrators concentration values of the T4 EIA kit are expressed in nmol/L. To calculate concentrations in µg/dl, the received concentration value in nmol/L shall be multiplied by 0.0775.

1 nmol/L = 0.0775 µg/dl

Sex, age	Units, nmol/L		Units alternative, µg/dl	
	Lower limit	Upper limit	Lower limit	Upper limit
Healthy donors	60	160	4.7	12.4
Males				
>61 yrs	60	129	4.7	10.0
Females				
>61 yrs	70	135	5.4	10.5
Children				
1-5 yrs	90	190	7.0	14.7
6-10 yrs	83	170	6.4	13.2
>10 yrs	60	160	4.7	12.4

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

3.1.1 Precision of Measurement

Repeatability (Intra assay repeatability) was determined by evaluation the coefficient of variation (CV) for 2 different samples during 1 day in 24 replicates on one series of ELISA kit.

Sample	Concentration, nmol/L	CV, %
1	17.5	4.36
2	110.7	3.67

Reproducibility (Inter assay reproducibility) was determined by evaluating the coefficients of variation for 2 samples during 5 days in 8-replicate determinations.

Sample	Concentration, nmol/L	CV, %
1	16.4	1.17
2	111.1	5.43

Reproducibility between lots was investigated by testing samples for one day on three lots. Each sample was run in 8 replicates.

Sample	Concentration1, nmol/L	Concentration2, nmol/L	Concentration3, nmol/L	CV, %
1	14.59	13.67	15.39	5.92
2	116.23	114.53	120.13	2.45

13.1.2 Trueness

The trueness of measurement is the degree of closeness of the average value obtained from a large number of measurement results to the true value. The bias of the measurement result (bias of measurements) is the difference between the mathematical expectation of the measurement result and the true value of the measurand. The bias was calculated for each sample and it was determined that it corresponds to the specified limits of ± 10%.

13.1.3 Linearity

Linearity was determined using sera samples with known T4 concentration (low and high) and mixing them with each other and buffer solution in different proportions. According to the measurements, linear range of kit is 0.75–15 nmol/L ±10%.

13.1.4 Analytical sensitivity

Limit of detection (LoD) – the lowest T4 concentration in the serum or plasma sample that is detected by the T4 EIA kit is no lower than 3 nmol/L.

Limit of quantification (LoQ) – the lowest concentration of the analyte in the sample that is determined quantitatively with the declared trueness for T4 EIA kit is 32 nmol/L.

13.1.5 Analytical specificity

For the analysis result is not affected by the presence in the sample of bilirubin in a concentration of up to 0.21 mg/mL and hemoglobin in a concentration of up to 10 mg/mL.

The cross-reactivity of T4 with other analytes is shown in the table:

Analyte	Cross-reactivity, %
T3	0.5
D-Thyroxin	30

14. REFERENCES

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6. Наказ МОЗ України №325 від 08.06.2015 «Про затвердження Державних санітарно-протиепідемічних правил і норм щодо поводження з медичними відходами».
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SAMPLES IDENTIFICATION PLAN

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

LOT _____ DATE _____

SAMPLES IDENTIFICATION PLAN

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

LOT _____ DATE _____

	Manufacturer
	*In vitro* diagnistic medical device
	Catalogue number
	Use-by date
	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
	Authorized representative in the European Community/European Union
	CE Conformity Marking

For any issues related to operation of the kit and technical support, please contact by telefon number

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