



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



CERTIFICATE

on compliance of Quality Management System

Registration Date:

August 02, 2024

No. UA.SM.214-21

Expiry Date: August 01, 2027

First edition: August 04, 2021

**THIS IS TO CERTIFY THAT
QUALITY MANAGEMENT SYSTEM CONCERNING**

**The Design and Development, Manufacture, Storage and Distribution
medical devices for in vitro diagnostics**

was implemented by: XEMA LLC

at the address: Akademika Yefremova St. 23, Kyiv, Ukraine, 03179

**meets the requirements of DSTU EN ISO 13485:2018
(EN ISO 13485:2016, IDT; ISO 13485:2016, IDT); ISO 13485:2016.**

Compliance control of the certified quality management system with the requirements of the specified standard is carried out through supervision, the frequency and procedures of which are regulated by the procedures of the conformity assessment body.

The conformity assessment body UKRMEDCERT LLC, address: str. Drahomanova, building 1-A, office 2, Kyiv, 02059, Ukraine, phone: +38-067-595-02-30, <https://ukrmedcert.org.ua>

Head of CAB



Tetiana SUKHENKO

The validity of a certificate of compliance can be verified in the online Register
<https://ukrmedcert.org.ua> or by phone +38-067-595-02-30.
The original version of this Certificate is issued in Ukrainian.





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Vertretung und Repräsentanz

Certificate

Of Marketing Authorization of Medical Product

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

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

Issued on the basis of the Declaration of conformity and registration taking into account 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 Medizinprodukte-Durchführungsgesetz (MPDG)

Manufacturer / Hersteller

XEMA LLC

UKRAINE, 03179 KYIV
Akademika Yefremova St. 23
qa@xema.com.ua; www.xema.in.ua

SRN: UA-MF-000032959

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:
Konformitätsbewertungsverfahren:

**EC DECLARATION OF CONFORMITY
(Annex III, except point 6, Directive 98/79/EC)
in connection with article 110(3) IVDR**

EU- KONFORMITÄTSEKTLARUNG

(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



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SRN: DE-AR-000006947

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))

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.

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

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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.	β 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

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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

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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



Date: **March 07, 2023**


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

Troponin I EIA

Catalogue number **REF K291**



For 96 determinations



In vitro diagnostic medical device



XEMA LLC
Akademika Yefremova St. 23
03179, Kyiv, Ukraine
tel.: +38 050 422-62-16
tel.: +38 044 294-69-78
E-mail: qa@xema.com.ua
www.xema.in.ua



Authorized Representative in EU:
Polmed.de Beata Rozwadowska
Fichtenstr. 12A, 90763 Fuerth, Germany
tel.: +49 911 931 639 67
E-mail: info@polmed.de
www.polmed.de

ASSAY PROCEDURE

Preparation of working conjugate solution

Conjugate Dilution Buffer 450 µL + Conjugate Concentrate 10 : 1 45 µL = Working conjugate solution

Working conjugate solution

T

50 µL

Dispensing of Calibrators, Control Serum and test samples

test samples

50 µL

SORB MTP

CAL

CAL

CONTROL

Incubation 1

+37 °C

60'

Working Conjugate Solution

T

50 µL

OD measuring, calculation of results

450 / 620-680 nm

Stop Solution

STOP

100 µL

Incubation 2

+18-25 °C

15'

Substrate Solution

SUBS TMB

100 µL

Washing 5 times

with 30 seconds soak time between each wash

K291

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

1. INTENDED USE

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

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Quantitative determination of troponin I (TnI) allows for laboratory testing diagnosis of acute myocardial infarction (AMI), recurrent MI and developed MI against the background of severe organic pathology of the myocardium. TnI is a protein with a molecular weight 22.5 kDa - is part of the troponin complex, which plays an important role in the regulation of muscle contractions of striated muscle cells and myocardium.

Three isoforms of human TnI isoforms are known: two specific for skeletal muscles, and one for the myocardium. Cardiospecific TnI isoform is expressed in no other tissues except the myocardium. Its structural differences allow using immunological methods to distinguish it from other isoforms. TnI appears in the bloodstream within 4–6 hours after onset of the chest pain attack and reaches its peak level during the first 16–20 hours. Within the first day after AMI cardiac TnI is released from necrotic myocardial tissue showing similar pattern to CKMB – the 'golden' AMI marker of the last 10 years. However, while CKMB remains elevated for two-three days after onset of the chest pain, TnI can be detected in serum or plasma for up to one week after the first symptoms of the AMI. Therefore, TnI can be used not only for early, and also for remote diagnosis of AMI, when a serum sample is obtained a few days after the development of a pain attack. In this case, TnI is similar to TNT - another representative of the troponin family from the group of lesion markers

myocardium. At the same time, it was shown (Adams et al., Amer. Heart J, 1996; 131: 308-12) that in the absence of any manifestations of coronary heart disease, concentrations of TNT (as well as levels of CKMB) in the blood often increase in patients who are on chronic dialysis, as well as in patients with chronic diseases of the skeletal muscles. This is explained by the fact that in patients of this group, cardiospecific forms of TNT and CKMB can be expressed in skeletal muscles. At the same time, the expression of the cardiospecific form of TnI in skeletal muscles and the increase in the concentration of this marker in the blood of patients of this group were not detected.

3. TEST PRINCIPLE

The determination of Troponin I 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 human Troponin I. Second antibodies – murine monoclonal antibodies to human Troponin I conjugated to the horseradish peroxidase is used as enzyme conjugate. The analysis procedure includes two stages of incubation:

- during the first stage Troponin I 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 Troponin I;
- 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 Troponin I 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 Troponin I in the calibration samples.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P291Z	SORB MTP	Microplate	-	1	96-well polystyrene strip microplate coated with murine monoclonal antibodies to troponin I; ready to use
C291Z	CAL 1	Calibrator C1	1 mL	1	Solution based on tris buffer (pH 7.2-7.4), free of human Troponin I, lyophilized
C291Z	CAL 2-5	Calibrators	1 mL	4	Solutions based on tris buffer (pH 7.2-7.4), containing 0.3; 1; 4 and 10 ng/mL of human Troponin I, contains red dye, lyophilized Note. Concentrations of troponin I in Calibrators may differ from the specified values, the exact values are indicated on the component labels
Q291Z	CONTROL	Control Serum	1 mL	1	Solution based on human serum, containing of known Troponin I content, with preservative, contains blue dye, lyophilized
T291XZ	CONJ 11X	Conjugate Concentrate	0.6 mL	1	Solution of murine monoclonal antibodies to human Troponin I conjugated to the horseradish peroxidase; 11x concentrate (red liquid)
ST291Z	DIL CONJ	Conjugate Dilution Buffer	6 mL	1	Buffer solution with detergent 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;
- 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 Troponin I EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25°C for 5 days is acceptable.

8.2. Storage

The Troponin I 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;
- 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;
- Conjugate Concentrate and Conjugate Dilution Buffer after opening the vial, can be stored tightly closed at +2...+8°C within 2 months;
- Calibrators and Control Serum after dissolving should be stored frozen in aliquots below **-15°C**.

NOTE: only one freezing/thawing cycle of Calibrators and Control Serum is allowed.

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 11 dilutions of Conjugate Concentrate in Conjugate Dilution Buffer (eg, 45 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 11 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	0.045	0.09	0.135	0.18	0.225	0.27	0.315	0.36	0.405	0.45	0.495	0.54
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

9.5. Calibrators and Control Serum preparation

Before first use of the kit dissolve the Calibrators and Control Serum: add 1 mL deionized water to each vial and mix thoroughly avoiding foam formation. Liquid Calibrators and Control Serum should be assayed within **30 minutes**, aliquoted and stored frozen below -15°C **immediately**.

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 Calibrators and Control Serum Приготовьте as described in 9.5.
- 10.3 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	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 **50 µL of Working conjugate solution** to all wells (see 9.4).
- 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**.
- 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 **with 30 seconds soak time between each wash**. 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 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 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 troponin I concentration in the calibrators ng/mL, (y) – OD versus troponin I 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 troponin I in tested samples from the calibration curve.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is above 0.2, 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 Troponin I. 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 antimouse 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 troponin I concentrations in the tested samples that are below the LoD (0.01 ng/mL) and also exceed the value of the upper Calibrator (10 ng/mL) should be provided in the following form : «the troponin I concentration of tested sample X is «lower than 0.01 ng/mL» or «higher than 10 ng/mL».

Sex, age	Units, ng/mL	
	Lower limit	Upper limit
Healthy donors	-	0.5

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, ng/mL	CV, %
1	2.92	5.2
2	4.64	4.8

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

Sample	Concentration, ng/mL	CV, %
1	2.77	5.0
2	4.87	5.4

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

Sample	Concentration1, ng/mL	Concentration2, ng/mL	Concentration3, ng/mL	CV, %
1	2.72	2.52	2.81	5.5
2	4.71	4.56	4.32	4.3

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 whether it corresponds to the specified limits of $\pm 10\%$.

13.1.3 Linearity

Linearity was determined using sera samples with known troponin I 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 0.3 - 10 ng/mL $\pm 10\%$.

13.1.4 Analytical sensitivity

Limit of detection (LoD) – the lowest troponin I concentration in the serum or plasma sample that is detected by the Troponin I EIA kit is no lower than 0.01 ng/mL.

Limit of quantification (LoQ) – the lowest concentration of the analyte in the sample that is determined quantitatively with the declared trueness for Troponin I EIA kit is 0.3 ng/mL.

13.1.5 Hook Effect

Hook effect is absent for all samples up to reasonably foreseen concentrations 10ng/mL.

13.1.6 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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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
	<i>In vitro</i> diagnostic 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

Akademika Yefremova St. 23

03179, Kyiv, Ukraine

tel.:+38 050 422-62-16

tel.:+38 044 294-69-78

E-mail: qa@xema.com.ua

www.xema.in.ua