EC DECLARATION OF CONFORMITY
EU- KONFORMITATSERKLARUNG

98/79/EC in connection with article 110(3) IVDR
98/79/EG in Verbindung mit Artikel 110 (3) IVDR

No.**XEMA_LLC- DC-01/2025**

Manufacturer: Hersteller:	**XEMA LLC** UKRAINE, 03179 KYIV Akademika Yefremova St. 23 Tel./Fax: +38 044 294-69-78 Email: qa@xema.com.ua www.xema.com.ua	**Single registration number (SRN)** Einmalige Registrierungsnummer: **UA-MF-000032959**
EC Authorized Representative: EU-Bevollmächtigte:	**Polmed.de Beata Rozwadowska** Fichtenstr. 12A 90763 Fürth Germany/Deutschland Tel: +49 911 931 639 67 www.polmed.de	**Single registration number (SRN)** Einmalige Registrierungsnummer: **DE-AR-000006947**
Product name: Produktbezeichnung:	**see annex / siehe Anhang**	
Classification (Risk class): Klassifizierung (Risikoklasse):	**Common/ Other IVD** Sonstige IVD-Produkte	
Conformity assessment procedure: Konformitatsbewertungsverfahren:	**Appendix III (points 1-5) of Directive 98/79/EC** Anhang III (Nr. 1-5) der Richtlinie 98/79/EG	

Standards applied/Angewandte Normen:

ISO 9000:2015	Quality management systems — Fundamentals and vocabulary
ISO 19011:2018	Guidelines for auditing management systems
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2019	Medical devices. Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 18113-1:2024	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2022)
EN ISO 18113-2:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022)

We hereby declare under our the sole responsibility, that the devices listed in the Annex meet all applicable provision of the EU (IVDD). The procedure according to Annex III of the Regulation (EU) 2017/746 (IVDR) has been followed.

Wir erklären hiermit in unserer alleinigen Verantwortung, dass die im Anhang genannten Produkte alle anwendbaren Bestimmungen der EG-Richtlinie 98/79/WG (IVDD)entsprechen. Das Verfahren gemäß Anhang III der Verordnung (EU) 2017/746 (IVDR) wurde eingehalten.

If the product is changed/transformed without the consent of the undersigned, this declaration becomes invalid with regard to the modified/converted product.

Wenn das Produkt ohne Zustimmung des Unterzeichneten geändert/transformiert wird, wird diese Erklärung in Bezug auf das modifizierte/konvertierte Produkt ungültig.

Validity/Gültigkeit: **until**/ bis: **31.12.2028**

Signature/ Unterschrift:
Name: **Oleksandra Zavaliei**
Position: Director "XEMA LLC"

Place and date of issue:
Ort und Datum der Ausgabe: Kyiv
26.05. 2025

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No.**XEMA_LLC- DC-01/2025**

Annex to Declaration of conformity
Anhang zur Konformitätserklärung

Product list /Produktliste

#	**Nomenclature term** Nomenklaturbezeichnung **EDMA**	**Cat. #** Katalog-Nr.:	**Name of device** Produktbezeichnung	**Nomenclature Code** Nomenklaturcode **EDMA**	**Category IVDD** Kategorie IVDD
1.	ASPERGILLUS	K021	GalMAg EIA	15-06-01-01-00	other
2.	HSV IgG	K104	HSV 1/2 IgG EIA	15-04-03-05-00	other
3.	HSV IgM	K104M	HSV 1, 2 IgM EIA	15-04-03-06-00	other
4.	HSV 2 IgG	K104B	HSV 2 IgG EIA	15-04-03-11-00	other
5.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA	15-01-08-03-00	other
6.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	anti-Treponema pallidum EIA	15-01-03-03-00	other
7.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA	15-01-03-05-00	other
8.	H. PYLORI ANTIBODY ASSAYS	K119G	Helicobacter pylori IgG EIA	15-01-04-03-00	other
9.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA	15-01-90-90-00	other
10.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA	12-10-03-01-00	other
11.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA	12-10-03-04-00	other
12.	MPO ANCA	K133	aMPO EIA	12-10-90-09-00	other
13.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	anti-TGlu IgG EIA anti-TGlu IgA EIA	12-10-90-21-00	other
14.	GIARDIA LAMBLIA	K171	anti-Giardia lamblia EIA	15-05-10-08-00	other
15.	OTHER PARASITOLOGY	K174	Ascaris IgG EIA	15-05-10-90-00	other
16.	ECHINOCOCCUS	K175	Echinococcus IgG EIA	15-05-10-04-00	other
17.	DISTOMATOSIS	K176	Opisthorchis IgG EIA	15-05-10-03-00	other
18.	GLIADIN ANTIBODIES	K180 K181	Gliadin IgG EIA Gliadin IgA EIA	12-10-90-06-00	other
19.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA	12-02-01-02-00	other
20.	THYROID STIMULATING HORMONE	K201	TSH EIA	12-04-01-11-00	other
21.	LUTEINISING HORMONE	K202	LH EIA	12-05-01-05-00	other
22.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA	12-05-01-04-00	other
23.	HUMAN GROWTH HORMONE	K204	GH EIA	12-06-04-02-00	other
24.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	hCG EIA	12-05-02-05-00	other
25.	PROLACTIN	K206	Prolactin EIA	12-05-01-08-00	other
26.	PROGESTERONE	K207	Progesterone EIA	12-05-01-06-00	other
27.	ESTRADIOL	K208	Estradiol EIA	12-05-01-03-00	other
28.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209	Testosterone EIA	12-05-01-10-00	other
29.	CORTISOL	K210	Cortisol EIA	12-06-02-04-00	other
30.	TRIIODOTHYRONINE	K211	T3 EIA	12-04-01-05-00	other
31.	THYROXINE	K212	T4 EIA	12-04-01-07-00	other
32.	FREE TRIIODOTHYRONINE	K213	fT3 EIA	12-04-01-01-00	other
33.	FREE THYROXINE	K214	fT4 EIA	12-04-01-02-00	other
34.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEAS EIA	12-05-01-02-00	other
35.	17 OH PROGESTERONE	K217	17-OH-progesterone EIA	12-05-01-07-00	other
36.	ESTRIOL	K218	free Estriol EIA	12-05-02-02-00	other
37.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	free Testosterone EIA	12-05-01-10-00	other
38.	CANCER ANTIGEN 125	K222	CA 125 EIA	12-03-01-06-00	other

#	Nomenclature term EDMA	Cat. #	Name of device	Nomenclature Code EDMA	Category IVDD
42.	CANCER ANTIGEN 15-3	K226	CA 15-3 (M12) EIA	12-03-01-02-00	other
43.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA	12-03-90-90-00	other
44.	ß HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	free β-HCG EIA	12-05-02-06-00	other
45.	CYFRA 21-1	K236	CYFRA 21-1 EIA	12-05-02-10-00	other
46.	SQUAMOUS CELL CARCINOMA ANTIGEN	K237	SCC (A) EIA	12-03-01-35-00	other
47.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA	12-05-02-10-00	other
48.	OTHER OTHER TUMOUR MARKERS	K239	HE4 EIA	12-03-90-90-00	other
49.	CANCER ANTIGEN 242	K243	CA242 EIA	12-03-01-08-00	other
50.	OTHER PREGNANCY TESTING HORMONES	K245	AMH EIA	12-05-02-90-00	other
51.	HUMAN PLACENTAL LACTOGEN HPL	K246	Placental lactogen EIA	12-05-02-07-00	other
52.	C-REACTIVE PROTEIN	K250	CRP EIA	12-11-01-09-00	other
53.	C-PEPTIDE	K267C	C-peptide EIA	12-06-01-01-00	other
54.	INSULIN	K267N	Insulin EIA	12-06-01-03-00	other
55.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA	12-05-01-09-00	other
56.	TROPONIN (T + I)	K291	Troponin I EIA	12-13-01-07-00	other
57.	LYME ANTIBODY IGG	K118G	Borelia burgdorferi IgG EIA	15-01-06-05-00	other
58.	LYME ANTIBODY IGM	K118M	Borelia burgdorferi IgM EIA	15-01-06-06-00	other
59.	EBV ANTIBODIES	K108V K108VM K108N	Epstein-Barr virus VCA IgG EIA Epstein-Barr virus VCA IgM EIA Epstein-Barr virus EBNA IgG EIA	15-04-04-04-00	other

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

Total IgE EIA

Catalogue number REF **K200**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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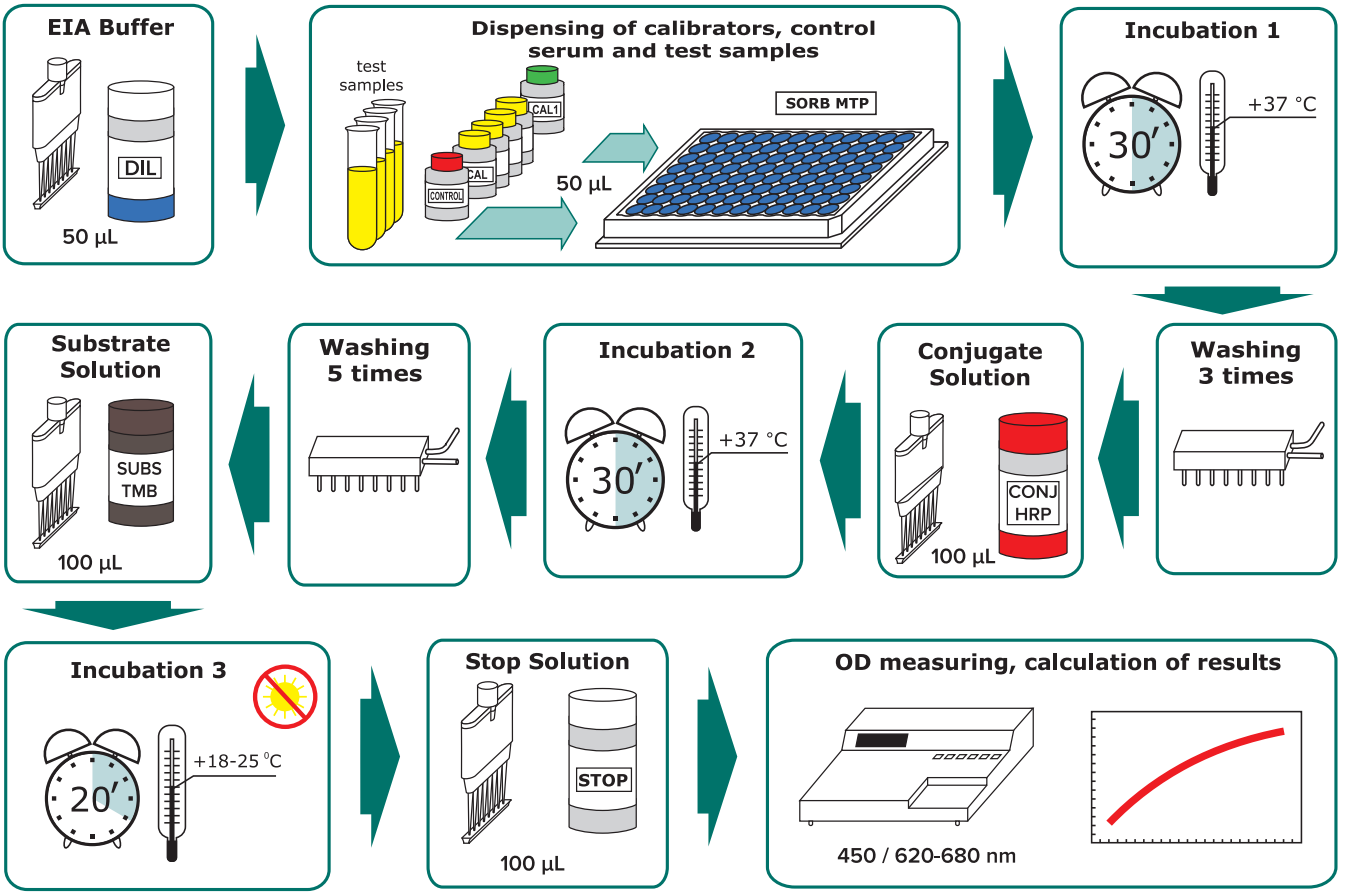
ASSAY PROCEDURE



During performing several independent series of tests, Calibrators and Control Serum should be used **each time**.

CONTENT

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

Total IgE EIA

1. INTENDED USE

The Total IgE EIA kit is an enzyme immunoassay, intended for the quantitative determination of total IgE concentration in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Total immunoglobulin E (IgE) serum level is widely reported as the laboratory marker of atopic diseases such as atopic asthma, atopic dermatitis, and pollenosis. An atopic (IgE-dependent) mechanism can also underlie gastroenterocolitis, urticaria, other forms of vasculitis (including systemic), cholecystitis, vulvovaginitis, and cystitis. Part of the drug allergy (mainly to penicillin and protein drugs) also develops according to the IgE-dependent mechanism. In all of the conditions listed above, the production of high titers of specific IgE antibodies can lead to an increase in the level of total IgE in the serum. A particularly high level of total IgE is characteristic of atopic dermatitis. In addition to atopic diseases, total serum IgE is significantly increased in parasitic infestations and mycoses (especially systemic), rarely in systemic autoimmune diseases and immunodeficiency states (especially in hyper-IgE syndrome), as well as in mastocytosis (mast cell tumor) and extremely rare IgE-myeloma. A decrease in the level of total IgE in serum (below 15 IU/mL in adults) is a rare and little-studied phenomenon described in hypogammaglobulinemia, some autoimmune diseases, ulcerative colitis, and primary biliary cirrhosis.

3. TEST PRINCIPLE

The determination of the total IgE 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 IgE. Second antibodies – rabbit polyclonal antibodies to IgE conjugated to the horseradish peroxidase is used as enzyme conjugate. The analysis procedure includes tree stages of incubation:

- during the first stage the total IgE from the specimen is captured by the monoclonal antibodies coated onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated with rabbit polyclonal antibodies bind to free epitopes of immobilized total IgE, 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 total IgE 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 total IgE in the calibration samples.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P200Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with murine monoclonal antibodies to total IgE, ready to use
C200Z	CAL 1	**Calibrator C1**	0.6 mL	1	Solution based on phosphate buffer, free of total IgE, with preservative, ready to use (colourless or yellow liquid)
C200Z	CAL 2-5	**Calibrators**	0.6 mL	4	Solutions based on phosphate buffer, containing 50; 200; 500 and 1000 IU/mL of total IgE, ready to use (red liquids)
Q200Z	CONTROL	**Control serum**	0.6 mL	1	Solution based on human serum, containing of known total IgE content, with preservative, ready to use (colourless or yellow liquid)
T200Z	CONJ HRP	**Conjugate Solution**	12 mL	1	Solution of rabbit polyclonal antibodies to human total IgE conjugated to the horseradish peroxidase, ready to use (red liquid)
S011Z	DIL	**EIA Buffer**	12 mL	1	Buffer solution with detergent and preservative, ready to use (blue liquid)
R055Z	SUBS TMB	**Substrate Solution**	12 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**	12 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 450/620-680 nm wavelength;
– dry thermostat for 37°C±1°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 Total IgE 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 Total IgE 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:

- the remaining strips should be immediately resealed in the bag along with the silica gel, closed with the zip-lock, 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. The remaining strips should be immediately resealed in the bag along with the silica gel and closed with the zip-lock to prevent moisture from affecting the plate's strips.

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

10. ASSAY PROCEDURE

10.1. Put the desired number of strips into the frame based on the number of test samples 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 **50 µL of EIA Buffer** to all wells.

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.

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 5 µL. 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 20 minutes**.
The incubation time can be varied depending on the intensity of the blue colour development.

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 450 nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution.

10.12. Plot a calibration curve in linear coordinates: (x) is the concentration of total IgE in the Calibrators IU/mL, (y) – OD versus concentration of total IgE (OD 450 nm / 620–680 nm). Manual or computerized data reduction is applicable at this stage. For the algorithm calculation (approximation) of the calibration curve, using the interval (segment-linear, point-to-point) method is recommended.

10.13. Determine the corresponding concentration of total IgE in tested samples from the calibration curve.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is below 0.15, the OD of CAL5 is above the critical value (see Quality control Data Sheet) 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 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 total IgE. Based on data obtained by XEMA LLC, the following normal range is recommended (see below).

NOTE: values of total IgE concentrations in the tested samples that are below the LoD (3 IU/mL) and also exceed the value of the upper calibrator (1000 IU/mL) should be provided in the following form: «the total IgE concentration of tested sample X is «lower than 3 IU/mL» or «higher than 1000 IU/mL».

12.2. The calibrators concentration values of the Total IgE EIA kit are expressed in IU/mL. To calculate concentrations in ng/mL, the received concentration value in IU/mL shall be multiplied by 2.4.

1 IU/mL = 2.4 ng/mL.

Sex, age	Units, IU/mL		Units alternative, ng/mL	
	Lower limit	Upper limit	Lower limit	Upper limit
< 6 months	-	12	-	28.8
6-12 months	-	30	-	72.0
1-3 yrs	-	45	-	108.0
4-6 yrs	-	70	-	168.0
7-9 yrs	-	90	-	216.0
10-15 yrs	-	120	-	288.0
>15 yrs	-	130	-	312.0

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, IU/mL	CV, %
1	10.6	4.33
2	116.2	5.47

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	12.5	8.36
2	113.4	1.47

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

Sample	Concentration 1, IU/mL	Concentration 2, IU/mL	Concentration 3, IU/mL	CV, %
1	12.7	13.3	12.3	3.66
2	115.5	117.8	115.1	1.25

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 total IgE 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 50-1000 IU/mL ±10%.

13.1.4. Analytical sensitivity

Limit of detection (LoD) – the lowest total IgE concentration in the serum or plasma sample that is detected by the Total IgE EIA kit is no lower than 3 IU/mL.

Limit of quantification (LoQ) – the lowest concentration of the analyte in the sample that is determined quantitatively with the declared trueness for Total IgE EIA kit is 50 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.

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

Analyte	Concentration, IU/mL	Cross-reactivity, %
IgA	1000	Not detected
IgM	1000	Not detected
IgG	1000	Not detected

14. LIMITATIONS

The diagnosis cannot be based on the test results and requires confirmation, including assessment of the clinical picture and patient history.

The results of serum tests in patients with immunosuppression and immunological disorders should be interpreted with caution.

15. REFERENCES

1. Zetterstrom and Hohansson S.G.O. Allergy 1981; 36:537.
2. Buckley R. H. Immunopharmacology of Allergic Disease 1979; 117.
3. Michel f. B., Bousquet J. and Greilier P. J. Allergy Clin. Immunol. 1980; 64:422.
4. Ishizaka T. Ann Allergy 1982; 48: 313.
5. Kulczyski A. Jr. J. Allergy Clin. Immunol. 1981; 68:5.
6. Наказ МОЗ України №1827 від 31.10.2024 «Про затвердження Державних санітарних норм та правил «Порядок управління медичними відходами, у тому числі вимоги щодо безпечності для здоров'я людини під час утворення, збирання, зберігання, перевезення, оброблення таких відходів».
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

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

LOT _____ DATE _____

Instruction version/date: 2026.01

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 _____

Instruction version/date: 2026.01

K200IE

	Manufacturer
IVD	*In vitro* diagnistic medical device
REF	Catalogue number
	Use-by date
LOT	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
EC REP	Authorized representative in the European Community/European Union
CE	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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ТОВ «ХЕМА»
ПАСПОРТ КОНТРОЛЮ ЯКОСТІ
XEMA LLC.
QUALITY CONTROL SHEET

Товариство з обмеженою відповідальністю «ХЕМА» / ХЕМА LLC
Паспорт контролю якості / Quality control data sheet № 271/601

Кат№ Cat.#	Скорочена назва Product item	Партія Lot	Дата вир. Mfg date	Придатний до Expiry date
K271	**«Загальний IgG-ІФА» / Total IgG EIA**	**601**	**2026-01**	**2027-08**

НАБІР РЕАГЕНТІВ ДЛЯ ІМУНОФЕРМЕНТНОГО ВИЗНАЧЕННЯ ЗАГАЛЬНОГО IgG В БІОЛОГІЧНИХ РІДИНАХ
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgG in human biological fluids

Набір відповідає вимогам технічної документації / Kit meets the requirements of Batch Release Criteria technical documentation

Умови зберігання: +2..+8°C / Storage conditions: +2..+8°C

Склад набору / Kit content

№	*Код Ref*	*Символ Symbol*	*Компонент Component*	*К-ть Qty*	*Од-ці Units*	*Партія Lot*	*Опис Description*
1	P271Z	SORB MTP	Планшет 96-лунковий полістироловий, стрипований, готовий до використання Total IgG EIA strips, 8x12 wells	1	шт/pcs	512	-
2	C271Z	CAL 1 - 5	Калібрувальні проби на основі трис-буфера (pH 7.2-7.4), що містять відомі кількості загального IgG - 0; 1; 5; 10; 25 г/л, готові до використання (по 1 мл кожна) Calibrator set, 1 mL each. The set contains 5 calibrators: 0; 1; 5; 10; 25 g/L	5	шт/pcs	6013	рідини синього кольору (калібрувальна проба С1 - безбарвна або жовтого кольору рідина)
3	Q271Z	CONTROL	Контрольна сироватка на основі сироватки крові людини з відомим вмістом загального IgG , готова до використання (1 мл) Control serum, 1 mL	1	шт/pcs	6013	безбарвна або жовтого кольору рідина
4	T271Z	CONJ HRP	Кон'югат, готовий до використання (12 мл) Conjugate, 12 mL	1	шт/pcs	6012	рідина червоного кольору
5	SP271Z	DIL SPE	ІФА-Буфер, готовий до використання (100 мл) EIA buffer, 100 mL	1	шт/pcs	601	рідина синього кольору
6	R055Z	SUBS TMB	Розчин субстрату тетраметилбензидину (ТМБ), готовий до використання (12 мл) Substrate solution, 12 mL	1	шт/pcs	5122	прозора безбарвна рідина
7	S008Z	BUF WASH 26X	Концентрат розчину для відмивання, 26х-кратний (30 мл) Washing solution concentrate 26x, 30 mL	1	шт/pcs	601	прозора безбарвна рідина
8	R050Z	STOP	Стоп-реагент, готовий до використання (12 мл) Stop solution, 12 mL	1	шт/pcs	601	прозора безбарвна рідина
9	K271I	-	Інструкція з використання Набору реагентів «Загальний IgG-ІФА» Instruction Total IgG EIA	1	шт/pcs	2026.01	-

Параметри контролю якості підтверджені
ТОВ "ХЕМА" / QC Passed

Начальник лабораторії з контролю виробництва ІФА та ІХА
Head of the ELISA and ICA production control laboratory

Мальцева Дар'я
Maltseva Daria

ХЕМА

ТОВ «ХЕМА»
ПАСПОРТ КОНТРОЛЮ ЯКОСТІ
ХЕМА LLC.
QUALITY CONTROL SHEET

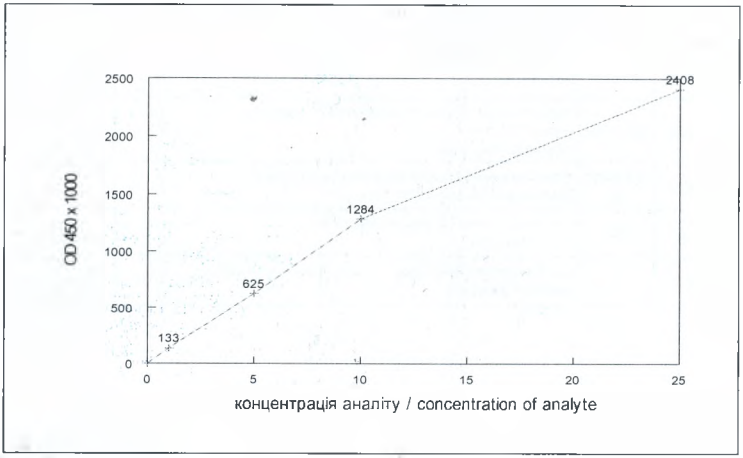
Параметри контролю якості
QC parameters

Параметр Parameter	Необхідний діапазон Required range	Отримане значення Actual value
Контрольні сироватки / Control		
Значення, г/л / Value, g/L	3 - 5.8	4.0
Коефіцієнт варіації, % / CV, %	< 10.0	Відповідає / Acceptable
Співвідношення ОГ, % / OD ratios, %		
B 1 / B 25 *100%	2 - 12	5.5
B 10 / B 25 *100%	30 - 78	53.3
Контроль достовірності / Test Validity		
ОГ/OD C1	< 0.15	Відповідає / Acceptable
ОГ/OD C5	> 1.50	Відповідає / Acceptable

Калібрувальні проби/ Calibrators
Не використовувати для обрахунків / Do not use for calculation

Номінал калібраторів, г/л Nominal, g/L		ОГ OD
C1	0	0.018
C2	1	0.151
C3	5	0.643
C4	10	1.302
C5	25	2.425

Калібрувальний графік (зразок) / Sample curve
Не використовувати для обрахунків / Do not use for calculation



Дата видачі / Issued 26.01.2026
ЛКВ / QC department

Параметри контролю якості підтверджені
ТОВ "ХЕМА" / QC Passed

Начальник лабораторії з контролю виробництва ІФА та ІХА
Head of the ELISA and ICA production control laboratory

Мальцева Дар'я
Maltseva Daria

ХЕМА

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgG in human biological fluids

Total IgG EIA

Catalogue number REF **K271**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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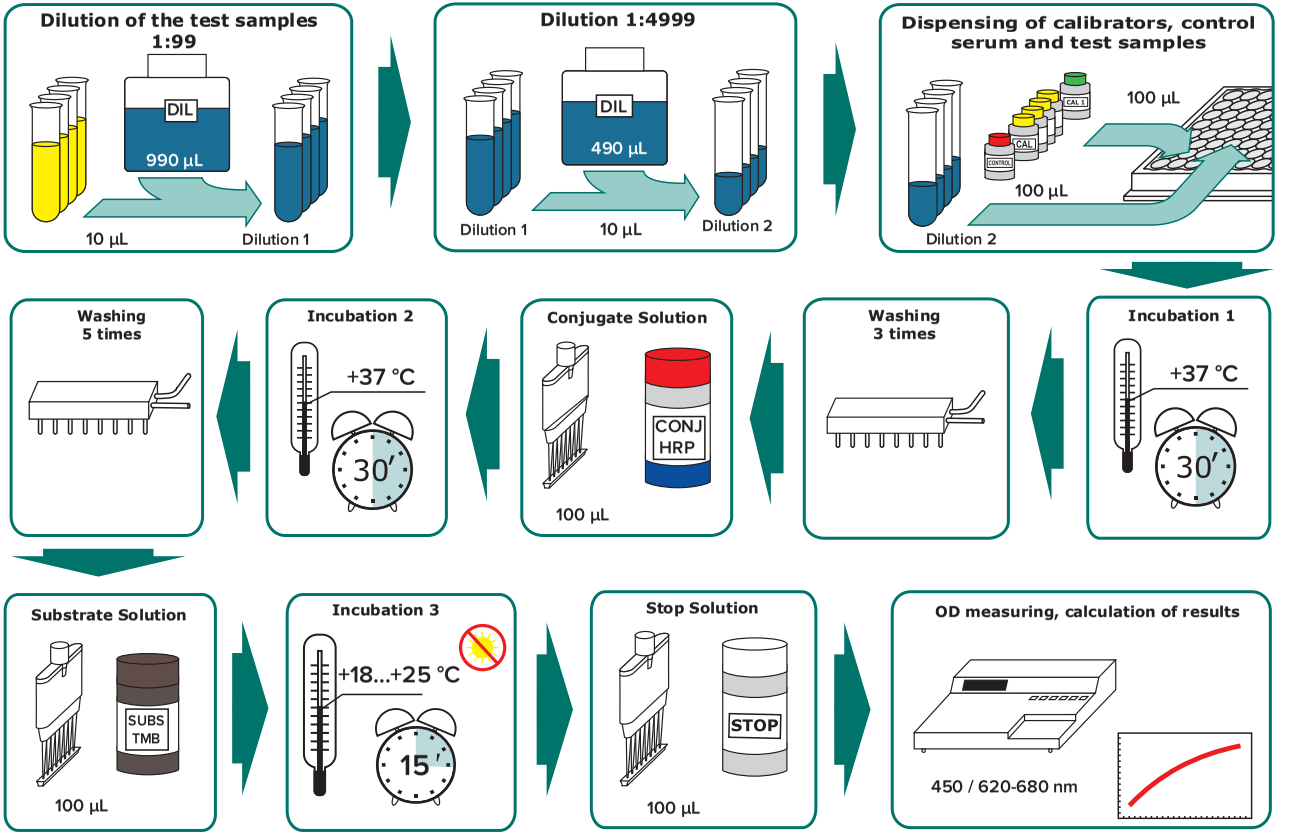
ASSAY PROCEDURE*



* For blood serum (plasma)
The method of dilution for other material types is given in table M.

During performing several independent series of tests, Calibrators and Control Serum should be used **each time.**

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgG in human biological fluids
Total IgG EIA

1. INTENDED USE

The Total IgG EIA kit is an enzyme immunoassay, intended for the quantitative determination of total IgG in biological fluids.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Immunoglobulin G (IgG) is the main part of serum γ–globulin fraction. IgG is secreted during secondary immune response and plays a key role in humoral immunity.

Decrease of serum IgG concentration below 5 g/L is a marker of severe life-threatening immunodeficiency. Determination of serum IgG concentration and IgG/IgA/IgM ratios can be used for monitoring of humoral immune status. Marked elevation of serum IgG may be observed in chronic inflammation, autoimmune diseases and myeloma.

3. TEST PRINCIPLE

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

- during the first stage total IgG from the specimen is captured by the antibodies coated onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated monoclonal antibodies bind to free epitopes of immobilized total IgG, 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 total IgG in the test specimen.

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

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P271Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with murine monoclonal antibodies to human total IgG, ready to use
C271Z	CAL 1	**Calibrator C1**	1.0 mL	1	Solution based on tris buffer (pH 7.2-7.4), free of total IgG, with preservative, ready to use (colourless liquid)
C271Z	CAL 2-5	**Calibrators**	1.0 mL	4	Solutions based on tris buffer (pH 7.2-7.4), containing 1; 5; 10 and 25 g/L of total IgG, with preservative, ready to use (blue liquids)
Q271Z	CONTROL	**Control Serum**	1.0 mL	1	Solution based on human serum, containing of known human total IgG content, with preservative, ready to use (colourless liquid)
T271Z	CONJ HRP	**Conjugate Solution**	12 mL	1	Solution of murine monocnoclonal antibodies to total IgG conjugated to the horseradish peroxidase, ready to use (red liquid)
SP271Z	DIL SPE	**EIA Buffer**	100 mL	1	Buffer solution with detergent and preservative, ready to use (blue liquid)
R055Z	SUBS TMB	**Substrate Solution**	12 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**	12 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 450/620-680 nm wavelength;
– dry thermostat for +37°C±1 °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. Saliva should be collected using a tampon. For this purpose, it must be soaked with saliva and placed in a clean container with a lid. For urine analysis, the first portion of morning urine is taken in 15 - 25 mL in a special dry sterile bottle or container. A sample of cerebrospinal fluid is collected by the method of lumbar puncture, which is performed by a doctor in the operating room. For this, the patient is placed on his side in the fetal position, the area where the cerebrospinal fluid is taken is anesthetized, and then a hollow needle is inserted between the vertebrae. The cerebrospinal fluid obtained during the puncture should be immediately delivered to the laboratory in sterile test tubes and by appropriate referral. It is necessary to analyze the clinical sample immediately because cellular elements are rapidly destroyed.

Before use, the test samples must be thoroughly centrifuged. Analysis of opaque samples may lead to false results.

7.3 Samples should be stored as follows:

- saliva and urine samples should be stored at +2…+8°C no longer than 6 days;
- serum (plasma) 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.

7.4. 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 Total IgG 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 Total IgG 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:

– the remaining strips should be immediately resealed in the bag along with the silica gel, closed with the zip-lock, 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. The remaining strips should be immediately resealed in the bag along with the silica gel and closed with the zip-lock to prevent moisture from affecting the plate's strips.

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 5000 fold (for example, add to the vial Dilution 1 (1:99): 10 µL of the test sample + 990 µL EIA buffer). In another vial, Dilution 2 (1:4999) add 10 µL Dilution 1 + 490 µL EIA buffer). Dilution 2 (1:4999) should be used in the analysis.

If suggested analyte concentration in the sample exceeds the 25 g/L, 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!

The method of dilution for other material types is given in table M.

Table M

Material type	Sample dilution example	EIA sample buffer into the well, µL	Sample into the well, µL	Calculation factor
blood serum or plasma	Dilution 1 (1:99): 10 µL sample + 990 µL EIA buffer. Dilution 2 (1:4999): 10 µL dilution 1 + 490 µL EIA buffer. Dilution 2 (1:4999) should be used in the analysis	0	100	1
saliva	-	90	10	0.002
urine	-	50	50	0.0004
cerebrospinal fluid	10 µL sample + 500 µL EIA buffer	0	100	0.01

10. ASSAY PROCEDURE

10.1. Put the desired number of strips into the frame based on the number of test samples 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.** For testing of blood serum or plasma pipet **100 µl of the diluted sample (DILUTION 2)** (SAMP) to the wells of the microplate according to the scheme below. See table M for the volumes of other materials. 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.

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	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 5 µL. 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**.
The incubation time can be varied depending on the intensity of the blue colour development.

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 450 nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution.

10.12. Plot a calibration curve in linear coordinates: (x) is the concentration of total IgG g/L in the calibrators, (y) – OD versus total IgG concentration (OD 450 nm / 620–680 nm). Manual or computerized data reduction is applicable at this stage. For the algorithm calculation (approximation) of the calibration curve, using the interval (segment-linear, point-to-point) method is recommended.

10.13. Determine the corresponding concentration of total IgG in tested samples from the calibration curve. In the case of additional preliminary dilution of the test sample (see 9.4), the obtained result should be multiplied by the dilution factor. Use Calculation factor listed in table M to calculate analyte concentration in different material types.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is below 0.15, the OD of CAL5 is above the critical value (see Quality control Data Sheet) 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 total IgG. Based on data obtained by XEMA LLC, the following normal range is recommended (see below).

NOTE: values of total IgG concentrations in the tested samples that are below the LoD (0.06 g/L) and also exceed the value of the upper calibrator (25 g/L) should be provided in the following form: «the total IgG concentration of tested sample X is «lower than 0.06 g/L» or «higher than 25 g/L».

Sex, age	Units, g/L	
	Lower limit	Upper limit
newborn	7.0	15
1-3 month	2.7	8.0
4-6 month	1.8	8.5
7-12 month	3.5	12
1-6 yrs	6.5	18
7-11 yrs	8.5	15
> 11 yrs	9.0	20

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1. Precision of Measurement

Reproducibility. The coefficient of variation of determining the content of total IgG in the same sample of biological fluids using the kit Total IgG EIA does not exceed 10%.

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 mezhurand. The bias was calculated for each sample and it was determined whether it corresponds to the specified limits of ± 10%.

13.1.3. Linearity

Linearity was determined using sera samples with known total IgG 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 1–25 g/L ±10%.

13.1.4. Sensitivity

The lowest total IgG concentration in the biological fluids that is detected by the Total IgG EIA kit is no lower than 0.06 g/L.

13.1.5. Specificity

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

Analyte	Cross-reactivity, %
IgA	< 0.1
IgM	< 0.1
IgE	< 0.1

14. REFERENCES

1. RG Hamilton – Human IgG subclass measurements in the clinical laboratory. Clin. Chem., Oct 1987; 33: 1707 – 1725.
2. V. A. Semenova, E. Steward-Clark, K. L. Stamey, T. H. Taylor, Jr., D. S. Schmidt, S. K. Martin, N. Marano, and C. P. Quinn – Mass Value Assignment of Total and Subclass Immunoglobulin G in a Human Standard Anthrax Reference Serum. Clin. Diagn. Lab. Immunol., Sep 2004; 11: 919 – 923.
3. Наказ МОЗ України №325 від 08.06.2015 «Про затвердження Державних санітарно-протиепідемічних правил і норм щодо поводження з медичними відходами».
4. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
5. 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 _____

Instruction version/date: 2024.07

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 _____

Instruction version/date: 2024.07

K271IE

	Manufacturer
IVD	*In vitro* diagnistic medical device
REF	Catalogue number
	Use-by date
LOT	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine

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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ТОВ «ХЕМА»
ПАСПОРТ КОНТРОЛЮ ЯКОСТІ
ХЕМА LLC.
QUALITY CONTROL SHEET

Товариство з обмеженою відповідальністю «ХЕМА» / ХЕМА LLC
Паспорт контролю якості / Quality control data sheet № 275/510

Кат№ Cat.#	Скорочена назва Product item	Партія Lot	Дата вир. Mfg date	Придатний до Expiry date
К275	**«Загальний IgA - ІФА» / Total IgA EIA**	**510**	**2025-11**	**2027-05**

НАБІР РЕАГЕНТІВ ДЛЯ ІМУНОФЕРМЕНТНОГО ВИЗНАЧЕННЯ ЗАГАЛЬНОГО IgA В СИРОВАТЦІ (ПЛАЗМІ) КРОВІ
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgA in human biological fluids

Набір відповідає вимогам технічної документації / Kit meets the requirements of Batch Release Criteria technical documentation

Умови зберігання. / Storage conditions. +2..+8°C

Склад набору / Kit content

№	Код Ref	Символ Symbol	Компонент Component	К-ть Qty	Од-ці Units	Партія Lot	Опис Description
1	P275Z	SORB MTP	Планшет 96-лунковий полістироловий, стрипований, готовий до використання total IgA EIA strips, 8x12 wells	1	шт/pcs	510	-
2	C275Z	CAL 1 - 5	Калібрувальні проби на основі трис-буфера (pH 7.2-7.4), що містять відомі кількості загального IgA - 0; 0.1; 0.5; 2; 5 г/л, готові до використання (по 1 мл кожна) Calibrator set, 1 ml each. The set contains 5 calibrators: 0; 0.1; 0.5; 2; 5 g/l	5	шт/pcs	5103	рідини синього кольору (калібрувальна проба С1 - безбарвна рідина)
3	Q275Z	CONTROL	Контрольна сироватка на основі сироватки крові людини з відомим вмістом загального IgA, готова до використання (1 мл) Control serum, 1 ml	1	шт/pcs	5103	безбарвна рідина
4	T275Z	CONJ HRP	Кон'югат, готовий до використання (12 мл) Conjugate, 12 ml	1	шт/pcs	5112	рідина синього кольору
5	S011Z4	DIL	ІФА-Буфер, готовий до використання (100 мл) EIA buffer, 100 ml	1	шт/pcs	5112	рідина синього кольору
6	S008Z	BUF WASH 26X	Концентрат розчину для відмивання, 26х-кратний (30 мл) Washing solution concentrate 26x, 30 ml	1	шт/pcs	510	прозора безбарвна рідина
7	R055Z	SUBS TMB	Розчин субстрату тетраметилбензидину (ТМБ), готовий до використання (12 мл) Substrate solution, 12 ml	1	шт/pcs	5083	прозора безбарвна рідина
8	R050Z	STOP	Стоп-реагент, готовий до використання (12 мл) Stop solution, 12 ml	1	шт/pcs	510	прозора безбарвна рідина
9	K275I	-	Інструкція з використання Набору реагентів «Загальний IgA - ІФА» Instruction total IgA EIA	1	шт/pcs	2025.11	-

Параметри контролю якості підтверджені
ТОВ "ХЕМА" / QC Passed

Начальник лабораторії з контролю виробництва ІФА та ІХА
Head of the ELISA and ICA production control laboratory

Мальцева Дар'я
Maltseva Daria

ХЕМА

ТОВ «ХЕМА»
ПАСПОРТ КОНТРОЛЮ ЯКОСТІ
ХЕМА LLC.
QUALITY CONTROL SHEET

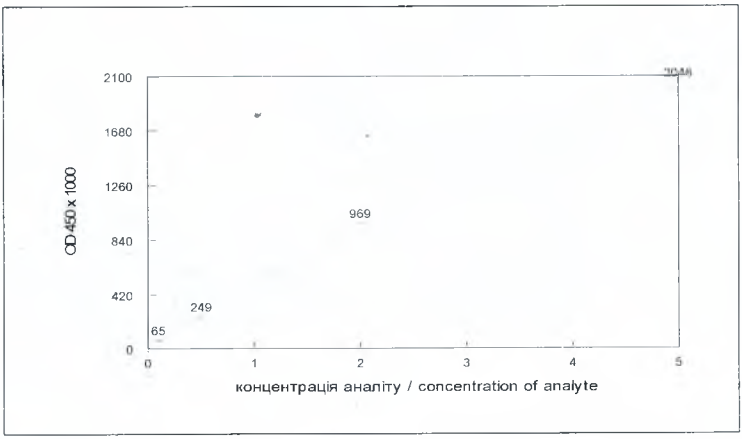
Параметри контролю якості
QC parameters

Параметр Parameter	Необхідний діапазон Required range	Отримане значення Actual value
Контрольні сироватки / Control		
Значення, г/л / Value, g/l	1.3 - 4.5	3.2
Коефіцієнт варіації, % / CV, %	< 10.0	Відповідає / Acceptable
Співвідношення ОГ, % / OD ratios, %		
B 0.1 / B 5 *100%	1 - 8	3.2
B 2 / B 5 *100%	35 - 65	47.4
Контроль достовірності / Test Validity		
ОГ/OD C1	< 0.15	Відповідає / Acceptable
ОГ/OD C5	> 1.30	Відповідає / Acceptable

Калібрувальні проби/ Calibrators
Не використовувати для обрахунків / Do not use for calculation

Номінал калібраторів, г/л Nominal, g/l		ОГ OD
C1	0	0.049
C2	0.1	0.114
C3	0.5	0.298
C4	2	1.018
C5	5	2.095

Калібрувальний графік (зразок) / Sample curve
Не використовувати для обрахунків / Do not use for calculation



Дата видачі / Issued 10.11.2025
ЛКВ / QC department

Параметри контролю якості підтверджені
ТОВ "ХЕМА" / QC Passed

Начальник лабораторії з контролю виробництва ІФА та ІХА
Head of the ELISA and ICA production control laboratory

Мальцева Дар'я
Maltseva Daria

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgA in human biological fluids

Total IgA EIA

Catalogue number REF **K275**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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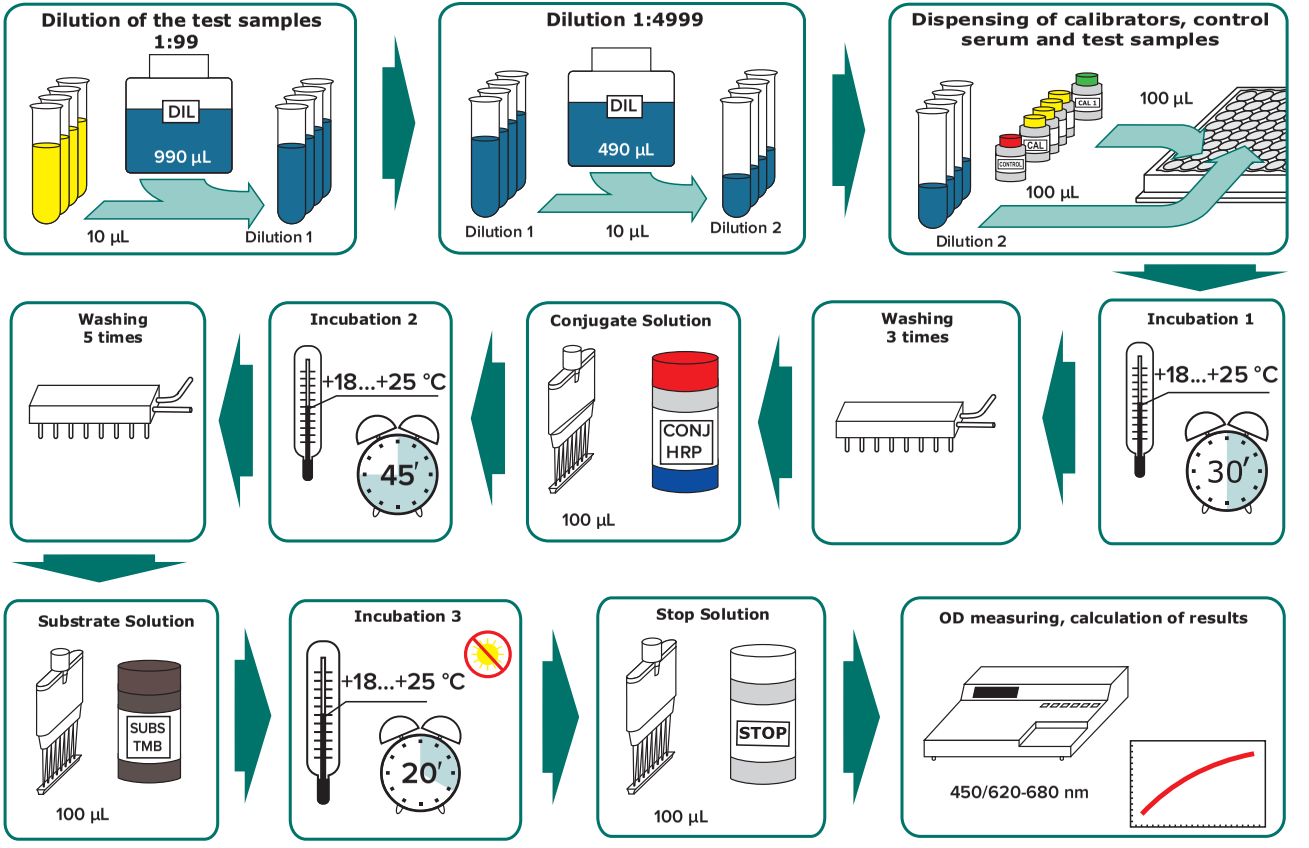
ASSAY PROCEDURE*



* For blood serum (plasma)
The method of dilution for other material types is given in table M.

During performing several independent series of tests, Calibrators and Control Serum should be used **each time.**

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgA in human biological fluids

Total IgA EIA

1. INTENDED USE

The Total IgA EIA kit is an enzyme immunoassay, intended for the quantitative determination of total IgA in biological fluids (see Table M).

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Immunoglobulin A (IgA) is a main factor of mucosal immune response to bacteria and viruses. Selective IgA deficiency is one of the most frequent hereditary disorders causing chronic infections inflammation in gastrointestinal, urinary and respiratory systems. Determination of IgA concentration in serum and other biological fluids can be used as screening for selective IgA deficiency and other immunodeficiency syndromes.

Marked elevation of serum IgA is observed in some autoimmune diseases and IgA myeloma.

3. TEST PRINCIPLE

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

- during the first stage total IgA from the specimen is captured by the antibodies coated onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated monoclonal antibodies bind to free epitopes of immobilized total IgA, 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 total IgA in test specimen.

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

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P275Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with murine monoclonal antibodies to human total IgA, ready to use
C275Z	CAL 1	**Calibrator C1**	1.0 mL	1	Solution based on tris buffer (pH 7.2-7.4), free of total IgA, with preservative, ready to use (colourless or yellow liquid)
C275Z	CAL 2-5	**Calibrators**	1.0 mL	4	Solutions based on tris buffer (pH 7.2-7.4), containing 0.1; 0.5; 2 and 5 g/L of total IgA, with preservative, ready to use (blue liquids)
Q275Z	CONTROL	**Control Serum**	1.0 mL	1	Solution based on human serum, containing of known human total IgA content, with preservative, ready to use (colourless or yellow liquid)
T275Z	CONJ HRP	**Conjugate Solution**	12 mL	1	Solution of murine monocnoclonal antibodies to total IgA conjugated to the horseradish peroxidase, ready to use (blue liquid)
S011Z4	DIL	**EIA Buffer**	100 mL	1	Buffer solution with detergent and preservative, ready to use (blue liquid)
R055Z	SUBS TMB	**Substrate Solution**	12 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**	12 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 450/620-680 nm wavelength;
- 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. Saliva should be collected using a tampon. For this purpose, it must be soaked with saliva and placed in a clean container with a lid. For urine analysis, the first portion of morning urine is taken in 15 - 25 mL in a special dry sterile bottle or container. A sample of cerebrospinal fluid is collected by the method of lumbar puncture, which is performed by a doctor in the operating room. For this, the patient is placed on his side in the fetal position, the area where the cerebrospinal fluid is taken is anesthetized, and then a hollow needle is inserted between the vertebrae. The cerebrospinal fluid obtained during the puncture should be immediately delivered to the laboratory in sterile test tubes and by appropriate referral. It is necessary to analyze the clinical sample immediately because cellular elements are rapidly destroyed.

Before use, the test samples must be thoroughly centrifuged. Analysis of opaque samples may lead to false results.

7.3 Samples should be stored as follows:

– saliva and urine samples should be stored at +2…+8°C no longer than 6 days;
– serum (plasma) 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.

7.4. 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 Total IgA 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 Total IgA 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:

– the remaining strips should be immediately resealed in the bag along with the silica gel, closed with the zip-lock, 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. The remaining strips should be immediately resealed in the bag along with the silica gel and closed with the zip-lock to prevent moisture from affecting the plate's strips.

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 blood serum (plasma) samples using EIA buffer 5000 fold (for example, add to the vial Dilution 1 (1:99): 10 µL of the test sample + 990 µL EIA buffer. In another vial, Dilution 2 (1:4999) add 10 µL Dilution 1 + 490 µL EIA buffer). Dilution 2 (1:4999) should be used in the analysis. The method of dilution for other material types is given in table M.

If suggested analyte concentration in the sample exceeds the 5 g/L, 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!

Table M

Material type	Sample dilution example	EIA sample buffer into the well, µL	Sample into the well, µL	Calculation factor
blood serum or plasma	Dilution 1 (1:99): 10 µL sample + 990 µL EIA buffer. Dilution 2 (1:4999): 10 µL dilution 1 + 490 µL EIA buffer. Dilution 2 (1:4999) should be used in the analysis	0	100	1
saliva	5 µL sample + 500 µL EIA buffer	90	10	0.2
urine	-	80	20	0.001
cerebrospinal fluid	-	50	50	0.0004

10. ASSAY PROCEDURE

10.1. Put the desired number of strips into the frame based on the number of test samples 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.** For testing of blood serum or plasma pipet **100 µL of the diluted sample (Dilution 2)** (SAMP) to the wells of the microplate according to the scheme below. See table M for the volumes of other materials. 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.

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	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 room temperature (+18...+25°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 5 µL. 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 **45 minutes at room temperature (+18...+25°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 20 minutes**.
The incubation time can be varied depending on the intensity of the blue colour development.

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 450 nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution.

10.12. Plot a calibration curve in linear coordinates: (x) is the concentration of total IgA g/L in the calibrators, (y) – OD versus total IgA concentration (OD 450 nm / 620–680 nm). Manual or computerized data reduction is applicable at this stage. For the algorithm calculation (approximation) of the calibration curve, using the interval (segment-linear, point-to-point) method is recommended.

10.13. Determine the corresponding concentration of total IgA in tested samples from the calibration curve. Use Calculation factor listed in table M to calculate analyte concentration in different material types. In the case of additional 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 below 0.15, the OD of CAL5 is above the critical value (see Quality control Data Sheet) 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 total IgA. Based on data obtained by XEMA LLC, the following normal range is recommended (see below).

NOTE: values of total IgA concentrations in the tested samples that are below the LoD (0.06 g/L) and also exceed the value of the upper calibrator (5 g/L) should be provided in the following form: «the total IgA concentration of tested sample X is «lower than 0.06 g/L» or «higher than 5 g/L».

Sex, age	Units, g/L	
	Lower limit	Upper limit
Healthy donors	0.9	5.0
> 61 yr	1.0	6.5
newborn	-	0.05
1-3 month	0.06	0.6
4-6 month	0.1	1.0
7-12 month	0.35	1.7
1-6 yrs	0.8	2.2
7-11 yrs	0.9	2.6

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1. Precision of Measurement

Reproducibility. The coefficient of variation of determining the content of total IgA in the same sample of biological fluids using the kit Total IgA EIA does not exceed 10%.

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 mezhurand. The bias was calculated for each sample and it was determined whether it corresponds to the specified limits of ± 10%.

13.1.3. Sensitivity

The lowest total IgA concentration in the biological fluids that is detected by the Total IgA EIA kit is no lower than 0.06 g/L.

13.1.4. 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, hemoglobin in a concentration of up to 10 mg/mL and triglycerides in a concentration of up to 10 mg/mL.

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

Analyte	Cross-reactivity, %
IgG	< 0.1
IgM	< 0.1
IgE	< 0.1

14. REFERENCES

1. Heiddis B. Valdimarsdottir and Arthur A. Stone – Psychosocial Factors and Secretory Immunoglobulin A. Critical Reviews in Oral Biology & Medicine, Jan 1997; 8: 461 – 474.
2. Amir H Abdul Latiff and Michael A Kerr – The clinical significance of immunoglobulin A deficiency. Ann Clin Biochem, Mar 2007; 44: 131 – 139.
3. Наказ МОЗ України №325 від 08.06.2015 «Про затвердження Державних санітарно-протиепідемічних правил і норм щодо поводження з медичними відходами».
4. Наказ МОЗ України №1827 від 31.10.2024 «Про затвердження Державних санітарних норм та правил «Порядок управління медичними відходами, у тому числі вимоги щодо безпечності для здоров'я людини під час утворення, збирання, зберігання, перевезення, оброблення таких відходів».
5. 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 _____

Instruction version/date: 2025.11

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
IVD	*In vitro* diagnistic medical device
REF	Catalogue number
	Use-by date
LOT	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine

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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ТОВ «ХЕМА»
ПАСПОРТ КОНТРОЛЮ ЯКОСТІ
ХЕМА LLC.
QUALITY CONTROL SHEET

Товариство з обмеженою відповідальністю «ХЕМА» / ХЕМА LLC
Паспорт контролю якості / Quality control data sheet № 277/510

Кат№ Cat.#	Скорочена назва Product item	Партія Lot	Дата вип. Mfg date	Придатний до Expiry date
K277	**«Загальний IgM-ІФА» / Total IgM EIA**	**510**	2025-10	**2027-05**

НАБІР РЕАГЕНТІВ ДЛЯ ІМУНОФЕРМЕНТНОГО ВИЗНАЧЕННЯ ЗАГАЛЬНОГО IgM В СИРОВАТЦІ (ПЛАЗМІ) КРОВІ
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgM in human biological fluids

Набір відповідає вимогам технічної документації / Kit meets the requirements of Batch Release Criteria technical documentation

Умови зберігання: / Storage conditions: +2..+8°C

Склад набору / Kit content

№	*Код Ref*	*Символ Symbol*	*Компонент Component*	*К-ть Qty*	*Од-ці Units*	*Партія Lot*	*Опис Description*
1	P277Z	SORB MTP	Планшет 96-лунковий полістироловий, стрипований, готовий до використання Total IgM EIA strips, 8x12 wells	1	шт/pcs	510	-
2	C277Z	CAL 1 - 5	Калібрувальні проби на основі трис-буфера (pH 7.2-7.4), що містять відомі кількості загального IgM - 0; 0.5; 2; 5; 10 г/л, готові до використання (по 1 мл кожна) Calibrator set, 1 ml each. The set contains 5 calibrators: 0; 0.5; 2; 5; 10 g/l	5	шт/pcs	5106	рідини пурпурового кольору (калібрувальна проба С1 - безбарвна або жовтого кольору рідина)
3	Q277Z	CONTROL	Контрольна сироватка на основі сироватки крові людини з відомим вмістом загального IgM , готова до використання (1 мл) Control serum (1 ml)	1	шт/pcs	5106	безбарвна або жовтого кольору рідина
4	T277Z	CONJ HRP	Кон'югат, готовий до використання (12 мл) Conjugate, 12 ml	1	шт/pcs	5102	рідина пурпурового кольору
5	S011Z4	DIL	ІФА-Буфер, готовий до використання (100 мл) EIA buffer, 100 ml	1	шт/pcs	508	рідина синього кольору
6	R055Z	SUBS TMB	Розчин субстрату тетраметилбензидину (ТМБ), готовий до використання (12 мл) Substrate solution, 12 ml	1	шт/pcs	5083	безбарвна рідина
7	S008Z	BUF WASH 26X	Концентрат розчину для відмивання, 26х-кратний (30 мл) Washing solution concentrate 26x, 30 ml	1	шт/pcs	510	прозора безбарвна рідина
8	R050Z	STOP	Стоп-реагент, готовий до використання (12 мл) Stop solution, 12 ml	1	шт/pcs	510	прозора безбарвна рідина
9	K277I	-	Інструкція з використання Набору реагентів «Загальний IgM-ІФА» Instruction Total IgM EIA	1	шт/pcs	2025.10	-

Параметри контролю якості підтверджені
ТОВ "ХЕМА" / QC Passed

Начальник лабораторії з контролю виробництва ІФА та ІХА
Head of the ELISA and ICA production control laboratory

Мальцева Дар'я
Maltseva Daria

ХЕМА

ТОВ «ХЕМА»
ПАСПОРТ КОНТРОЛЮ ЯКОСТІ
ХЕМА LLC
QUALITY CONTROL SHEET

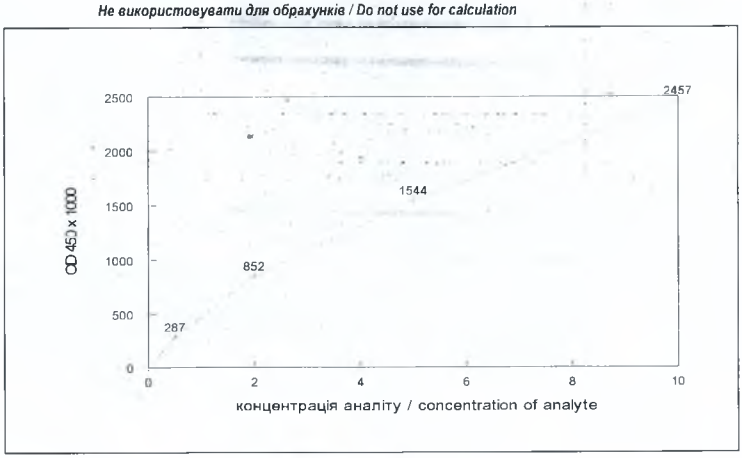
Параметри контролю якості
QC parameters

Параметр Parameter	Необхідний діапазон Required range	Отримане значення Actual value
Контрольні сироватки / Control		
Значення, г/л / Value, g/l	1.7 - 2.7	2.2
Коефіцієнт варіації, % / CV, %	< 10.0	Відповідає / Acceptable
Співвідношення ОГ, % / OD ratios, %		
B 0.5 / B 10 *100%	1 - 15	11.7
B 5 / B 10 *100%	35 - 85	62.8
Контроль достовірності / Test Validity		
ОГ/OD C1	<	0.15
ОГ/OD C5	>	1.5

Калібрувальні проби/ Calibrators
Не використовувати для обрахунків / Do not use for calculation

Номінал калібраторів, г/л Nominal, g/l	ОГ OD
C1	0	0.009
C2	0.5	0.296
C3	2	0.861
C4	5	1.553
C5	10	2.466

Калібрувальний графік (зразок) / Sample curve
Не використовувати для обрахунків / Do not use for calculation



Дата видачі / Issued 07.11.2025
ЛКВ / QC department

Параметри контролю якості підтверджені
ТОВ "ХЕМА" / QC Passed

Начальник лабораторії з контролю виробництва ІФА та ІХА
Head of the ELISA and ICA production control laboratory

Мальцева Дар'я
Maltseva Daria

ХЕМА

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgM in human biological fluids

Total IgM EIA

Catalogue number REF **K277**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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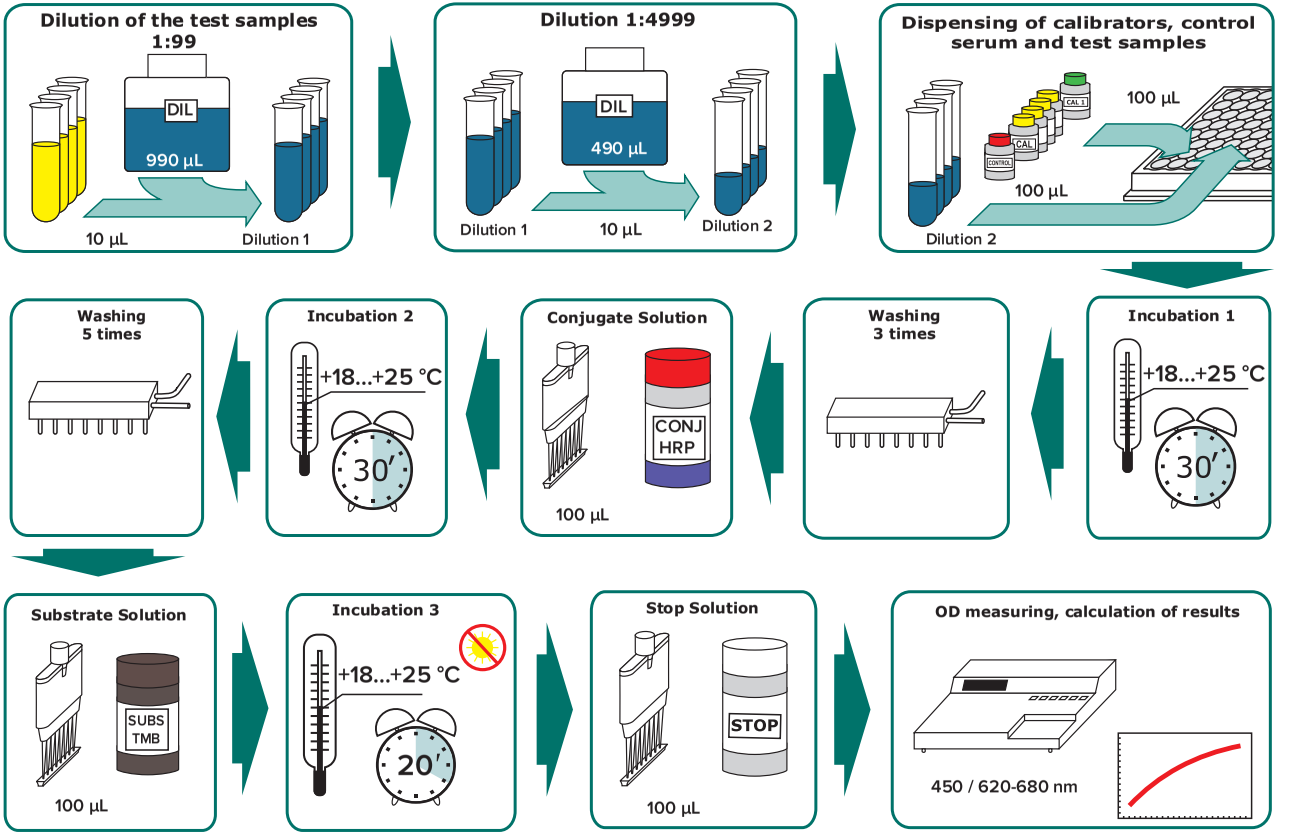
ASSAY PROCEDURE*



* For blood serum (plasma)
The method of dilution for other material types is given in table M.

During performing several independent series of tests, Calibrators and Control Serum should be used **each time.**

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the quantitative determination of total IgM in human biological fluids

Total IgM EIA

1. INTENDED USE

The Total IgM EIA kit is an enzyme immunoassay, intended for the quantitative determination of total IgM in biological fluids (see Table M).

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Immunoglobulin M (IgM) is secreted during primary immune response and exists in monomeric and pentameric forms. Elevated serum IgM is observed in chronic inflammation, macroglobulinemia and IgM myeloma. Decreased IgM level may occur in some immunodeficiency syndromes. A sharp increase in IgM levels is characteristic of macroglobulinemia (Waldenström's disease) and IgM myeloma.

3. TEST PRINCIPLE

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

- during the first stage total IgM from the specimen is captured by the antibodies coated onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated monoclonal antibodies bind to free epitopes of immobilized total IgM, 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 total IgM in test specimen.

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

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P277Z	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with murine monoclonal antibodies to human total IgM, ready to use
C277Z	CAL 1	**Calibrator C1**	1.0 mL	1	Solution based on tris buffer, free of total IgM, with preservative, ready to use (colourless liquid)
C277Z	CAL 2-5	**Calibrators**	1.0 mL	4	Solutions based on tris buffer, containing 0.5; 2; 5; and 10 g/L of total IgM, with preservative, ready to use (purple liquids)
Q277Z	CONTROL	**Control Serum**	1.0 mL	1	Solution based on human serum, containing of known human total IgM content, with preservative, ready to use (colourless liquid)
T277Z	CONJ HRP	**Conjugate Solution**	12 mL	1	Solution of murine monocnoclonal antibodies to total IgM conjugated to the horseradish peroxidase, ready to use (purple liquid)
S011Z4	DIL	**EIA Buffer**	100 mL	1	Buffer solution with detergent and preservative, ready to use (blue liquid)
R055Z	SUBS TMB	**Substrate Solution**	12 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**	12 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 450/620-680 nm wavelength;
- 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. Saliva should be collected using a tampon. For this purpose, it must be soaked with saliva and placed in a clean container with a lid. For urine analysis, the first portion of morning urine is taken in 15 - 25 mL in a special dry sterile bottle or container. A sample of cerebrospinal fluid is collected by the method of lumbar puncture, which is performed by a doctor in the operating room. For this, the patient is placed on his side in the fetal position, the area where the cerebrospinal fluid is taken is anesthetized, and then a hollow needle is inserted between the vertebrae. The cerebrospinal fluid obtained during the puncture should be immediately delivered to the laboratory in sterile test tubes and by appropriate referral. It is necessary to analyze the clinical sample immediately because cellular elements are rapidly destroyed.

Before use, the test samples must be thoroughly centrifuged. Analysis of opaque samples may lead to false results.

7.3 Samples should be stored as follows:

– saliva and urine samples should be stored at +2…+8°C no longer than 6 days;
– serum (plasma) 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.

7.4. 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 Total IgM 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 Total IgM 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:

– the remaining strips should be immediately resealed in the bag along with the silica gel, closed with the zip-lock, 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. The remaining strips should be immediately resealed in the bag along with the silica gel and closed with the zip-lock to prevent moisture from affecting the plate's strips.

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 the blood serum (plasma) samples using EIA buffer 5000 fold (for example, add to the vial Dilution 1 (1:99): 10 µL of the test sample + 990 µL EIA buffer). In another vial, Dilution 2 (1:4999) add 10 µL Dilution 1 + 490 µL EIA buffer. Dilution 2 (1:4999) should be used in the analysis. The method of dilution for other material types is given in table M.

If suggested analyte concentration in the sample exceeds the 10 g/L, 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!

Table M

Material type	Sample dilution example	EIA sample buffer into the well, µL	Sample into the well, µL	Calculation factor
blood serum or plasma	Dilution 1 (1:99): 10 µL sample + 990 µL EIA buffer. Dilution 2 (1:4999): 10 µL dilution 1 + 490 µL EIA buffer. Dilution 2 (1:4999) should be used in the analysis	0	100	1
saliva	-	90	10	0.002
urine	-	50	50	0.0004
cerebrospinal fluid	-	80	20	0.001

10. ASSAY PROCEDURE

10.1. Put the desired number of strips into the frame based on the number of test samples 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.** For testing of blood serum or plasma dispense **100 µL of the diluted sample (Dilution 2)** (SAMP) to the wells of the microplate according to the scheme below. See table M for the volumes of other materials. 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.

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	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 room temperature (+18...+25°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 5 µL. 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 room temperature (+18...+25°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 20 minutes**.
The incubation time can be varied depending on the intensity of the blue colour development.

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 450 nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution.

10.12. Plot a calibration curve in linear coordinates: (x) is the concentration of total IgM g/L in the calibrators, (y) – OD versus total IgM concentration (OD 450 nm / 620–680 nm). Manual or computerized data reduction is applicable at this stage. For the algorithm calculation (approximation) of the calibration curve, using the interval (segment-linear, point-to-point) method is recommended.

10.13. Determine the corresponding concentration of total IgM in tested samples from the calibration curve. In the case of additional preliminary dilution of the test sample (see 9.4), the obtained result should be multiplied by the dilution factor. Use Calculation factor listed in table M to calculate analyte concentration in different material types.

11. TEST VALIDITY

The test run shall be considered valid if the OD of CAL1 is below 0.15, the OD of CAL5 is above the critical value (see Quality control Data Sheet) 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 total IgM. Based on data obtained by XEMA LLC, the following normal range is recommended (see below).

NOTE: values of total IgM concentrations in the tested samples that are below the LoD (0.06 g/L) and also exceed the value of the upper calibrator (10 g/L) should be provided in the following form: «the total IgM concentration of tested sample X is «lower than 0.06 g/L» or «higher than 10 g/L».

Sex, age	Units, g/L	
	Lower limit	Upper limit
Healthy donors	0.7	3.7
newborn	0.1	0.35
1-3 month	0.12	0.9
4-6 month	0.25	1.2
7-12 month	0.35	1.0
1-6 yrs	0.55	2.2
7-11 yrs	0.65	1.7

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1. Precision of Measurement

Reproducibility. The coefficient of variation of determining the content of total IgM in the same sample of biological fluids using the kit Total IgM EIA does not exceed 10%.

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 mezhurand. The bias was calculated for each sample and it was determined whether it corresponds to the specified limits of ± 10%.

13.1.3. Sensitivity

The lowest total IgM concentration in the biological fluids that is detected by the Total IgM EIA kit is no lower than 0.06 g/L.

13.1.4. Specificity

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

Analyte	Cross-reactivity, %
IgA	< 0.1
IgG	< 0.1
IgE	< 0.1

14. REFERENCES

1. Erik J. Wiersma, Cathy Collins, Shafie Fazel, and Marc J. Shulman Structural and Functional Analysis of J Chain-Deficient IgM J. Immunol., Jun 1998; 160: 5979 – 5989.
2. Наказ МОЗ України №1827 від 31.10.2024 «Про затвердження Державних санітарних норм та правил «Порядок управління медичними відходами, у тому числі вимоги щодо безпечності для здоров'я людини під час утворення, збирання, зберігання, перевезення, оброблення таких відходів».
3. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
4. 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 _____

Instruction version/date: 2025.10

SAMPLES IDENTIFICATION PLAN

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

LOT _____ DATE _____

Instruction version/date: 2025.10

K2771E

	Manufacturer
IVD	*In vitro* diagnistic medical device
REF	Catalogue number
	Use-by date
LOT	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine

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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UkrMedCert

8О047
Сертифікація
систем менеджменту

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.