Allele
Innovating
Biotechnologies Center

MANUAL OF THE DETECTION KIT FOR CLASS G IMMUNOGLOBULINS (IGG) TO SARS-COV-2 CORONAVIRUS BY IMMUNO-ENZYME METHOD

"SARS-CoV-2-IgG-ELISA"

Manual

CATALOGUE NUMBER REF **AL-EL-1**

ТУ №21.10.60-001-83076696-2020

For 96 studies

IVD *For in vitro diagnostics*

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Contents

1. General description of the kit

Full name	"Detection kit for class G immunoglobulins (IgG) to coronavirus SARS-CoV-2 by immuno-enzyme method "
Brief name	SARS-CoV-2-IgG-ELISA
Catalogue number	AL-EL-1
Shelf life of the kit	1 year
Detection range	Qualitative: positive and negative control
Control samples	2 (are not included in the kit)
Total assay time	Not more than 120 minutes
Assay scheme	Two stages
Volume of biological material for the assay (blood serum/plasma)	10 mcl
Number of detections	The kit is designed for 96 detections including controls. For manual and automatic methods
Preparedness of the kit components for use	Preliminary preparation of the working solution of the wash buffer (WB). The other components are to use.
Package	The plate is packed in a plastic foil coated bag with a zip fastening mechanism.
Maintenance documentation	Manual of SARS-CoV-2-IgG-ELISA V-05-2020 kit

2. Application of the kit

The “SARS-CoV-2-IgG-ELISA” reagent kit is designed for the qualitative detection of class G immunoglobulins for SARS-CoV-2 coronavirus in human serum or plasma and is recommended for in vitro diagnosis and epidemiological studies.

2.1. Relevance of the problem

Widespread incidence of the new coronavirus infection COVID-19 caused by the SARS-CoV-2 virus has set complex tasks to the medical community, connected with a quick and reliable diagnostics and efficient treatment of the patients with this infection. The most dangerous complications associated with a high mortality rate among patients with COVID-19 who are monitored in intensive care units include acute respiratory distress syndrome (ARDS). The main role in the pathogenesis of ARDS is played by the excessive response of the immune system, as a result of which a systemic inflammatory response syndrome (cytokine storm) can develop.

This specificity of viral disease presumes the production of antibodies to the components of viral particles. The detection of these antibodies confirms a past illness or asymptomatic carriage and indicates the presence of immunity. The duration and intensity of immunity to SARS-CoV-2 have not been studied well enough so far, so, in the event of a repeated threat of the disease, repeated studies can be carried out.

2.2. Diagnostic methods for the new coronavirus infection COVID-19

Initially, SARS-CoV-2 infection can be confirmed by the detection of pathogen RNA in biological samples of the patient, such as bronchoalveolar lavage, sputum, oropharyngeal swabs. SARS-CoV-2 RNA can be diagnosed from the first days after infection and is a fairly sensitive

study. Currently, these tests are widely used and represented by kits of both foreign and domestic production. The test systems of the PCR-RT and LAMP format (loop isothermal amplification) are mainly used.

The disadvantages of PCR-based diagnostics are that the persistence of the virus in the tissues is observed for a short time. According to the studies, 90% of the tests for SARS-CoV-2 viral RNA in nasopharyngeal swabs become negative 8-10 days after the onset of symptoms, and, thus PCR test systems can give false-negative results during a later period after infection. Besides, false-negative PCR test results can be obtained with an asymptomatic course of the disease in a patient. Serological research methods based on the diagnosis of specific antibodies (immunoglobulins) to the SARS-CoV-2 virus are devoid of these drawbacks. Methods for detection of serum antibodies include colloidal gold immunochromatography, ELISA, chemiluminescent immunoassay, etc. Specific IgG antibodies appear in the blood of patients with SARS-CoV-2 already 12 days after the onset of the symptoms and can be detected for a long time, while the titer of specific IgG antibodies in the recovery phase is about 4 times higher than in the acute phase. Positive specific IgG can be used as a diagnostic criterion in patients with suspected COVID-19 with a negative nucleic acid test, to detect asymptomatic and obliterated/supressed forms of COVID-19, to determine the duration and intensity of immunity to SARS-CoV-2, as well as for identification of potential plasma donors that can be used in the treatment of severe forms of COVID-19.

3. Assay principle

The “SARS-CoV-2-IgG-ELISA” reagent kit is a test system based on the method of indirect enzyme-linked immunosorbent assay. A recombinant SARS-CoV-2 virus antigen is applied to the bottom of the wells of a polystyrene collapsible / non-separable plate, which during the incubation process interacts with SARS-CoV-2 antibodies present in the test sample. Then, antibodies to human immunoglobulins of class G (IgG) labeled with the enzyme (horseradish peroxidase) are added to the formed immune complex. After performance of a substrate-enzymatic reaction with the participation of a chromogen (tetramethylbenzidine, TMB), the obtained results are recorded. If there are specific anti-SARS-CoV-2 class G immunoglobulins (IgG) in the sample, the optical density in the well exceeds the values of the negative control samples, and is proportional to the content of specific class G antibodies in the sample.

4. Application field of the kit

The “SARS-CoV-2-IgG-ELISA” kit is intended for use in clinical laboratory diagnostics. The “SARS-CoV-2-IgG-ELISA” kit is used to detect a specific class G immunoglobulins (IgG) for the SARS-CoV-2 coronavirus in all individuals without gender and age limitations, with or without SARS symptoms. The “SARS-CoV-2-IgG-ELISA” kit is meant for professional use only. Only for diagnostics in vitro. For medical organizations irrespective of their legal status.

5. Potential users

To perform an assay with this reagent kit it will be necessary to attract specialists not younger than 18 with higher or secondary medical, biological or other educationc, without any medical counterindications for vaccinations, treatment with specific drugs and work with the use of personal protective equipment. Personnel must have skills to work biochemical reagents and modern laboratory equipment.

6. Indications and counterindications for use of the kit

No counterindications or side-effects while working with the “SARS-CoV-2-IgG-ELISA” kit have been found. The “SARS-CoV-2-IgG-ELISA” kit is meant only for intended application one time.

7. Test samples

To perfrom enzyme immunoassay, the use of serum or plasma samples is permissible. The required temperature regime for storing serum and plasma samples: 2 ... 8 ºC up to 5 days or -18 ... -22 ºC up to 6 months.

8. Preparation of test samples for the study

Before commencement of an assay using the “SARS-CoV-2-IgG-ELISA” kit, samples stored in a refrigerator or freezer should be thawed at a temperature of 18 to 25 ° C and mixed thoroughly. Before the assay, it is necessary to centrifuge the samples for 15 minutes at a speed of 3000 rpm. It’s not permissible to use samples with expressed hemolysis or chyle, as well as samples, in which bacterial growth is present. It is not permissible to perform repeated freeze-thawing cycles of the samples.

The required volume of the test sample of serum or blood plasma for analysis is 10 mcl. Anticoagulants do not affect the assay results.

9. The kit composition

Name	Volume, ml	Quantity, pieces	Description
Immunosorbent, 96-well cell plate, polystyrene, Separable 12 strips*8 wells / non-separable, 96 wells (IS)	-	1	In a plastic foil coated bag, ready to use
Wash buffer, 25x concentrate, (WB)	29	1	Transparent colourless liquid
Serum diluent, (SD)	17	1	Transparent violet liquid
Monoclonal antibodies to human IgG conjugated to horseradish peroxidase (conjugate)	17	1	Transparent pink liquid
Tetramethylbenzidine solution in substrate buffer, chromogen (TMB)	17	1	Colourless or pale-yellow transparent liquid
0.5% sulfuric acid solution (stop reagent)	17	1	Transparent colourless liquid
Positive control sample **(К+)**	1,3*	1	Transparent colourless liquid

Negative control sample **(К-)**	2*	1	Transparent light-yellow liquid
Film to cover the plate	-	3	-
Quick manual of the "SARS-CoV-2-IgG-ELISA" reagent kit. Full version of the manual is available on the manufacturer's website.	-	1	-

* - substance containing / not containing native or recombinant human chimeric IgG (or fragments thereof) to SARS-CoV-2 antigens. In case of presence of components derived from human biological material, pathogen reduction is performed. Control biological material does not contain p24 HIV-1, HBsAg, antibodies to antigens to HIV 1,2, antibodies to VHC.

10. Necessary additional equipment not included in the kit

10.1. A spectrophotometer allowing you to measure the optical density of solutions in the wells of a tablet at a wavelength of 450 nm;

10.2. A thermostatic shaker incubator, maintaining the temperature (37 ± 1) ° C;

10.3. A device to wash the wells of tables with washing buffer;

10.4.4. Dispensers single-channel and / or multi-channel with replaceable tips, with volume up to 10 mcl; up to 200 mcl; up to 1000 mcl;

10.5. Disposable bowls for reagents;

10.6.6. Pharmaceutical refrigerator, with temperature range 2…8 ºC;

10.7. Measuring cylinder, volume up to 100 ml, up to 1000 ml;

10.8. Laboratory filter paper;

10.9. Distilled or deionized water.

11. Requirements for packaging and labelling of the kit

11.1. Packaging

11.1.1. The outer and inner packaging of the kit must be whole, without deformations. The bottles with screw caps must not leak when turned upside down.

11.1.2. The bottles with reagents, the pack with the plate (IS) and the application instruction are packed in a cardboard box with a liner (lodgement) made of cardboard.

11.1.3. The plate (IS) is hermetically packed in a pack of combined material with a lock, and every pack contains commercial prepack silica gel.

11.1.4. К+ and К- are dispensed into conical 2 ml bottles with a screw cap.

11.1.5. Conjugate, PPC, TMB stop reagent are dispensed into plastic 20 ml bottles with a crew cap.

11.1.6. Wash buffer (x25 concentrate) must be in 30 ml plastic bottles with a screw cap.

11.2. Labelling

11.2.1. The graphic design of the bottles with reagents, immunosorbent packs, plastic bags with a lock or boxes comply with GOST P 51088-2013 and GOST P ИСО18113-2-2015.

11.2.2. Each bottle of the kit and the bag with IS have black and white or multi-coloured self-adhesive labels listing the abbreviated name of the manufacturer, the abbreviated name of the reagent kit, the reagent volume (liquid reagents), series (batch, LOT) number of the kit, shelf life (best before) and storage conditions, warning notice: "Only for in vitro diagnostics";

11.2.3. The pack with IS and the bottles with conjugate, PPC, wash buffer, TMB, K+, K-, and stop reagent must list the commercial (trade) name of the reagent kit.

11.2.4. Each kit (box) or the label stuck onto each kit (box) has a marking listing, in accordance with GOST P 51088-2013: manufacturer's name, registered address, e-mail, link to the manufacturer's website in the form of QR-code, full and abbreviated name of the regent kit, composition of the kit (names of the components, quantity, volume), catalogue number of the kit, number of assay this kit is designed for (including control samples), series (batch, LOT) number of the kit, shelf life (best before) and storage conditions, warning notice: "Only for in vitro diagnostics", "Read the application instruction", "Caution! Read the application instruction", full version of the kit manual download link, link to the manufacturer's website in the form of QR-code, registration number, the number of these technical specifications conditions.

12. Functional (technical) characteristics

Lower detection threshold	When diluting the positive control sample "K+" (or analogical one in term of antibodies contents) by 100 times, the result of assay is positive.
Specificity	Negative sample "K-" must be interpreted as negative. Positive sample "K+" must be interpreted as positive.
Reproducibility	The study established variation coefficient of optical densities of the repletion of the positive sample "K+". The variation coefficient is not more than 8%.
Absence of false-positive /false negative results	Negative control sample – when performing the enzyme immunoassay in the wells with "K-" (all the values of optical density in the wells with "K-" ≤ 0,2 a.u.). Positive control sample - when performing the enzyme immunoassay in the wells with "K+" (the value of optical density in the well with K+ ≥ 0,5 a.u.).
Biological preparations for production and control	Positive control sample – substance containing native or recombinant chimerical human IgG to the SARS-CoV-2 antigens (or its fragments). In case of presence of components derived from human biological material, pathogen reduction is carried out by heating at a temperature of (56 ± 1) ° C for 3 hours. The control biological material does not contain p24 HIV-1, HBsAg, antibodies to HIV antigens 1,2, antibodies to HCV. Negative control sample – substance, which does not contain native or recombinant chimerical human IgG to the SARS-CoV-2 antigens (or its fragments). In case of presence of components derived from human biological material, pathogen reduction is carried out by heating at a temperature of (56 ± 1) ° C for 3 hours. The control biological material does not contain p24 HIV-1, HBsAg, antibodies to HIV antigens 1,2, antibodies to HCV.

13. Precautions and recommendations for use of the kit

ATTENTION! Follow the instructions closely to obtain accurate results. The manufacturer is not responsible and assumes no liability for incorrect results of the study owing to non-observance of the instructions requirements.

13.1 Do not use together reagents of different series, batches, lots and kits of other manufacturers. Do not use reagents after expiry date;

13.2 Use clean volumetric ware and automatic pipettes accurate to within mot more than 5 % when making a solution and preparing for the enzyme immunoassay;

13.3 It's inadmissible to draw the reagents for pipetting the plate directly from the bottle. Put the necessary amount of the solution into the bowl for reagents and start pipetting the plate. It's inadmissible to pour the remaining reagents from the bowl back into the bottle;

13.4 Use replacement disposable tips for each reagent and for each sample to prevent cross-contamination;

13.5 Use one recommended volume of the sample as specified in the instruction, otherwise it may affect the results validity;

13.6 Dust and chemicals such as sodium hypochloride, acids, alkalis, etc. can affect the conjugate enzymatic activity. Do not perform the assay in the presence of these substances;

13.7 Do not expose to light the chromogen solution (TMB);

13.8 Make sure that the temperature inside the incubator is 37^0C;

13.9 Avoid long intervals between the steps of the procedure. Keep equal condition for all the wells;

13.10 Do not let the wells dry after washing. Do not let bubbles from when adding the reagents;

13.11 Do not touch the bottom and surface of the wells. Fingerprints and scratches may affect the accuracy of the readings;

13.12 Make sure there are no bubbles in the wells when spectrophotometer is used.

14. Safety requirements

Attention! All human blood samples should be considered potentially infectious.

14.1 Laboratories performing assays to detect the IgG to the SARS-CoV-2 coronavirus are required to ensure the safety of work in compliance with the requirements of the legislation in the field of sanitary and epidemiological safety. The work with the test samples, if necessary, must be performed in compliance with the requirements Sanitary Regulations 1.3.3118-13 "Work safety with microorganisms of I-II pathogenicity groups (risk groups)", Sanitary Regulations 1.2.036-95 "Procedures for keeping a record of, storage, handover and transportation of microorganisms of pathogenicity groups", Sanitary and Epidemiological Regulations 2.1.7.2790-10 "Sanitary and epidemiological requirements for handling medical waste".

14.2 Potential risk of using reagent kits according to Nomenclature Classification of Medical Devices, approved by Order of the Ministry of Healthcare of the Russian Federation No. 4н of 6 June 2012 (revised version of Order of the Ministry of Healthcare of the Russian Federation of 25.09.2014 N 557н) – class 3.

14.3 The reagent kit is meant only for professional use. The work should be performed in a specially equipped laboratory room meeting the requirements Sanitary Regulations

1.3.2322 “Work safety with microorganisms of III-IV pathogenicity groups (risk groups) and pathogenic agents of parasitical diseases”. When using the regent kit it is necessary to observe the requirements “Instructions on measures to prevent the spread of infectious diseases when working in clinical and diagnostic laboratories of medical and preventive treatment institution” (approved by the Ministry of Healthcare of the USSR 17.01.1991) and GOST P 52905-2007 “Medical laboratories. Safety requirements”.

14.4 When using the reagent kit and the test samples use personal protective equipment: mask, medical overall, head wear, rubber or plastic gloves, special footwear, protective glasses or a screen), as blood serum and plasma samples should be viewed as potentially infected biomaterial.

14.5 It is necessary to simultaneously provide personnel with disinfectant and or horseradish peroxidase contained in conjugate solution and make sure the personnel observes the rules of biological safety and requirements for organization and performance of work to prevent contamination of the test samples, rooms and equipment.

14.6 Clean hands after work with the reagent kit and samples in accordance with the effective regulatory documentation.

14.7 All the components of the reagent kit, except the stop-reagent, are nontoxic. The stop-reagent has irritant effect. Avoid spray dissemination and contact with skin or mucous membrane. In case of contact, rinse the affected area with plenty of running water.

15. Waste disposal

Disposal and recycling of reagent kits should be performed in accordance with Sanitary and Epidemiological Regulations 2.1.7.2790-10 “Sanitary and epidemiological requirements for handling medical waste” and МУ-287-113 “Recommended practices for disinfection, pre-sterilization cleaning and sterilization of medical products”.

15.1 Wash solutions must be collected in a special container, treated with disinfectants approved for use in the territory of the Russian Federation in the prescribed manner and disposed of as class B waste.

15.2 Solid waste collected in a special container must be decontaminated in accordance with Sanitary and Epidemiological Regulations 2.1.7.2790-10 “Sanitary and epidemiological requirements for handling medical waste” and disposed of as class B waste.

15.3 Unused expired reagent kits must be dekitted before disposal..

15.3.1 Unused washing solution concentrate must be disposed of as class A waste.

15.3.2 Unused positive and negative controls, conjugate, serum diluent and immunosorbent must be decontaminated and disposed of as Class B medical waste.

15.3.3 Unused TMB chromogen concentrate and stop reagent should be disposed of as class E waste.

15.3.4 All the materials used during the enzyme-linked immunosorbent assay (tips, bottles, plates, containers for samples) and the workplace must be disinfected in accordance with the requirements Sanitary Regulations 1.3.3118-13 and Recommended Practices МУ-87-113.

15.4 Recycling of reagent kits and used materials must be carried out by specialized organizations licensed to dispose of medical waste.

15.5 Enzyme-linked immunosorbent assay

15.6 Manual procedures for the assay

15.6.1 Bring the reagents to room temperature (18-25°C) during the period of 15-30 minutes.

15.6.2 Prepare the working solution of the wash buffer.

ATTENTION! If the bottle of the wash buffer concentrate contains sediment of salts, the bottle should be stored at 37 ºC until complete dissolution occurs.

The contents of the bottle with 25x concentrate of the wash buffer must be diluted with distilled water in accordance with the "wash buffer dilution table". Use only clean tubes for dilution of the wash buffer.

Wash buffer dilution table:

Number of used IS strips	**25x concentrate, ml**	**dH_2O, ml**	**Total volume, ml**
1	2	48	50
2	4	96	100
3	6	144	150
4	8	192	200
5	10	240	250
6	12	288	300
7	14	336	350
8	16	384	400
9	18	432	450
10	20	480	500
11	22	528	550
12	24	576	600

15.6.3 3. Extract the necessary number of IS strips from the plate. Place the strips in the holder. For each performance you need to add to the test samples three controls: negative control (K-) twice and positive control (K+), see the plate scheme template for the assay performance (when performing an assay on one strip it is allowed to use for K- and K+ per one well)..

Plate scheme template for the assay performance::

K-	Sample No.6	Sample No.14
K-	Sample No.7	Sample No.15
K+	Sample No.8	Sample No.16
Sample No.1	Образец №9	Sample No.17
Sample No.2	Sample No.10	Sample No.18
Sample No.3	Sample No.11	Sample No.19
Sample No.4	Sample No.12	Sample No.20
Sample No.5	Sample No.13	Sample No.21

15.6.4 Add 100 mcl of solution for serum dilution (PPC) into all the wells, except the control ones (K+, K-);

15.6.5 Add 10 mcl of the test samples into all the wells, except the control ones (K+, K-), and stir thoroughly by pipetting. Add 100 mcl of the positive control sample (K+) into well K+, and 100 mcl of negative control sample (K-) into wells K-;

15.6.6 Incubation No. 1: stick up the plate with a film and incubate for 30 minutes at 370C. It is recommended to use an incubator with a shaking option (shaker-incubator);

15.6.7 Washing No. 1: after the incubation, remove the film and dispose of it. Wash the plate wells 5 times with a wash buffer (WB) by adding 300 mcl into each well. Each time leave the wells filled for 30-60 seconds. After the last (fifth) washing, turn the plate over onto the paper towel (filter paper) and tap on the plate to remove the liquid;

15.6.8 Add 100 mcl of conjugate into all the wells;

15.6.9 Incubation No. 2: stick up the plate with a film and incubate for 30 at 370C. It is recommended to use an incubator with a shaking option (shaker-incubator);

15.6.10 Washing No. 2: after the incubation, remove the film and dispose of it. Wash the plate wells 5 times with a wash buffer (WB) by adding 300 mcl into each well. Each time leave the wells filled for 30-60 seconds. After the last (fifth) washing, turn the plate over onto the paper towel (filter paper) and tap on the plate to remove the liquid.

15.6.11 Manifestation of colour reaction: Add 100 mcl of chromogen (TMB) into each well and stir by pipetting. Incubate the plate in darkness for 15 minutes at 370C.

15.6.12 Arresting a reaction: add 100 mcl of stop-reagent into each well and stir by pipetting. Measure the optical density not later than 10 minutes after adding the stop-reagent.

15.7 **Use of EIA analyzers**

The SARS-CoV-2-IgG-ELISA reagent kit is adapted for any open semi-automatic and automatic enzyme immunoassay analyzers. Considering the use of automatic analysis systems, the volume of kit components is increased by 10%, however, additional volume of reagents may be needed for some analyzer models. The necessary additional kit components are provided by the manufacturer upon preliminary request..

16. Calculation and interpretation of the results

Measurements of optical density are made spectrophotometrically at a wavelength of 450 nm with a “zero” setting of the instrument (blank) over the air.

For each enzyme-linked immunosorbent assay, the critical value of optical density (ODcrit.) and the “grey zone” are calculated. The "grey zone" is an interval from ODcrit. - 10% to ODcrit. + 10%. The test sample is taken into account as positive if the OD of this sample is above the “grey zone”, as doubtful if the OD is within the “grey zone”, and negative if the OD is below the “grey zone”. Options of the interpretation of the results are presented in the table "interpretation of the studies results”.

16.1. Enzyme-linked immunosorbent assay quality control range.

The results of the studies are considered to be reliable if an average value of optical density (OD) in the wells of negative control sample (K-) is ≤0,2 a.u., while the value of optical density (OD) in the well of the positive control sample (K+) ≥ 0,5 a.u.

16.2. Calculation and interpretation of enzyme-linked immunosorbent assay results.

For interpretation of the results OD (K-)average is calculated using the following formula:

$$\mathbf{OD(K\text{-})average = (OD(K\text{-})_1+OD(K\text{-})_2)/2 \qquad (1),}$$

Where OD (K-)average – average value of OD in the wells with K-;

$OD(K\text{-})_1$ – optical density value in the well with K- in the first repeat

$OD(K-)_2$ – optical density value in the well with K- in the second repeat

Then ODcrit. is calculated using the following formula:

$$\mathbf{OD_{crit.} = OD(K-)_{average} + 0,25} \qquad \mathbf{(2),}$$

Where ODcrit. – is the critical value of optical density.

The assay result can be also presented as a degree of positiveness (COI):

$$\mathbf{COI = OD\ of\ the\ sample/ODcrit,} \qquad \mathbf{(3),}$$

Where OIC — degree of positiveness of the sample.

Table of interpretation of the studies results:

Interpretation of the result	**ODcrit measurement**	**Degree of positiveness (COI)**
Positive result	OD of the test sample ≥ ODcrit + 10%	**> 1,1**
Negative result	OD of the test sample ≤ ODcrit - 10%	**< 0, 9**
Borderline result	OD of the test sample = ODcrit ± 10%	**0,9 – 1,1**

17. Storage and transportation conditions

17.1. Storage of the kit in the manufacturer's packaging should be carried out at a temperature of +2 ... + 8 ° C until the end of the of the shelf life in cold chambers or refrigerators providing a specified temperature regime with daily temperature recording.

17.2. The reagent kit should be transported by roofed transport (automobile, railway or air transport) at a temperature of +2 ... + 8 ° C in a thermal container. Transportation is allowed at temperatures up to 25 ° C for not more than five days. No freezing.

17.3. In case of incomplete (fractional) use of the Kit, components should be stored in the following manner:

17.3.1. Unused immunosorbent strips (IS) should be carefully glued with paper for the plate and store at a temperature +2…+8 °C for not more than 2 months;

17.3.2. Serum diluent, conjugate, chromogen (TMB), stop-reagent, after opening the bottles, should be stored at a temperature +2…+8 °C until the end of the shelf life of the Kit;

17.3.3. Control samples (K+, K-), after opening the bottles, should be stored at a temperature +2…+8 °C for not more than 2 months;

17.3.4. Wash buffer concentrate (WBC) should be stored at a temperature e +2…+8°C until the end of the shelf life of the Kit. The prepared wash buffer should be stored at room temperature (+18…+25 °C) for not more than 5 days or at a temperature +2…+8 °C for not more than 30 days.

18. Manufacturer's warranty

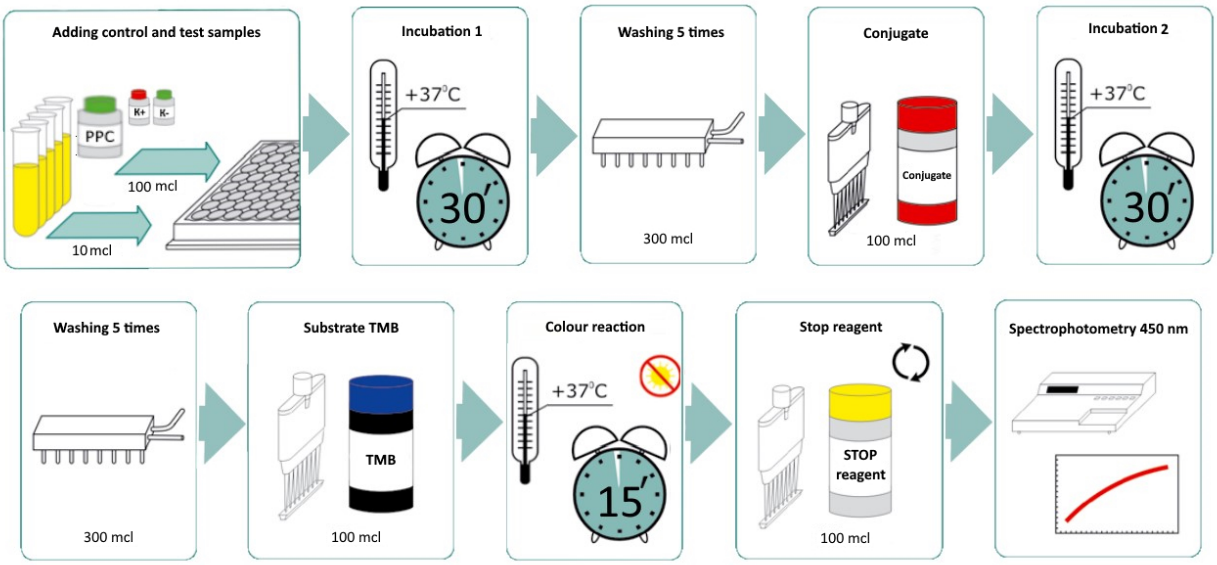
The manufacturer guarantees the compliance of the functional characteristics of the reagent kit with the requirements specified in the technical and maintenance documentation, within the specified shelf life, subject to all the conditions of transportation, storage and use. The shelf life

of the SARS-CoV-2-IgG-ELISA kit is 12 months from the kit manufacturing date. The requirements for the transportation, storage and use of the SARS-CoV-2-IgG-ELISA kit are specified in paragraph 17 of these instructions.

19. Claims procedure

Any complaints about the specific and physical properties of the test system should be addressed to the manufacturer: ”Allel” LLC, Tvardovsky str., 8, office V, room 8, Moscow, 123458
Phone: +7 (495) 780-92-96
https://alleltech.com/

20. Concise scheme of "SARS-CoV-2-IgG-ELISA" assay



21. List of symbols

Symbol	Symbol meaning
	Manufacturer
	Manufacturing date
	Catalogue number
	Batch code
	Use By (year, month)
	Temperature limitation
	In Vitro Diagnostic Medical Device
	Caution, consult accompanying documents
	Do not use if package damaged
	EIA strips
	Control sample
	Conjugate
	Substrate solution (TMB)
	Washing solution concentrate
	Stop reagent
	EIA buffer (serum diluent)