

EKVITESTLAB LLC



Velyka Vasylkivska St. 114 03150 Kyiv, Ukraine Tel. 0-800-31-89-87

e-mail: info@equitest.com.ua

www.equitest.com.ua

STATEMENT

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

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

Date: 03 January 2025

Signature: Director Apra Vurchu



Declaration of Conformity

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

EKVITESTLAB LLC

Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150, tel. 0(800)31-89-87; +38 (044)334-89-87 e-mail: info@equitest.com.ua, web-site: www.equitest.com.ua

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

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

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

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

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

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

Our current Quality System is formatted to international standards:

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

Corporate Contact Information

EKVITESTLAB LLC

Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150

tel. 0(800)31-89-87; +38 (044)334-89-87

e-mail: info@equitest.com.ua

RESPONSIBLE PERSON'S name: Anna Yurchuk

Position: Director

SIGNATURE:

Date: October 25, 2021

Stamp

European Authorized Representative:

Registered Address:

Obelis s.a.

Bd. Général Wahis 53 B-1030 Brussels, Belgium Phone: 32.2.732.59.54

Fax: 32.2.732.60.03 E-mail: mail@obelis.net

Representative: Mr. Gideon ELKAYAM (CEO)



anti-Lamblia

ELISA kit for the qualitative detection of antibodies to *Giardia lamblia (intestinalis)*

Instructions for use





REF EI-606



((

EQUI anti-Lamblia

ELISA kit for the qualitative detection of antibodies to до *Giardia lamblia (intestinalis)*

1. INTENDED USE

The «EQUI anti-Lamblia» is ELISA kit intended to qualitatively detect antibodies to *Giardia lamblia (intestinalis)* in human serum or plasma by enzyme-linked immunosorbent assay (ELISA) to diagnose giardiasis. The testing procedure is designed for both manual arrangement with automatic pipettes and standard equipment, and for automated «open» immunoassay analysers.

Target group: children, pet owners, citizens of rural areas, summer house owners.

Usage: ELISA kit is used in clinical diagnostic laboratories and other institutions engaged in *in vitro* diagnostics.

2. CLINICAL SIGNIFICANCE

Giardiasis is considered one of the most common parasitic diseases of the small intestine in the world. This infection is a major cause of acute and chronic diarrhea, especially in children. The etiological agent of giardiasis is *Giardia lamblia*, which is also called *Giardia intestinalis* or *Giardia duodenalis*.

Giardia lamblia are unicellular flagellate protozoa that parasitize in the intestines of humans and some other mammals. During the life cycle of these parasites, two stages alternate: cysts, resistant to external conditions, and a vegetative form - trophozoites. Infection occurs when cysts enter the human gastrointestinal tract. After experiencing the effects of gastric acid, cysts in the duodenum turn into trophozoites, which parasitize in the upper parts of the small intestine. They absorb nutrients from the intestinal lumen, block parietal digestion and disrupt the motility of the intestine.

Humans get infected via fecal-oral routes through cyst-contaminated food, water, unwashed hands, and so on. Giardia can also be transmitted to humans from infected cats, dogs, and livestock. Giardiasis is especially common in regions with poor sanitation. In addition, human-to-human transmission is common in preschools.

In many cases, the invasion of Giardia occurs without clinical manifestations. In other cases, the first symptoms of giardiasis appear in 1-3 weeks after infection. They are most often manifested by spasms, bloating, nausea and diarrhea, which leads to dehydration and weight loss. The acute form of the disease can last up to two weeks and end in recovery without additional treatment or become chronic. Chronic giardiasis develops when the duration of the invasion is longer than 2 month and the exacerbation of clinical manifestations (diarrhea) is cyclical. *Giardia lamblia* parasitism can lead to malabsorption syndrome, which disrupts the absorption of carbohydrates and fats, as well as the metabolism of vitamins B12, A and C.

Immune response to invasion and non-immune factors are important to control the development of the disease and the severity of clinical manifestations. Both

Edition 7, 18.02.2022

humoral and cellular immunity play the part in the eradication of the pathogen, the role of which is still subjected to scientific research. In addition, partial resistance to re-infection is formed due to protective mechanisms of the body.

Typically, to diagnose giardiasis, the duodenal contents and feces are examined for trophozoites and cysts of giardiasis. In case of the chronic course of the disease, cysts get excreted periodically, and, considering this, the additional tests should be performed regularly for several weeks. Another method of diagnosing giardiasis is to detect *Giardia lamblia* antigens in the feces. However, serodiagnosis with the detection of specific antibodies to Giardia antigens is an important step in assessing the immune response of patients. Detection of specific IgM antibodies suggests an acute stage of giardiasis. However, the detection of specific IgG and IgA antibodies should be interpreted with caution: in some regions they persist for a long time after infection, while in others their level decreases after eradication of the pathogen.

3. ANALYSIS PRINCIPLE

The procedure of testing for *Giardia lamblia* specific antibodies in «EQUI anti-Lamblia» ELISA kit is based on «indirect» solid-phase ELISA with a two-stage incubation. Recombinant *Giardia lamblia* antigens are entrapped in the wells. During the first step of incubation of the test samples in the wells of the ELISA plate, *Giardia lamblia*-specific antibodies, if present in the samples, bind to the solid phase antigens. The wells are washed to remove unbound antibodies and have only specific antigen-antibody complexes left. Then, a conjugate of anti-species (anti-IgG and anti-IgA) monoclonal antibodies with horseradish peroxidase is added, which binds to solid-phase immune complexes. Unbound components are removed by washing. Antigen-antibody complexes are detected by adding a solution of chromogen 3,3',5,5'-tetramethylbenzidine (TMB) with hydrogen peroxide. After 30-minute incubation, the reaction is stopped by adding the stop solution. The optical density (OD) in the wells is determined using a spectrophotometer at 450/620-695 nm. The intensity of the yellow colour is proportional to the level of antibodies in the sample.

4. MATERIALS AND EQUIPMENT

4.1. Contents of the ELISA kit

M	icr	ao	late
		~ ~	

STRIPS	1 x 96 wells	Each plate well is coated with <i>Giardia lamblia</i> purified antigens. The wells are detachable. After the first opening, store unused strips in the package at 2-8 °C for a maximum of 6 months
CONTROL +	1 x 0,35 ml	Positive control Conjugated specific monoclonal antibody solution with preservative (pink). Store at 2-8 °C
CONTROL -	1 x 1,2 ml	Negative control Negative human serum with a preservative (yellow). Store at 2-8 °C

Edition 7, 18.02.2022 4/16

DILSAMPLE	1 x 11 ml	Buffer solution with a milk extract, a detergent and a preservative (purple). Store at 2-8 °C
SOLN CONJ	1 x 13 ml	Conjugate solution (ready to use) Buffer solution of monoclonal antibodies to human IgG and IgA, conjugated with horseradish peroxidase, with stabilizers and preservative (green). Store at 2-8 °C
		TMB solution (ready to use)
SOLNTMB	1 x 13 ml	TMB solution, $\rm H_2O_2$, a stabilizer, a preservative (colourless). Store at 2-8 °C
[TWEEN WASH 20x]	1 x 50 ml	Washing solution TWEEN (20x concentrated) 20-fold phosphate buffer concentrate with Tween-20 (colourless). Dilute TWEEN detergent (20x) at 1:20 with distilled or deionized water (e. g., 5 mL of concentrate + 95 mL of water for 8 wells) before use. Store the diluted solution at 2-8 °C for a maximum of 7 days
SOLN STOP	1 x 13 ml	Stop Solution (ready to use) $0.5 \text{ mol H}_2\text{SO}_4$ solution (colourless). Store at 2-8 °C

The ELISA kit also includes adhesive films (2 items), sample application plan (1 item), checklist, and instruction for use.

4.2. Optional reagents, materials and equipment

Automatic single and multichannel pipettes 10–1000 μ L, tips, volumetric laboratory glassware (10–1,000 mL), deionized or distilled water, thermostat at 37 °C, automatic or semi-automatic plate washer, spectrophotometer (reader) for microplates at 450/620-695 nm, appropriate containers for potentially contaminated waste, timer, filter paper, disposable powder-free gloves, disinfectants.

5. PRECAUTIONS AND SAFETY

5.1. Precautions

Be sure to read the instructions for use carefully before the test. The validity of the test results depends on strict following of the test procedure.

- do not use the ELISA kit components after the expiry date;
- do not use for analysis or mix components of different batches, components of kits for different nosologies, or reagents from other manufacturers with the «EQUI anti-Lamblia» ELISA kit;
- do not freeze the ELISA kit or its contents;
- after using a reagent, close each vial with its cap;
- when washing, control filling and complete aspiration of solution from the wells;
- use a new pipette tip each time you add samples or reagents;
- prevent direct sunlight from reaching the reagents from the ELISA kit;
- SOLN|TMB| solution must be colourless before use. Do not use the solution if its colour is blue or yellow. Avoid contact of SOLN|TMB| with metals or metal ions. Use only clean glassware thoroughly rinsed with distilled water;

Edition 7, 18.02.2022 5/16

- do not use reagents with colour not in line with para. 4.1;
- under no circumstances should the same glassware be used for SOLNICONJ and SOLNITMB:
- do not evaluate the test results visually (without a reader);
- any optional equipment that is in direct contact with biological material or kit components should be considered contaminated and requires cleaning and decontamination;
- the ELISA kit includes materials for 96 tests. Dispose of the used components as well as any remaining unused components.

5.2. Safety requirements

- all reagents in the ELISA kit are for laboratory professional use for *in vitro* diagnosis only and may only be used by qualified personnel;
- conduct the tests in disposable powder-free gloves and goggles only;
- do not eat, drink, smoke, or apply make-up in the test room;
- do not mouth-pipette the solutions;
- controls from the «EQUI anti-Lamblia» ELISA kit have been tested and found to be for anti-HIV1/2, anti-HCV and anti-*Treponema pallidum* antibodies and HBsAg negative; however, controls and test samples should be handled as potentially hazardous infectious materials;
- some of the kit components contain low concentrations of harmful substances and can damage skin or mucoga. In case of contact of SOLNITMB, SOLNISTOP and SOLNICONJ with mucous membranes or skin, immediately wash the affected area with plenty of water;
- in case of spillage of acid-free solutions, e. g. sera, treat the surface with a disinfectant solution and then wipe dry with filter paper. Otherwise first neutralize acid with sodium bicarbonate solution and then wipe the surface dry as described above.

5.3. Waste inactivation and disposal

- the liquid waste must be inactivated, for example, with hydrogen peroxide solution at the final concentration of 6% for 3 hours at room temperature, or with sodium hypochlorite at the final concentration of 5% for 30 minutes, or with other approved disinfectants;
- the solid waste must be inactivated by autoclaving at a temperature not less than 132°C:
- do not autoclave the solutions that contain sodium azide or sodium hypochlorite;
- disposal of inactivated waste must be conducted due to national laws and regulations.

6. STORAGE AND STABILITY

ELISA kit is stable up to the expiry date stated on the label when stored at 2-8°C. The kit should be transported at 2-8°C. Single transportation at a

Edition 7, 18,02,2022 6/16

temperature up to 23°C for two days is possible.

7. SAMPLE COLLECTION, TRANSPORTATION AND STORAGE GUIDELINES

Collect blood from the vein into the sterile test tube. Test tube must be marked with patient ID and date of sample collecting. Blood before serum separation can be stored at 2-8 °C for 24 hours, avoiding freezing.

Serum or plasma can be stored at 2-8 °C for maximum 3 days. Frozen serum can be stored for longer periods of time at -20 °C or -70 °C. Thaw frozen samples and keep them at room temperature for 30 minutes before use. After thawing, the stir samples to achieve homogeneity. Avoid repeated freezing-thawing cycles for test samples. If serum (or plasma) is turbid, remove insoluble inclusions by centrifugation at 3000 rpm for 10-15 minutes. Do not use serum samples with hyperlipidemia, hemolysis, and bacterial growth.

Transport serum samples in insulated containers. To do that, put closed labelled tubes in a plastic bag, tightly seal it and place in the centre of an insulated container. Put the frozen cold packs on the bottom, along the side walls of the insulated container and on top of the serum samples.

8. REAGENT PREPARATION

NOTE! It is very important to keep all ELISA kit components for at least 30 min at room temperature 18-25 °C before the assay!

8.1. Microplate preparation

To prevent water condensation in the wells, keep the STRIPS for 30 minutes at a room temperature before opening. Open the vacuum pack, detach the appropriate number of wells, and carefully pack the remaining wells with a desiccant and store tightly zip-locked at 2-8 °C. Storing the packed plate this way ensures its stability for 6 months.

8.2. Washing solution preparation

To prepare detergent, dilute TWEEN WASH 20x at 1:20 (1+19) with distilled or deionized water and stir. E. g., 5 mL of concentrate + 95 mL of water, which is enough for 8 wells. If there are crystals present in the detergent concentrate, heat the vial at 37 °C until the crystals dissolve completely (15–20 minutes). Store the diluted solution at 2-8 °C for a maximum of 7 days.

9. ASSAY PROCEDURE

- 9.1. Prepare the necessary number of wells (four wells for controls and a necessary number of wells for test samples) and insert them into the ELISA plate frame. Be sure to add control wells in every test run.
- 9.2. Fill in the sample application plan.
- 9.3. Prepare the detergent as per para. 8.2.
- 9.4.Add 80 µL of DILISAMPLE into each plate well.
- 9.5.Add 20 μL of controls and test samples into the wells:

CONTROL + - into well A1,

CONTROL - into wells B1, C1 and D1,

and test samples into the remaining wells.

Edition 7, 18.02.2022 7/16

At the time of adding, the solution changes its colour from brown to blue. Pipette the mix in the wells carefully to avoid foaming.

- 9.6. Cover the strips up with adhesive film and incubate for 30 minutes at 37 °C.
- 9.7. Remove and discard the adhesive film and wash all wells 5 times with automatic washer or 8-channel pipette as follows:
 - aspirate the content of all wells into a liquid waste container;
 - add a minimum of 300 μl of diluted washing solution to each well, soak each well for 30 seconds;
 - aspirate the content of all wells again. The residual volume after every aspiration should be less than 5 μ l;
 - repeat the washing step 4 more times;
 - after the final aspiration, eliminate extra moisture by tapping the plate against a piece of filter paper.
- 9.8.Add 100 µL of SOLNICONJ into each well. Cover the strips with a new piece of adhesive film and incubate for **30 minutes at 37 °C**.
- 9.9. Following incubation, remove the film carefully and wash the wells five times as described in para. 9.7.
- 9.10. Add 100 μL of SOLN TMB into the wells; do not touch the bottom and the walls of the plate wells.
- 9.11. Incubate the strips for **30 minutes** in a dark place at a room temperature of 18-25 °C. Do not use adhesive film at this stage.
- 9.12. Add 100 µL of SOLNSTOP into each strip well to stop the enzymatic reaction; adhere to the same sequence of actions as when adding SOLNTMB. At the time of adding, the solution colour changes from blue to yellow, and clear solution slightly changes its shade.
- 9.13. Measure the optical density (OD) of the wells at 450/620-695 nm wavelength using an ELISA microplate reader within 5 minutes after stopping the reaction. Pay attention to the cleanness of the plate bottom and the absence of bubbles in the wells before reading.

Measurement at the single wavelength of 450 nm is possible, in that case, it is needed to leave one well for blank (only $\overline{\text{SOLN}|\text{TMB}}$) and $\overline{\text{SOLN}|\text{STOP}}$ must be added in blank well).

10. CALCULATION AND INTERPRETATION OF RESULTS

10.1. Calculation of results

Calculate the average OD for the negative control (\overline{Nc}) , Cut off (CO) and a sample positivity index (IP_{sample}) .

$$\overline{Nc}$$
 = (Nc1 + Nc2 + Nc3)/3; CO = \overline{Nc} + 0,25
 IP_{sample} = OD_{sample}/CO, where OD_{sample} is the OD sample.

10.2. Quality control (assay validation)

The test results are considered valid if they meet the following requirements:

Edition 7, 18.02.2022 8/16

$$CONTROL$$
 + OD ≥ 1,0
 $CONTROL$ - OD ≤ 0,150

If any of the OD values <u>for</u> the negative control is beyond the above interval, it should be discarded, and Nc is calculated based on the remaining OD values for the negative control. If several OD values for the negative control fail to meet the above requirements, the test is considered invalid and requires a new run.

10.3. Interpretation of results

$$IP_{sample} > 1,1$$
 POSITIVE $0,9 \le IP_{sample} \le 1,1$ BORDERLINE* $IP_{sample} < 0,9$ NEGATIVE

11. PERFORMANCE CHARACTERISTICS

11.1. Analytical performance characteristic

Precision of measurement

Intra assay repeatability

The coefficient of variation (CV) for two sera with different levels of specific antibodies was evaluated in 32 replicates on one series of ELISA kits.

Sample No.	OD_av	IP_{av}	CV, %
14L	0,679	2,47	6,5
16L	0,490	1,79	6,6

Inter assay reproducibility

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated for 3 days in 3 sets of analysis, 8 replicates in each analysis.

Sample No.	OD_av	IP_{av}	CV, %
14L	0,670	2,39	5,55
16L	0,463	1,65	7,06

Analytical specificity

The test results are not affected by bilirubin at up to 0.21 mg/mL (361.8 μ mol/L), haemoglobin at up to 10 mg/mL and triglycerides at up to 10 mg/mL (11.3 mmol/l) present in the sample.

Edition 7, 18.02.2022 9/16

^{*} Uncertain samples are recommended to be re-examined in two wells of the ELISA kit. If the results are again uncertain, a new sample should be selected and analyzed in 2-4 weeks. In case of repeated indeterminate results, such samples shall be considered negative.

11.2. Diagnostic characteristics

Studies of the characteristics of the method in comparison with a similar commercial ELISA kit were performed on a sample of characterized sera, the target group of children and a group of donors. The relative sensitivity of «EQUI anti-Lamblia» ELISA kits was determined from a group of 23 serum samples that were tested for antibodies to *Giardia lamblia* and characterized as positive in a commercial ELISA kit. All sera were also determined to be positive in «EQUI anti-Lamblia» kits, so the relative sensitivity equals 100%. For 148 serum samples of children that were tested and characterized in commercial analogues, the relative specificity of «EQUI anti-Lamblia» ELISA kits was 92.86%, the percentage of coincidence - 93.24%. According to a similar principle, for 238 serum samples of donor blood, the relative specificity was 97% and the percentage of coincidence was 96.64%.

12. LIMITATIONS OF ASSAY

The final diagnosis cannot be made solely on the basis of serological test results, sunce clinical manifestations of the disease and laboratory data (such as the detection of cysts in faecal samples or trophozoites in duodenal contents; the results of detection of *Giardia lamblia* antigen in faeces) should be taken into account as well.

Addionally, cross-reactions with antibodies to antigens of other parasites cannot be completely ruled out.

Giardia lamblia-specific antibodies may not be detected in case of children with persistent and prolonged giardiasis.

It should be noted that IgG antibodies to *Giardia lamblia* can be detected via ELISA for a long time, even after successful treatment.

13. DIFFICULTIES THAT CAN OCCUR DURING THE ASSAY PROCEDURE

Possible reasons	Solution	
High background	d in all wells	
Contaminated washer	Clean the washer head and rinse according to the instructions for use	
Poor quality or contaminated water	Use purified water with specific resistance ≥ 10 MΩ · cm	
Use of poorly washed glassware	Use chemically clean utensils	
Use of chlorinated disinfectants	Do not use chlorine disinfectants	
Use of contaminated tips	Use new tips	
Increased incubation times or change in the temperature conditions	Adhere to the incubation regime according to the instructions for use	
High background in a row of wells		

Edition 7, 18.02.2022 10/16

Repeat application of TMB solution	TMB solution should be applied once	
Contamination of the automatic pipette nozzle with conjugate solution	Clean the pipette and dial carefully liquid	
Contamination of one of the washer's channel	Clean the flush channel, rinse washer	
Received OD of the positive cont	rol is below the border value	
One of the reagents (conjugate solution or TMB solution) was not prepared in a correct way or was not added	Re-conduct ELISA, pay attention to the correctness of the introduction of these reagents	
Reduced incubation times at any stage	Incubate according to instructions for use	
The colour density of the wells fails to meet the obtained optical density value		

14. TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

In case of technical problems, you can obtain assistance by contacting the manufacturer.

Edition 7, 18.02.2022 11/16

REFERENCES

- Adam R. D. Biology of Giardia lamblia // Clinical Microbiology Reviews. 2001. -Vol. 14(3). - P. 447–475.
- 2. CDC Giardia // https://www.cdc.gov/parasites/giardia/index.html.
- 3. Choy S. H., Al-Mekhlafi H. M. et al. Prevalence and Associated Risk Factors of Giardia Infection among Indigenous Communities in Rural Malaysia // Scientific Reports. 2014. Vol. 4, Article number: 6909.
- 4. DuPont H. L. Giardia: both a harmless commensal and a devastating pathogen // Journal of Clinical Investigation. 2013. Vol. 123(6). P. 2352–2354.
- 5. Faubert G. Immune Response to Giardia duodenalis // Clinical Microbiology Reviews. 2000. Vol. 13(1). P. 35–54.
- 6. Lopez-Romero G., Quintero J. et al. Host defences against Giardia lamblia // Parasite Immunology. 2015. -Vol. 37(8). P. 394-406.
- 7. Saghaug C. S., Sørnes S. et al. Human Memory CD4+ T Cell Immune Responses against Giardia lamblia // Clinical and Vaccine Immunology. 2016. Vol. 23, No. 1. P. 11-18.
- 8. Solaymani-Mohammadi S. and Singer S. M. Giardia duodenalis: The Double-edged Sword of Immune Responses in Giardiasis // Experimental Parasitology. 2010. Vol. 126 (3). P. 292–297.
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
- Закон України «Про відходи» // Відомості Верховної Ради України. -1998. - №36-37.
- 11. Наказ МОЗ України №325 від 08.06.2015 «Про затвердження Державних санітарно-протиепідемічних правил і норм щодо поводження з медичними відходами».
- 12. Постанова КМУ від 02 жовтня 2013р. №754 «Про затвердження технічного регламенту щодо медичних виробів для діагностики in vitro».
- 13. Hanna Tolonen, Kari Kuulasmaa, Tiina Laatikainen, Hermann Wolf and the European Health Risk Monitoring Project. Recommendation for indicators, international collaboration, protocol and manual of operations for chronic disease risk factor surveys Part 4.Storage and transfer of serum/plasma samples// Finnish National Public Health Institute 2002// https://thl.fi/ publications/ehrm/product2/part_iii4.htm
- 14. Surveillance Guidelines for Measles, Rubella and Congenital Rubella Syndrome in the WHO European Region. Annex 3.Collection, storage and shipment of specimens for laboratory diagnosis and interpretation of results// Geneva: World Health Organization; 2012 Dec.

Edition 7, 18.02.2022 12/16

Manufacturer Authorized Representative in the European Community EC REP In vitro diagnostic medical device IVD REF Catalogue number Date of manufacture Use by date LOT Batch code Temperature limit Contains sufficient for <n> tests Caution Non-Sterile Ţį

Consult instructions for use

Keep away from sunlight

Keep dry

C Compliance with EU safety requirements

Edition 7, 18.02.2022

For questions and suggestions regarding the ELISA kit contact:

Obelis s.a.

Bd Général Wahis 53

1030 Brussels

Belgium

Tel: +(32)2 732-59-54 Fax: +(32)2 732-60-03

mail@obelis.net

EC REP

Ekvitestlab LLC Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150

Tel: 0(800)31-89-87, +38 (044)334-89-87,

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

Edition 7, 18.02.2022

ASSAY PROCEDURE SCHEME

Keep all reagents for 30 min at temperature18-25°C before use

Dispense 80 μ l DIL SAMPLE into the wells (purple)

Add to 20 µl of controls and samples into the wells:

A1 - CONTROL +, B1, C1, D1 - CONTROL -,

other wells - examined samples

(change of colour from purple to blue)

Cover strips with an adhesive film, incubate for 30 min at 37°C

Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 μ l per well)

Add 100 µl of SOLN CONJ into all wells (green)

Cover strips with an adhesive film, incubate for 30 min at 37°C

Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 μ l per well)

Add 100 µl of SOLN TMB into all wells

Incubate for 30 min in the dark at 18-25°C

Add 100 µl of SOLN STOP into all wells (change of colour from blue to yellow)

Measure the optical density (OD) with an ELISA microplate reader at 450/620-695 nm

CALCULATION OF RESULTS

Nc = (Nc1 + Nc2 + Nc3)/3;

CO = Nc + 0.25;

 $IP_{sample} = OD_{sample}/CO$

Nc - the average value of OD 3-x CONTROL -

CO - Cut off

 $\ensuremath{\mathsf{IP}_{\mathsf{sample}}}$ - sample positivity index

INTERPRETATION OF RESULTS

ID > 11	POSITIVE	
IP _{sample} > 1,1	1 OSITIVE	
$0.9 \le IP_{\text{sample}} \le 1.1$	BORDERLINE	
IP _{sample} < 0,9	NEGATIVE	





Cepmudikam Certificate

№ Q1M 804 255 C1



Система управління якістю виробника:

Quality management system of manufacturer

Товариство з обмеженою відповідальністю «ЕКВІТЕСТЛАБ»

«EKVITESTLAB» Limited Liability Company

Місцезнаходження юридичної особи: вул. Велика Васильківська 114, м. Київ, 03150, Україна Location of the legal entity: 114 Velyka Vasylkivska St., Kyiv, 03150, Ukraine Фактичне місцезнаходження: Україна, 03057, м. Київ, проспект Берестейський 60/2 Actual location: 60/2 Beresteysky Avenue, Kyiv, 03057, Ukraine

відповідає вимогам:

meets the requirements of

ДСТУ EN ISO 13485:2018 Вироби медичні. Системи управління якістю. Вимоги щодо регулювання (EN ISO 13485:2016, IDT; ISO 13485:2016, IDT

Medical devices - Quality management systems -Requirements for regulatory purposes)

Сфера застосування:

Scope

Проектування, розробка, виробництво, зберігання та реалізація ІФА-наборів для діагностики in vitro

Design, development, production, storage and sale of ELISA kits for in vitro diagnostics

Сертифікат виданий ТОВ «Український Інститут Стандартів», місцезнаходження: будинок 1, вулиця Олександрівська, місто Київ, 03062, Україна. Атестат акредитації НААУ від 30 червня 2020 року № 8О141.

Certificate is issued by LLC Ukrainian Standards Institution: building 1, Oleksandrivska street, Kyiv, 03062, Ukraine. Accreditation certificate registered on June 30, 2020 No. 80141

Рішення №: 255-000 Decision No.:

Дата видачі: 01.04.2024

GNITION ARRANG

Issue date:



Дійсний з: 01.04.2024 Effective date:

Дійсний до: 31.03.2027 Expiry date:

Наталія СТЕПАНКІВСЬКА Natalia STEPANKIVSKA

80141 Сертифікація систем менелжменту

Сертифікат чинний за умови проведення щорічного наглядового аудиту. Чинність сертифікату необхідно перевірити на офіційному веб-сайті www.usi.biz.ua або за телефоном: +38-050- 818-7-333

Certificate is valid if the annual surveillance audit has been conducted The validity of the certificate shall be checked on the official website www.usi.biz.ua or by tel.: +38-050-818-7-333