ALGIMED TECHNO

The product portfolio

algimed-techno.com

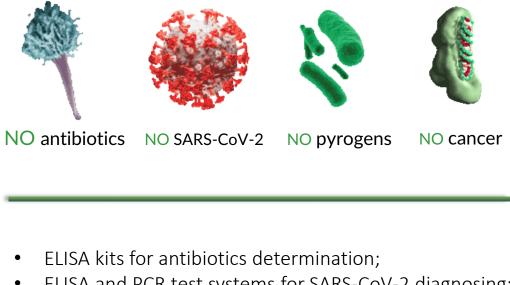




The company is the manufacturer of diseases diagnosis test systems, food safety control test systems, basic research and industrial control kits, as well as LAL test consumables.



Product lines:



- ELISA and PCR test systems for SARS-CoV-2 diagnosing;
- LAL-reagent Water and LAL test tubes;
- Kits for microRNA quantitative analysis.

ISO 9001:2015 and ISO 13485:2016

On June 16, 2020, production was officially certified according to ISO 9001:2015 standard

ISO 9001:2015 is an international standard dedicated to Quality Management Systems. It outlines a framework for improving quality and a vocabulary of understanding for any organization looking to provide products and services that consistently meet the requirements and expectations of customers and other relevant interested parties in the most efficient manner possible.

On August 12, 2020, production was officially certified according to ISO 13485:2016 standard

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.





ELISA kits for the detection and quantification of antibiotics in food

Ready to use ELISA kits for detection and/or quantification of antibiotic residues in food and raw materials.

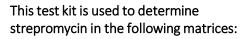
ELISA antibiotic tetracycline test kit



This test kit is used to determine tetracycline in the following matrices:

Milk (raw, pasteurized, sterilized) - Milk powder – Butter – Cheese - Sour cream – Kefir – Yogurt – Cottage cheese – Milk whey – Reconstituted milk powder infant formula – Reconstituted powdered milk whey – Meat – Meat products – Eggs – Honey – Fish & shrimps

ELISA antibiotic strepromycin test kit



Milk (raw, pasteurized, sterilized) – Milk powder – Milk whey – Butter – Cheese – Yogurt – Kefir – Cottage cheese – Sour cream – Reconstituted milk powder infant formula – Milk-based cocktails – Ice cream – Condensed milk – Honey – Fat – Salo (including speck) – By-products (liver, kidney) – Meat – Meat products – Eggs – Canned meat

ELISA antibiotic chloramphenicol test kit

This test kit is used to determine chloramphenicol in the following matrices:

Milk (raw, pasteurized, sterilized) – Milk powder – Meat – Honey – Cheese – Butter – Eggs – Ready-to-eat meat products – Cottage cheese – Yogurt – Kefir – Sour cream – Reconstituted milk whey, milk powder whey – Reconstituted milk powder infant formula Milk-based cocktails – Salo – Speck – Animal fat – Fish – Fish products – Shrimps – By-products – Canned meat



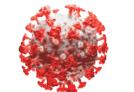
ELISA antibiotic bacitracin test kit

This test kit is used to determine bacitracin in the following matrices:

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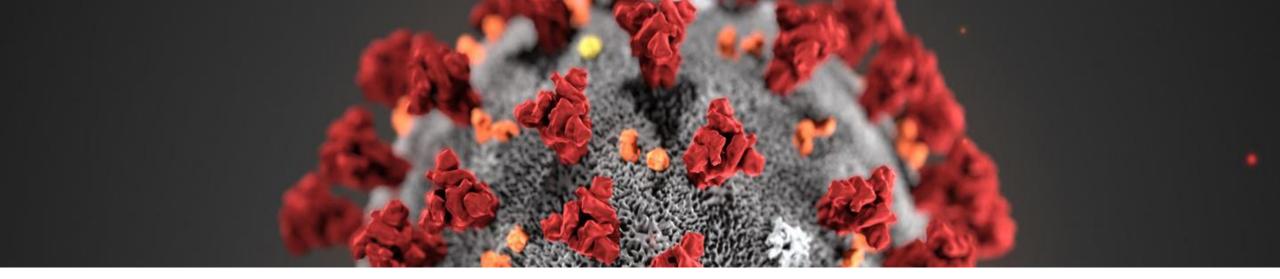
Milk (raw, pasteurized, ultra-sterilized, sterilized) –Reconstituted milk powder – Meat, ready-to-eat meat products – Eggs – Fee.





NO SARS-CoV-2

Solutions aimed at identifying SARS-CoV-2



PCR test kits

PCR test kits and have been created for clinical laboratory diagnostics and research.

They are used for the qualitative determination of 2019-nCoV coronavirus RNA in clinical samples (nasal secretion, nasopharyngeal swab, oropharyngeal swab, sputum, endotracheal aspirate, bronchoalveolar lavage, rectal smear, plasma, human serum).

ELISA test kits

ELISA kits have been created to determine the antibodies presence or absence to SARS-CoV-2 in human serum and plasma. ELISA kits manufactured by Algimed Techno are intended for in vitro use only.



AlPREP extraction kit provides the preanalytical stage for the biological samples subsequent analysis.

Purity of extracted DNA/RNA (A260/A280 ratio) is at least 1.7 for biological samples.

The efficiency of DNA/RNA extraction is ranged from 30 up to 70% (at least 30%).

The obtained purified DNA/RNA sample can be used for subsequent analysis by PCR, RT-PCR and their variations.

Extraction kit ALPREP (release form 5) enables the automatic DNA & RNA purification from biological samples.

Ready-to-use extraction kit excludes manual dosing operations, except for the sample transfer into the wells of the plate.

Ready-to-use extraction kit is presented in 96 deep-well plates. All necessary plastic consumables (plates and tips) are included.

There is no need to program the station due to the ready-to-use protocol.

The validation and adaptation protocols have been approved by trusted manufacturers and national certification bodies and allow to obtain correct results.

Real -Time PCR kit ALSENSE-SARS-CoV-2-RT-qPCR qualitative identification by RT-PCR method.



The working principle is based on a one-step real-time fluorescent reverse transcription PCR technology.

The kit detects the following genes: 3 loci of the 2019-nCoV coronavirus ORF1ab gene and 2019-nCoV coronavirus S, E, and N genes.

Sensitivity:

- from 100 copies/ml;
- from 5 genomic equivalents in reaction.

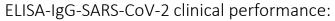
Kits are configured to process 48/96 clinical samples. Real -Time PCR kit ALSENSE-SARS-CoV-2-RTqPCR includes all necessary reagents for RT-PCR, including inner control, negative control and positive control.

ELISA kits ELISA-IgG-SARS-CoV-2 and ELISA-IgM-SARS-CoV-2 semiquantitative detection of human IgG and IgM against SARS-CoV-2.



Kits provide semiquantitative detection of human IgG/IgM against SARS-CoV-2 nucleocapsid protein in serum, EDTA, heparin, ACD or citrate plasma.

The working principle is based on indirect non-competitive two-step ELISA. At first step negative and positive controls, diluted human serum (plasma) are incubated in microtiter plate, precoated with recombinant full length SARS-CoV-2 nucleocapsid protein. If specific **IgG/IgM** antibodies are present in sample they will bind to the antigen. At the second step bound **IgG/IgM** detected with enzyme conjugate (HRP-labelled anti-human **IgG/IgM** antibodies).



- Sensitivity: 92%
- Specificity: 100%

ELISA-IgM-SARS-CoV-2 clinical performance:

- Diagnostic sensitivity: 100%
- Analytical specificity: 97,3%





IgGRBD-SARS-CoV-2 ELISA kit: semiquantative detection SARS-CoV-2 RBD specific antibody

The kit is designed to determine the level of IgG to the SARS-CoV-2 glycoprotein S RBD site in human serum and plasma in order to assess post-infectious or post-vaccination immunity against coronavirus infection.

Specific IgG to the SARS-CoV-2 S glycoprotein RBD site have virus-neutralizing activity due to blocking the virus binding to the ACE2 human cell receptor. Information on the level of such immunoglobulins in the patients' blood plasma could lead to conclusions about:

- Re-infection risk assessment;
- Donor plasma suitability for transfusion in patients with severe coronavirus infection;
- The vaccination effectiveness.

Clinical performance:

- Sensitivity: 100%
- Specificity: 100%







Products for LAL-test, the modern method of determining drugs pyrogenicity, has become commonly used in recent years.

Depyrogenated test tubes AL-TUBE



Algimed Techno offers depyrogenated test tubes of all basic sizes currently presented on the market. Test tubes are packed into two layers of foil and are depyrogenized at a temperature of 250 °C within 1 hour. The content of bacterial endotoxins in test tubes AL-TUBE is less than 0.005 EU/ml. Test tubes guality control is done by the kinetic chromogenic method using reagents and software manufactured by Lonza, USA.

LAL-reagent Water AL-WATER

LAL-reagent water AL-WATER meets the requirements for WFI, and contains bacterial endotoxins in a quantity of less than 0.005 EU/ml. LAL Reagent water quality control is done by the kinetic chromogenic method, using reagents and software manufactured by Lonza, USA. The bacterial endotoxins content index is indicated in the certificate for each lot of LAL reagent water AL-WATER.



LAL test set AL-TEST Standard

Ready to use LAL test set includes everything needed. The ratio of the components of the set is selected for 300 definitions, which corresponds to the verification of 36-40 samples by qualitative method (method A) or 15-18 samples by quantitative method



Sample container AL-CONTAINER

Sterile depyrogenated containers are used to collect test samples. AL-CONTAINER is certified for bacterial endotoxin absence. The volume of containers is 60 ml.



(method B).



Kits for basic development: **miRNA assay**

ALMIR – miRNA Assay Kits



A modern technological solution for basic research and development of new clinical diagnostic methods.

Method

RT-qPCR is the common approach for miRNA analysis in laboratory practice due to its low-cost and reliability. The kit implements the original technology of two-claws reverse transcription followed by quantitative PCR with two miRNA-specific primers, that provides exceptional accuracy of analysis.

Principles of analysis

1. The results of the quantitative analysis of the miRNA significantly depend on the quality of the RNA isolated from biological samples.

2. Due to short length the mature miRNA molecule not only undergoes reverse transcription but also elongation. These modifications are necessary to enable the next step of quantitative PCR.

3. The presence of very similar or immature form of miRNA can interfere with RT-qPCR results. Assay duration

Assay duration: 2.5 – 3 hours, including RT (45 «) and PCR (60»).

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