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INgezim® COVID 19 CROM

Prod. Ref: 50.CoV.K.41

Dual recognition immunochromatographic assay for detection of antibodies specific to SARS-CoV-2 in blood, serum or plasma samples.

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KIT CONTENTS:

Component	Units
Individually packaged devices	25
Dropper with chromatography buffer (4 ml)	1
20 µl graduated micropipettes	25
Finger prick lancets	25

OTHER NECESSARY MATERIALS/REAGENTS NOT SUPPLIED:

Cotton and antiseptic for use after finger prick.

KIT CONSERVATION:

All kit components must be kept between 4 °C and 25 °C, in their original packaging, until use.

APPLICATION

INgezim® COVID 19 CROM qualitatively determines the total antibodies (IgG, IgA, and IgM) specific to SARS-CoV-2 in a single blood, serum, or plasma sample by using nucleoprotein (N protein) as an antigen for detection of virus antibodies. This rapid, point-of-care test delivers results in only 10 minutes and can be performed outside of the laboratory. The test is intended for use by healthcare professionals, not for self-diagnosis.

As a serological test, this tool is complementary to direct detection of the pathogen and can assist in the gathering of epidemiological information on disease prevalence.

PRINCIPLE OF THE ASSAY

Dual-recogniton immunochromatographic assay.

The membrane contains a test line (T), in which the SARS-CoV-2 N protein (3) is immobilized, and a control line (C), formed by a specific monoclonal antibody (4) of the control protein. SARS-CoV-2 antibodies present in the sample react with the black latex particles coated with the latex/protein/antibody complex, migrate across the membrane, and bind to the protein contained within the test line, resulting in a coloured T line. If the sample has no SARS-CoV-2 antibodies, no colour will appear on the T line. The C line must always appear blue or the test is invalid.

SAMPLES

The test can be performed using:

- Fresh blood samples obtained at the time, from finger pricks using the lancet provided in the kit.
- Blood samples obtained via venous puncture. In these cases, the use of anticoagulants is recommended (in order to avoid clots that could interfere with the assay). These samples can be kept at 4oC until they are used, for a maximum period of 48 hours.
- Fresh serum or plasma samples kept at 4°C or frozen at -20°C.

It is not recommended to use heat-inactivated samples.

PROCEDURE:

- It is very important that refrigerated blood or serum samples are temperature-adjusted beforehand.
- Remove the diagnostic device from the bag and place it on a flat surface.

A. BLOOD SAMPLES

To obtain a finger-prick sample using the lancet, see this video:

SCAN ME

1. Use the lancet to lightly prick a fingertip.
2. Sample collection: place the supplied pipette over the drop of blood and fill the reservoir (20 µL). If the blood sample is already in a tube, use the pipette in the same way.
3. Perform the assay immediately, to prevent the blood from clotting in the capillary tube. Place the drop onto the circular window of the device by covering the hole of the capillary tube and gently pressing the top of the pipette.
4. Wait 1 minute for the sample to absorb and slowly add 3 drops of the supplied chromatography buffer. Wait between drops for the liquid to absorb into the membrane.
5. Interpret the result 10 minutes after adding the chromatography buffer.

B. SERUM SAMPLES

1. Sampling: Use a pipette to take 10 µL of serum.
2. Place the serum sample onto the circular window of the device.
3. Add 3 drops of the supplied chromatography buffer. Wait between drops for the liquid to absorb into the membrane.
4. Interpret the result 10 minutes after adding the chromatography buffer.

THE VOLUMES AND TIMES INDICATED MUST BE RESPECTED FOR THE TEST TO WORK CORRECTLY

C. READING AND INTERPRETING THE RESULTS

POSITIVE: (presence of SARS-CoV-2-specific antibodies): A BLUE line appears at position "C" (control) and a GREY line appears at position "T" (test).

NEGATIVE: (absence of SARS-CoV-2-specific antibodies): A BLUE line appears at position "C" (control) only.

INVALID: The test is invalid if the BLUE line does not appear at position "C" (control), regardless of whether or not a line appears at the "T" (test) position.

It is advisable not to define any sample as negative until 10 minutes after the analysis was performed.

OPERATING SPECIFICATIONS

The results obtained with the studied samples are those described here. These results do not imply guaranteed specifications. The test operating data was obtained from human serum samples. For further information on the particular operating specifications, please contact INGENASA.

1. PRECISION: There is no inter-device variation (5 replicates)
2. DIAGNOSTIC SPECIFICITY = 99% (146 serums were classified as: positive by PCR and negative by serology; negative by PCR and serology; or historically negative (prior to 2019)).
3. RELATIVE SENSITIVITY WITH RESPECT TO PCR 73% (157 serums)
4. RELATIVE SENSITIVITY WITH RESPECT TO ELISA = 91% (315 serums)
5. ANALYTICAL SENSITIVITY: 94.5% from the 19th day after the onset of symptoms.
6. INTERFERENCE: Hyperlipidic, haemolysed or icteric samples with concentrations greater than 3mg/ml haemoglobin, 1.5mg/ml triglycerides and 0.05mg/ml bilirubin, or microbiologically contaminated and turbid samples may affect test performance and should not be used.
7. CROSS-REACTIVITY: Human serum samples positive for other respiratory coronaviruses (229E, NL63, OC43 and HKU1) have been used. The results indicate that there is no cross-reactivity with antibodies specific to these agents. Neither have interferences been found for antibodies for other respiratory viruses such as Influenza or RSV.

LIMITATIONS OF THE PROCEDURE

- Bacterial contamination or repeated freezing/thawing of samples may affect the results. Hyperlipidic, haemolysed, or microbiologically contaminated and turbid samples may affect test performance and should not be used.
- The test only indicates the presence/absence of SARS-CoV-2-specific antibodies in the sample and should not be used as the sole criterion for diagnosing a SARS-CoV-2 infection.
- The results should be checked against clinical data and other available information.

WARNINGS

- In accordance with Article 1, Paragraph 2b of European Directive 98/79/EC, the use of in-vitro diagnostic medical devices is envisaged by the manufacturer to ensure the suitability, performance, and safety of these products. Consequently, the testing procedure, information, precautions, and warnings in the instructions for use must be followed rigorously. No changes to the test procedure are permitted, nor is any use in combination with other products not approved by the manufacturer. The user is solely responsible for any such changes. The manufacturer is not responsible for false results nor incidents arising as a result of these. The manufacturer is not responsible for any results obtained by visual analysis of patient samples.
- The diagnosis of an infectious disease should not be established on the basis of a single test result. An accurate diagnosis must take into account the patient's clinical history, symptomatology, and serological data.
- In immunocompromised patients and newborns, serological data has only limited value.
- Only for *in-vitro* diagnosis.
- Read all instructions for use carefully, before starting.
- Keep reagents at room temperature prior to use.
- Do not mix reagents or instructions from different kits.
- Do not use the kits after the expiry date or mix components from different batches.
- Do not eat, drink, or smoke while handling the reagents and/or samples.
- Do not pipette the reagents by mouth.

SAFETY NOTE

The chromatography buffer has a sodium azide component of less than 1% v/v and does not need to be labelled according to European regulations. **Safety data sheets are available on request.**

WASTE CONSIDERATIONS

Waste from chemicals and preparations is generally considered to be hazardous waste. The disposal of this type of waste is regulated by national and regional laws and regulations. Contact your local authorities or waste management companies for advice on how to dispose of hazardous waste.

In these devices, the microspheres remain attached to the solid matrix throughout the entire life cycle of the device and therefore paragraph 1 of Article 3(5) of Directive (EC) No. 1907/2006 does not apply to the marketing of this product.

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TECHNICAL ASSISTANCE AND ORDERS

For more information on how this product works, or if you have a complaint, please contact:

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