eurofins | Ingenasa

CE IVD

Product ONLY for professional use

INgezim® COVID 19 CROM

Prod. Ref: 50.CoV.K.41/s

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

INMUNOLOGIA Y GENETICA APLICADA, SA (INGENASA)
Avda. de la Institución Libre de Enseñanza 39, 8ª planta– 28037
MADRID (SPAIN)
Tel: (+34)91 3680501
www.ingenasa.com

IT-73840 IT-73780 9191.INGE 9175.ING2

KIT CONTENTS (*Easy* format):

Component	Units
Immunochromatographic strips	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 is designed to qualitatively determine the total antibodies specific for the SARS-CoV-2 virus N protein in human serum or blood samples. This is a rapid, *point-of-care* test, in other words, it can be carried out outside the laboratory. In the EU, these *point-of-care* diagnostic tests for COVID-19 are intended for use by health professionals. **The product cannot be used by individuals as it is NOT a self-diagnosis test.**

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

The INgezim® COVID 19 CROM test is an immunochromatographic assay based on the use of coloured latex microspheres that bond to the proteins of interest: the black particles are covalently boundd to the N protein of SARS-CoV-2, and the blue particles to a control protein, to indicate that the immunochromatography develops correctly.

The membrane contains a test line (T), in which the SARS-CoV-2 N protein is immobilised; and a control line (C), formed by a specific monoclonal antibody of the control protein. If SARS-CoV-2 antibodies are present in the sample, they will react with the black latex particles coated with the N protein. The latex/protein/antibody complex will migrate across the membrane and bind to the protein contained in the test line, resulting in a coloured 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 TO USE

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 the refrigerated blood or serum samples are temperature-adjusted beforehand.
- Remove the diagnostic immunochromatographic strip from the tube and place it on a flat surface.

A.- BLOOD SAMPLES:

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

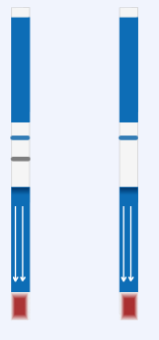
1. Use the lancet to lightly prick a fingertip.
2. Sample collection: place the supplied pipette over the drop of blood and fill the reservoir (20 µL). If the blood sample is already in a tube, use the pipette in the same way.
3. Perform the assay immediately, to prevent the blood from clotting in the capillary tube. Place the drop onto the sample capture zone on the strip (indicated by white arrows): to do this, cover the hole of the capillary tube and gently press the top of the pipette.
4. Wait one minute for the sample to be absorbed and slowly add 3 drops of the supplied chromatography buffer (wait between drops for the liquid to be absorbed 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 sample pad on the strip (indicated by white arrows).
3. Add 3 drops of the supplied chromatography buffer (wait between drops for the liquid to be absorbed 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 in position "C" (test control) and a GREY line appears in 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 ten minutes have elapsed 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-strip 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 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 the 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 therefore 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 strips, the microspheres remain attached to the solid matrix throughout the entire life cycle of the strip and therefore paragraph 1 of Article 3(5) of Directive (EC) No. 1907/2006 does not apply to the marketing of this product.

REFERENCES:

1 Mizumoto, K. et al, (2020). Estimating the asymptomatic proportion of coronavirus disease 2019 (COVID 19) cases on board the Diamond Princess cruise ship, Yokohama, Japan, 2020. Euro Surveill. 2020;25(10):pii=2000180.

2 Bai, Y., et al. Presumed Asymptomatic Carrier Transmission of COVID 19. JAMA (2020). https://doi.org/10.2807/1560-7917.ES.2020.25.10.2000180.

3 Aguilar, J. et al. Investigating the Impact of Asymptomatic Carriers on COVID 19 Transmission medRxiv 2020.03.18.20037994; doi: https://doi.org/10.1101/2020.03.18.20037994

4 He, X. et al. Temporal dynamics in viral shedding and transmissibility of COVID 19. medRxiv 2020.03.15.20036707; doi: https://doi.org/10.1101/2020.03.15.20036707.

5 Wölfel, R., Corman, V.M., Guggemos, W. et al. Virological assessment of hospitalized patients with COVID-2019. Nature (2020). https://doi.org/10.1038/s41586-020-2196-x

6 Zhao, J. Jr et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. medRxiv 2020 doi: https://doi.org/10.1101/2020.03.02.200301895

7 Zhang, W. et al. Molecular and serological investigation of 2019-nCoV infected patients: implication of multiple shedding routes, Emerging Microbes & Infections (2020) 9:1, 386-389, DOI: 10.1080/22221751.2020.1729071.

8 Wu LP, et al. Duration of antibody responses after severe acute respiratory syndrome. Emerg Infect Dis. 2007;13(10):1562–1564. doi:10.3201/eid1310.070576.

9 Bao, L. et al Reinfection could not occur in SARS-CoV-2 infected rhesus macaques. BioRxiv March, 2020. doi: https://doi.org/10.1101/2020.03.13.99022.

10 Okba, N.M.A. et al. SARS-CoV-2 specific antibody responses in COVID 19 patients. MedRxiv, March 2020. doi: https://doi.org/10.1101/2020.03.18.20038059.

11 Corman, V et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. 2020;25(3):pii=2000045. https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045

TECHNICAL ASSISTANCE AND ORDERS

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

INGENASA

Avda. de la Institución Libre de Enseñanza 39, 8ª planta – 28037 MADRID
Tel (+34) 91 368 0501
email: soportetecnico@ingenasa.com

For orders please contact:

INGENASA
Avda. de la Institución Libre de Enseñanza 39, 8ª planta – 28037 MADRID
Tel (+34) 91 368 0501
email: facturacion@ingenasa.com