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ELISA TEST RESULTS REPORT FOR SARS-CoV-2

PATIENT'S NAME: NOMBRE APP1 APP2
ID/PASSPORT: IDENTIFICACION
DATE OF BIRTH: 20/11/1995
GENDER: MUJER
REASON: Motivo de la prueba de ejemplo
SAMPLE CODE: TEST CODE
TEST NAME: ELISA test for SARS-CoV-2
RECIEVED SAMPLE: Peripheral venous blood
ASSAY CARRIED OUT: Enzyme Linked Immunosorbent Assay (ELISA)

RESULTS:

- SARS-CoV-2 IgA Antibodies (Immunoassay)

Result: 0,33 ODI* NEGATIVO

Interpretation ranges:

ODI < 0.9	NEGATIVE
ODI ≥ 0.9 to < 1.0	UNDETERMINED
ODI ≥ 1	POSITIVE

- SARS-CoV-2 IgM Antibodies (Immunoassay)

Result: 1,21 ODI* POSITIVO

Interpretation ranges:

ODI < 0.8	NEGATIVE
ODI ≥ 0.8 to < 1.0	UNDETERMINED
ODI ≥ 1	POSITIVE

- SARS-CoV-2 IgG Antibodies (Inmunoassay)

Result: 0,95 ODI* INDETERMINADO

Interpretation ranges:

ODI < 0.9	NEGATIVE
ODI ≥ 0.9 to < 1.0	UNDETERMINED
ODI ≥ 1	POSITIVE

A negative immune response in the ELISA result does not exclude the possibility of a positive immune response to SARS-CoV-2: false negative immune responses may be due to the stage of infection (e.g. sample obtained prior to the development of a cellular immune response), or comorbidities that affect immune functions. Patients in the early stages of infection may not produce detectable levels of antibodies.

A positive immune response in the ELISA result should not be the sole or definitive basis for determining SARS-CoV-2 infection. A positive immune response in the ELISA should be followed by additional medical evaluation and diagnostic evaluation for active COVID-19 disease. Serum / plasma from patients with other microorganisms such as Epstein-Barr virus, adenovirus, influenza virus, and pneumonia might produce false positive results.

*ODI = Optical Density Index

The procedure and the results obtained have been validated by:

Name and surname:

Test Doctor

Signature:

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Guidelines on the results of the ELISA test:

The ELISA test, performed with a blood sample, is used to determine the presence of the three antibodies that are generated in response to the SARS-CoV-2 infection and their levels. This test allows evaluating the immune response of a person after exposure to the virus.

It is very important to note that this immune response is highly variable from one individual to another. Antibody determination test results should be assessed in conjunction with the patient's clinical data.

The classical immune response to viral pathogens generally involves the production of IgA and IgM in the first phase of infection and it is followed by the production of IgG. IgA and IgM can be detected from the 5th to the 7th day after the onset of symptoms.

- IgA antibodies are secreted on mucosal surfaces. Its detection and quantification in plasma reflects the immune function of the mucosa.
- IgM antibodies can be detectable up to 6 weeks later. They are the most nonspecific initial immune response against infection.
- IgG antibodies are generally produced later in the course of infection, being detectable around the 11th-14th day after the onset of symptoms. IgG is a more durable antibody associated with potential viral neutralizing activity.

In general terms, the results of the measurement of antibodies by ELISA can be interpreted following these recommendations:

PCR	IgA/IgM	IgG	Interpretation
+	-	-	Presymptomatic phase
+	+/-	+/-	Initial phase (approx. 1-7 days)
+/-	+	+/-	2nd phase (8-14 days)
+/-	++	++	3rd phase > 15 days
-	+/-	++	Infection overcome (immune)

Based in "INTERPRETACIÓN DE LAS PRUEBAS DIAGNÓSTICAS FRENTE A SARS-CoV-2. 24 de abril de 2020. Versión 2" published by Ministerio de Sanidad, Instituto Carlos III in collaboration with SEIMC (Sociedad Española de Enfermedades Infecciosas y Microbiología Clínica).

Therefore, according to the results:

- IgM/IgA (-) / IgG (-) indicates that either the patient has not been infected or is in the window period during which the antibodies are not detectable. PCR is recommended.
- IgM/IgA (+) / IgG (-) indicates that the patient is in the early phase of infection. PCR is recommended.
- IgM/IgA (+) / IgG (+) indicates that the patient is in the acute phase of the infection or that it is resolved or in the process of resolution.
- IgM/IgA (-) / IgG (+) indicates infection overcome.

In case of obtaining an IgM UNDETERMINED result, it can correspond to several clinical situations:

- If the individual shows symptoms, we recommend performing the PCR test to rule out the presence of the virus in the upper airways (nose / mouth). A positive PCR would confirm that the patient is between days 7-12 of infection and that undetermined IgM is likely to become positive after a few days.
- If the individual does not present symptoms, we recommend repeating the serology after 10-15 days to see the evolution of the antibodies and/or to rule out possible interferences.

A false positive SARS-CoV-2 IgM can result from cross-reactions with other past viruses. In these cases the PCR test is expected to give a negative result.

NOTE: The results of the antibody determination, mainly IgM but sometimes also IgA, could give false positives. Life Length works with the highest quality standards in laboratory tests. The different efforts for the global development of the ELISA tests for SARS-CoV-2 report the possibility of presenting these false positives. In case of obtaining positive results for IgA or IgM and not having presented the symptoms described as characteristic of this infection (fever, dry cough, headache, shortness of breath, among the main ones) we recommend going to your GP, follow the guidelines that she/he indicates and repeat the analysis in approximately 15 days. The ELISA test is a tool to support the diagnosis of COVID-19. Only the PCR test can confirm or rule out the presence of viral particles in an individual's upper airways and their potential to be or not contagious with COVID-19.

References:

1. Interpretación de las Pruebas Diagnósticas Frente a SARS-CoV-2. 24 de abril de 2020. Versión 2 published by Ministerio de Sanidad, Instituto Carlos III in collaboration with SEIMC (Sociedad Española de Enfermedades Infecciosas y Microbiología Clínica). https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov-China/documentos/INTERPRETACION_DE_LAS_PRUEBAS.pdf
2. Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2 [published online ahead of print, 2020 May 6]. JAMA. 2020;10.1001/jama.2020.8259. doi:10.1001/jama.2020.8259.
3. Bohn MK, Lippi G, Horvath A, et al. Molecular, serological, and biochemical diagnosis and monitoring of COVID-19: IFCC taskforce evaluation of the latest evidence [published online ahead of print, 2020 May 27]. Clin Chem Lab Med. 2020;/j/cclm.ahead-of-print/cclm-2020-0722/cclm-2020-0722.xml. doi:10.1515/cclm-2020-0722.