

Patient Name: PUBLIC, JOHN Q

MRN:

DOB • Age • Sex: 05/19/2000 • 20 yrs • Male

Ordering Physician: Oehrle, John S

Interpace Diagnostics Accession #: RP20-05368

Case Accessioned: 05/19/2020

Specimen Received: 05/19/2020

External Accession #:

Specimens Received

1. Blood, Public J (Public J; Collected 05/18/2020)

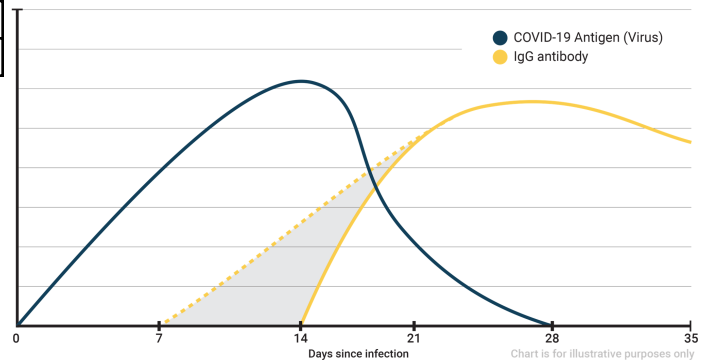
Documents Received

SEROLOGY TEST RESULTS

Antibody Tested	Ratio*	Interpretation
SARs-CoV-2 IgG	0.321	Negative

* Ratio is defined as the optical density of the clinical sample divided by the optical density of the calibrator.

Variation of the Levels of SARs-CoV-2 RNA Antigen and IgG After Infection



ABOUT THIS TEST

This enzyme immunoassay (ELISA) test, created by EUROIMMUN, provides qualitative measurement of human SARS-CoV-2 IgG antibodies present in a blood. When infected with the SARS-CoV-2 virus, the immune system responds by producing blood circulating molecules known as antibodies. IgG is a class of antibodies that appears in circulation approximately 7 to 10 days after infection and remain detectable for many months.

A positive test result for SAR-CoV-2 IgG antibody indicates that it is likely that you currently have, or previously have had COVID-19, and that your body has produced an antibody response to the SARS-CoV-2 virus. Your health care provider can determine how to best care for you based upon this test result, your symptoms, exposure history and other relevant factors.

It should be noted there is a small possibility that this test result is falsely positive. A negative test result for SARS-CoV-2 IgG indicates that the IgG antibodies to the virus causing COVID-19 were not identified in your blood sample. Because the body does not produce this antibody until 7-10 days following infection, a negative result does not rule out the possibility of exposure to SARS-CoV-2. A negative result may occur in the early stages of your illness before your body has produced IgG antibodies against the virus. This means that you could have COVID-19 even though the test is negative. Your health care provider can assess your symptoms, exposure history, and other factors, in addition to this test result in order to best determine how to care for you.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

TEST PERFORMANCE CHARACTERISTICS

Based on EUROIMMUN validation, this test is 100% sensitive at detecting SARS CoV IgG antibodies if performed greater than or equal to 21 days post-onset of symptoms and is 81.1% sensitive at detecting SARS CoV IgG antibodies if performed greater than or equal to 11 days post-PCR confirmation of infection.

An independent clinical agreement validation study including 30 antibody positive and 80 antibody negative samples, with positives confirmed by nucleic acid amplification (NAAT) indicates 90% sensitivity, 100% specificity, 100% PPV, and 99.5% NPV.

REGULATORY

FDA Status

While this test has not been FDA cleared or approved, it has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the ACT, 21 U.S.C. and 360bbb-3(b)(1), unless the authorization is terminated or revoked. Interpace Diagnostics is a high complexity CLIA Certified lab (CLIA# 39D1024654).

Limitations and Disclaimers (provided by EUROIMMUN kit manufacturer – see kit insert)

Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for patient management decision. The sensitivity of the test early after infection is unknown. False positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Samples with positive results should be confirmed with alternative testing methods and clinical findings before a diagnostic determination is made. Cross-reactivity was observed with anti-SARS-CoV-1 IgG antibodies. A negative result can occur if the quantity of antibodies of the SARS-CoV-2 virus present in the specimen is below the detection limits for the assay, or if the virus has undergone minor amino acid mutations in the epitope recognized by the antibody used in the test. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease. This test is not for the screening of donated blood. It is not known at this time if the presence of antibodies of SARS-CoV-2 confers immunity to re-infection.

End of Report

INTERPRETED BY

Electronically verified by Sydney D. Finkelstein, MD
Date: 2020.05.29 09:23:18 EDT

Sydney D. Finkelstein, MD
Medical Director

May 29, 2020

Report Date



Interpace Diagnostics, 2515 Liberty Avenue, Pittsburgh, PA 15222
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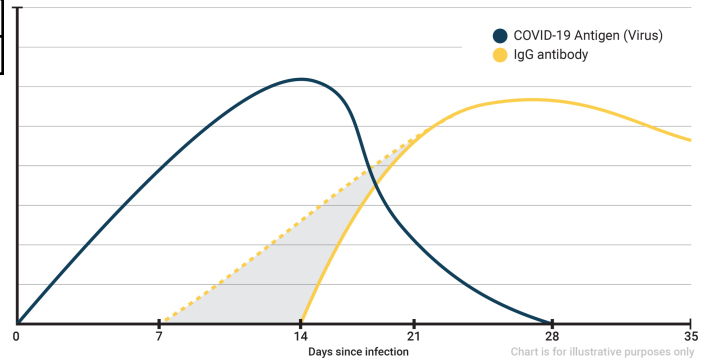
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SEROLOGY TEST RESULTS

Antibody Tested	Ratio*	Interpretation
SARs-CoV-2 IgG	10.229	Positive

* Ratio is defined as the optical density of the clinical sample divided by the optical density of the calibrator.

Variation of the Levels of SARs-CoV-2 RNA Antigen and IgG After Infection



ABOUT THIS TEST

This enzyme immunoassay (ELISA) test, created by EUROIMMUN, provides qualitative measurement of human SARS-CoV-2 IgG antibodies present in a blood. When infected with the SARS-CoV-2 virus, the immune system responds by producing blood circulating molecules known as antibodies. IgG is a class of antibodies that appears in circulation approximately 7 to 10 days after infection and remain detectable for many months.

A positive test result for SAR-CoV-2 IgG antibody indicates that it is likely that you currently have, or previously have had COVID-19, and that your body has produced an antibody response to the SARS-CoV-2 virus. Your health care provider can determine how to best care for you based upon this test result, your symptoms, exposure history and other relevant factors.

It should be noted there is a small possibility that this test result is falsely positive. A negative test result for SARS-CoV-2 IgG indicates that the IgG antibodies to the virus causing COVID-19 were not identified in your blood sample. Because the body does not produce this antibody until 7-10 days following infection, a negative result does not rule out the possibility of exposure to SARS-CoV-2. A negative result may occur in the early stages of your illness before your body has produced IgG antibodies against the virus. This means that you could have COVID-19 even though the test is negative. Your health care provider can assess your symptoms, exposure history, and other factors, in addition to this test result in order to best determine how to care for you.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

TEST PERFORMANCE CHARACTERISTICS

Based on EUROIMMUN validation, this test is 100% sensitive at detecting SARS CoV IgG antibodies if performed greater than or equal to 21 days post-onset of symptoms and is 81.1% sensitive at detecting SARS CoV IgG antibodies if performed greater than or equal to 11 days post-PCR confirmation of infection.

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End of Report

INTERPRETED BY

Electronically verified by Sydney D. Finkelstein, MD
Date: 2020.05.28 16:26:27 EDT

Sydney D. Finkelstein, MD
Medical Director

May 28, 2020

Report Date



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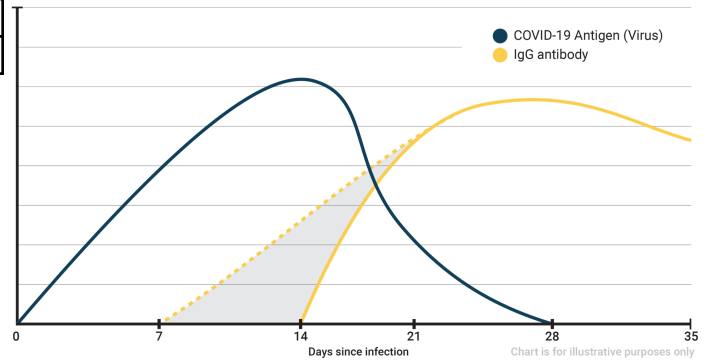
SEROLOGY TEST RESULTS

Antibody Tested	Ratio*	Interpretation
SARs-CoV-2 IgG	0.943	Borderline

IgG antibody testing indicates a “borderline” result at the threshold between negative and positive status. Repeat testing after an interval is recommended. If this patient is recovering from COVID-19, retesting a re-draw 7 to 14 days from now is indicated to determine the immune status

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End of Report

INTERPRETED BY

Electronically verified by Sydney D. Finkelstein, MD
Date: 2020.05.29 10:19:45 EDT

Sydney D. Finkelstein, MD
Medical Director

May 29, 2020

Report Date



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