OmniPATH™ COVID-19 Total Antibody ELISA Test

thermo scientific

IVD **For In Vitro Diagnostic Use Only**

For Emergency Authorization Use Only

Rx Only

REF 10662401

1 plate - 88

Intended Use

The OmniPATH™ COVID-19 Total Antibody ELISA Test is an Enzyme-Linked Immunosorbent Assay (ELISA) intended for qualitative detection of total antibodies (including IgM, IgA and IgG) to SARS-CoV-2 in human serum run manually or using the Dynex AGILITY automated ELISA workstation. The OmniPATH COVID-19 Total Antibody ELISA Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The OmniPATH COVID-19 Total Antibody ELISA Test should not be used to diagnose acute SARS CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate (automated method) and high (manual and automated method) complexity tests.

Results are for the detection of SARS CoV-2 total antibodies. Total antibodies (including IgM, IgA and IgG) to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies presence post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the OmniPATH COVID-19 Total Antibody ELISA Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the OmniPATH COVID-19 Total Antibody ELISA Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different assay.

The OmniPATH COVID-19 Total Antibody ELISA Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation of the Test

Coronavirus Disease 2019 (COVID-19) is caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. The virus is thought to spread mainly from person to person. Respiratory droplets/ secretions produced when an infected person coughs or sneezes is thought to be the primary means of transmission. There is limited information available characterizing the spectrum of clinical illness associated with COVID-19, but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.), but can also be asymptomatic.

The OmniPATH COVID-19 Total Antibody ELISA Test detects total antibodies (including IgG, IgM and IgA) to SARS-CoV-2. The test is intended for the qualitative detection of antibodies indicative of recent or prior SARS-CoV-2 infection.

Test Principle

The test kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative detection of anti-SARS-CoV-2 total antibodies in human serum specimens.

The assay uses recombinant spike protein in a two-step sandwich format. In the first reaction step patient samples are incubated in the antigen-coated microwells. If present, specific antibodies (IgM/IgA/IgG) will bind to the antigens. To detect the bound antibodies, a second reaction is carried out with horseradish peroxidase labelled recombinant antigen (enzyme conjugate) which catalyzes a color reaction.

Test Kit Contents

Component	Contents	Quantity
Microtiter Plate (Ready to Use)	Coated with recombinant SARS-CoV-2 antigen protein	12 strips x 8 wells
Enzyme Conjugate (Ready to Use)	Recombinant antigen conjugated to horseradish peroxidase (HRP) in protein-based buffer	12 mL x 1 vial
Negative Control (Ready to Use)	Solution composed of casein, newborn calf serum, glycerol, sucrose, Triton X-100, ProClin300 (as preservative) in a citrate/ phosphate buffer, pH 7.4.	0.5 mL x 1 vial
Low Positive Control (Ready to Use)	Solution containing horse anti-SARS-CoV-2	0.5 mL x 1 vial
Positive Control (Ready to Use)	Solution containing horse anti-SARS-CoV-2	0.5 mL x 1 vial
Wash Buffer Concentrate (20x concentrate)	With NaCl, Tween	50 mL x 1 vial
Chromogenic Reagent A (Ready to Use)	Hydrogen peroxide solution (H_2O_2)	7 mL x 1 vial
Chromogenic Reagent B (Ready to Use)	3, 3', 5, 5' - tetramethylbenzidine (TMB) solution	7 mL x 1 vial
Stop Solution (Ready to Use)	Diluted sulfuric acid (H_2SO_4)	7 mL x 1 vial
Microplate Sealers		3

Additional Required Materials

Components	Supplier	Cat. No.
Distilled or deionized water to dilute the 20x wash concentrate to 1x.	Thermo Fisher Scientific	10977023
Absorbent paper	Thermo Fisher Scientific	74218-00
Adhesive film (to reseal pouch for remnant strips)	Thermo Fisher Scientific	232698
Gloves and eye / face protection	Thermo Fisher Scientific	6355-0001
Graduated Cylinder to prepare Wash Buffer	Thermo Fisher Scientific	3662-0250
Plastic container to store prepared Wash Buffer	Thermo Fisher Scientific	312114-0032, 312104-0032 2125-1000, 2104-0016
Calibrated multi-channel pipettes capable of delivering 50 µL, 100 µL and 300 µL volumes	Thermo Fisher Scientific	4672080BT
Pipette tips for the above	Thermo Fisher Scientific	94420513
Disposable reagent waste reservoir	Thermo Fisher Scientific	8086, 8094
Adhesive microplate sealers (if needed)	Thermo Fisher Scientific	AB-5000
Manual or automated Microplate washing system	Thermo Fisher Scientific	516500
Dry-heat incubator, capable of maintaining 37°C ± 2°C	Thermo Fisher Scientific	51028135
Refrigerator 2-8°C	Thermo Fisher Scientific	TSX5005GA, TSX2330FA
Single or dual wavelength Microplate reader equipped with 450 nm filter	Thermo Fisher Scientific	51119000
Laboratory Timer		
Laboratory Centrifuge – if needed	Thermo Fisher Scientific	75009521(120V) 75009515 (230V) + 75003017 (rotor) + 75003001 Bucket + 75007309 (lid) + 7507303 (plate carrier)

Storage and Stability

The unopened reagents are stable until the expiration date when stored at 2 to 8°C, and the opened kit is stable for up to 1 month from the date of opening at 2 to 8°C.
Do not freeze reagents or expose them to temperatures above 32°C.

⚠ Warnings and Precautions

DANGER: OmniPATH Covid-19 Total Antibody ELISA Test contains <0.1% Gentamicin sulfate.

WARNING: OmniPATH Covid-19 Total Antibody ELISA Test contains 0.05-0.1% mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-4-isothiazolin-3-one, 10-30% Sulfuric acid, 0.01-0.1% Hydrogen peroxide and 3-7% Ethyl alcohol. Handle with Care.

H314 - Causes Severe skin and burns and eye damage
H315 - Causes skin irritation
H317 - May cause allergic skin reaction
H227 - Combustible liquid

Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Avoid breathing dust/fume/gas/mist/vapors/spray. Contaminated work clothing should not be allowed out of the workplace. In case of inadequate ventilation wear respiratory protection. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN: Wash with plenty of soap and water. Specific treatment (remove from exposure and treat symptoms). Refer to other portions of precautionary text on this label, SDS or other product information sheets, as appropriate. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Dispose of contents/container to location in accordance with local/regional/national/international regulations. In the case of accidental spill, clean and dispose of material according to your laboratory's standard operating procedures and local, state, and country regulations, with consideration that the material contains potentially infectious materials.

In the case of damaged packaging on arrival, contact your technical support representative (contact details listed at the end of this instructions for use).

Exercise the standard precautions required for handling all laboratory reagents.

Precautions for Users

- For in vitro diagnostic use.
- Do not mix materials from different kit lot numbers.
- Do not use kits beyond the expiration date.

☣ **CAUTION:** Materials of animal origin must be handled just as c[ontagious] ly as a p[otentially infectious] sample. In the event of exposure, the directives of the responsible health auth[orities] should be followed.

⚠ **CAUTION:** The reagents included with the OmniPATH COVID-19 T[otal] ntibody ELISA contain ProClin less than 0.1% (v/v). Avoid contact with skin and muc[ous] membranes. Flush affected areas with copious amounts of water. Seek immediate medical [attention] if reagents are ingested or come into contact with eyes. M[ay cause] allergic skin reacti[on] Wear protective gloves. If skin irritation or rash occurs: Get medica[l] ttention.

Procedural Precautions

- The product must only be [used] by trained laboratory personnel [who are] certified under the Clinical Labo[ratory] Improvement Amendments of 1988 (CLIA), [42] U.S.C 263a, that meet requirem[ents to] perform moderate or high complexity tests.
- Do not use expir[ed] gents.
- Do not use the kit [if the] ackaging of [the] mponents is visibly damaged.
- Do not mix reagents [from] ther [kits] at have different lot numbers or are from other manufacturers.
- Do not [use] kit compon[ents if] contamination is [suspected].
- B[ring] to room tem[perature] re (15-30°C) before use.
- [Read] the instr[uctions] n for use carefully. Use o[nly] the latest electronic version provided with the test kit.
  The pipetting v[olumes], as well as the i[ncubation] durations and temperature times must be strictly adh[ered] to.
  Use a new [pipette tip] each specimen.
  Microplate washing is a cri[tical] p in this procedure and failure to follow the correct [procedure] may lead to erroneous results. Follow the required number of wash cycles and ensure that all wells are completely filled and then completely emptied.
- Observe Good Laboratory Practice (GLP) and safety guidelines.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- This test has been authorized only for the presence of total antibodies against SARS CoV-2, not for any other viruses or pathogens.
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate (automated method) or high (manual and automated method) complexity tests.

Sample Collection

Sample Handling and Storage Condition

- Follow procedures within your laboratory to avoid cross contamination of patient specimens.
- Samples may be stored at room temperature (15-30°C) for no longer than 8 hours. If the test will not be completed within 8 hours, refrigerate the serum samples at 2-8°C for no longer than 48 hours.[9]
- Samples that will not be tested within the time frames outlined above should be stored at ≤ -20°C and may be subjected to 1 freeze-thaw cycle.[9]
- As an alternative to the above, sample stability may be established by each laboratory.

Serum Preparation

Collect whole blood in a serum separator tube (SST) or a r[ed top] or equivalent [tube] appropriate for isolation of serum. Refer to the serum collection tub[e] [manu]facturer's instructions for serum preparation, including centrifugation.

It is important to immediately transfer the liquid compo[nent] (serum) after serum prepara[tion] into a clean polypropylene tube. If the serum is [not] analyzed [immediately], the serum should be kept at 2-8°C for up to 48 hours, apportioned [into] referred sized [aliquots], stored at -20°C o[r] er if exceeding 9 days. It is important to av[oid] eeze-thaw cycles be[cause] this may be det[rimental] to serum components. Samples whic[h are] emolyzed, icteric or lipem[ic] invalidat[e] ain tests.

Manual Assay Procedu[re]

Note: If using the automa[ted] de, programi[ng] the OmniPATH assay on the Dynex Agility instrument should be done in c[onfig]uration w[ith] e instrument manufacturer per the instrument's instructions for u[se].

1. Bring rea[gents] s to room temper[ature] (15-30°C) for a[t] t 30 minutes before use.
2. Allow for [the] t Blank/Control deter[mina]ons (tw[o] gent Blank, two Negative Control, two Low [Positive] tive Control and two Pos[itive]) per run.
3. A full or p[artial] al plate may be run. Store th[e] dual strips from a partial plate run in the original p[ouch] d seal the entire opening with adhesive tape. Do not use broken strips.
4. Determin[e the] Buffer needed for the run. 24 mL total of 1X Wash [Buffer] is r[equired] for each r[un] controls and/or samples run. Volume to be prepared is (n strips) plus sufficient excess to ensure adequate quantity for use with manual or aut[omated] wash. To prepare a 1X Wash Buffer, mix 1 part of the 20X Wash Buffer with 19 p[arts] purified water thoroughly in an appropriately sized container to achieve homogeneity. 1X Wash Buffer may be stored at 2-8°C for up to 30 days.
5. [Add] control wel[ls] 50 µL control solution directly to individual wells (except for the t[wo] agent Blank wells).
6. Fo[r] ple wells, add 50 µL sample serum to each well.
7. Mix well by gentle shaking, cover the microplate wells with an adhesive sealer, and inc[ubate] for **30 minutes at 37±2°C**.
8. Microplate Washing: discard the liquid in the wells then fill each microwell with [350] µL of working Wash Buffer (1X). Leave the wash buffer in each well for **5 seconds** and then remove the wash solution from all the wells. Repeat 4 times for a total of 5 washes. Firmly tap the inverted microplate on absorbent paper to thoroughly remove all residual liquid from the wells. The preceding manual wash may be performed with an automated plate washer.
9. Add 100 µL of the Enzyme Conjugate to each well at the same rate and in the same order as the samples. Cover the microplate with an adhesive sealer and incubate for **30 minutes at 37±2°C**.
10. Microplate Washing: wash the microwells by following the procedure as described in step 8.
11. Add 50 µL each (100 µL total) of Chromogenic Reagent A and Chromogenic Reagent B, to each well at the same rate and in the same order as the addition of the patient specimens. Mix well by gentle shaking, cover the microplate with an adhesive sealer, and incubate for **10 minutes at 37±2°C** protected from direct sunlight.
12. Add 50 µL of Stop Solution to each well at the same rate and in the same order as the Chromogenic Reagents. Gently tap the microplate several times to ensure that the reagents are thoroughly mixed.
13. Set the microwell reader to read at a wavelength of 450nm and measure the optical density (OD) of each well against the mean of two Reagent Blank wells. Read the microplate within a maximum of **10 minutes** of the addition of the Stop Solution.

Quality Control

Use 2 replicates of the Positive Control, 2 replicates of the Low Positive Control, and 2 replicates of the Negative Control on each microplate every time the test is performed.

Qualification of Negative Control (NC) values:
The absorbances of each NC must be less than 0.105.

Qualification of Low Positive Control (LPC) value:
The absorbance value of the LPC must be greater than or equal to 0.200

Qualification of Positive Control (PC) value:
The absorbance value of the PC must be greater than LPC.

Test Validation Criteria

- Mean Neg Control OD < 0.105
- Low Positive Control OD ≥0.200
- Positive Control OD > Low Positive Control OD

Calculation/Interpretation of Results

The cutoff value is 0.105.
Specimen results are determined using the calculated specimen index ratio.
Specimen index ratio = Specimen OD / 0.105

Interpretative Guide	
Specimen Index Ratio	Interpretation
< 1.0	Negative
≥ 1.0	Positive

Assessment of the OmniPATH COVID-19 Total Antibody ELISA Test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

Limitations of the Procedure

- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA and meet requirements to perform moderate or high complexity tests.
- This test has been authorized only for the presence of total 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 diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- The OmniPATH COVID-19 Total Antibody ELISA Test is authorized for use with a manual assay procedure and with the Dynex Agility automated ELISA workstation. Assay performance has not been established for use on other automated instrument platforms.
- Assay results should not be used to diagnose or exclude acute COVID-19. Direct viral nucleic acid detection or antigen detection methods should be performed if acute infection is suspected.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- The detection of anti-SARS-CoV-2 antibodies is dependent on the presence of the analyte in the specimen, a negative result can occur if the quantity of antibodies to SARS-CoV-2 present in the specimen are below the detection limit of the assay. During the acute infection phase and/or for immunosuppressed patients, anti-SARS-CoV-2 antibodies might not be detectable. Thus, a negative result does not preclude or rule out COVID 19 infection.
- Heterophilic antibodies in samples may cause interference in immunoassays. These antibodies may be present in blood samples from individuals regularly exposed to animals or who have been treated with animal serum products. Results that are inconsistent with clinical observations indicate the need for additional testing.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence in assessing the need for a second but different serology test to confirm an immune response.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- SARS-CoV-2 total antibodies may be below detectable levels in patients who have been exhibiting symptoms for more than 15 days.
- The results obtained with this test should only be interpreted in conjunction with clinical findings and the results from other laboratory tests and evaluations.
- It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
- Performance characteristics have not been evaluated for neonatal or pediatric patients.
- The test kit is validated for the qualitative determination of anti-SARS-CoV-2 total antibodies in human serum only.
- This test should not be used for human donor screening or screening of donated blood.

Conditions of Authorization for the Laboratory

The OmniPATH COVID-19 Total Antibody ELISA Test Letter of Authorization, along with the authorized Fact Sheet for Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on FDA's website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

Authorized laboratories using the OmniPATH COVID-19 Total Antibody ELISA Test ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product will use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Thermo Fisher Scientific (techsupport.diagnostics.mtn@thermofisher.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All laboratory personnel using your product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must be trained and be familiar with the interpretation of results of your product.
- Thermo Fisher Scientific, authorized distributors and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate (automated method) through (manual and automated methods) complexity tests" as "authorized laboratories."

Performance Characteristics

1) Precision/Reproducibility

This study was conducted using the Dynex AGILITY® automated ELISA workstation. Testing was conducted using one lot of the OmniPATH COVID-19 Total Antibody ELISA test kit and one instrument. Three (3) controls and 4 human serum panels were assayed in duplicate at two separate times per day on 15 different days.

Sample	N	Mean	Within-Run		Within-Laboratory[1]	
			SD	%CV	SD	%CV
Negative Control	60	0.001	0.009	N/A	0.008	N/A
Low Positive Control	60	0.575	0.017	2.96	0.123	21.44
High Positive Control	60	1.461	0.066	4.53	0.149	10.21
Negative Sample	60	0.014	0.005	N/A	0.006	N/A
Low-Positive Sample	60	0.150	0.017	11.18	0.030	19.91
Mid-Positive Sample	60	1.041	0.087	8.37	0.179	17.22
High-Positive Sample	60	1.864	0.101	5.41	0.220	11.80

[1] Includes within-run, between-run and between-day variability
OD = optical density; SD = standard deviation; N/A = Not applicable

2) Analytical Specificity/Cross Reactivity

The OmniPATH COVID-19 Total Antibody ELISA Test was evaluated for potentially cross-reacting antibodies. A total of 240 specimens from 16 different categories were tested. Results show that 239 specimens were negative, and 1 specimen was positive using the OmniPATH COVID-19 Total Antibody ELISA Test. The data are summarized in the table below:

Category	N	Positive	Negative
Antinuclear Antibody (ANA)	10	0	10
Chlamydophila pneumoniae IgG	30	1	29
Chlamydophila pneumoniae IgM	6	0	6
CMV IgG	25	0	25
CMV IgM	25	0	25
Haemophilus influenza IgG	10	0	10
Mycoplasma pneumoniae IgG	25	0	25
Mycoplasma pneumoniae IgM	25	0	25
HCoV-HKU1 spike IgG (2 ug/mL)	1	0	1
HCoV-OC43 spike IgG (3 ug/mL)	1	0	1
Epstein-Barr Virus (EBV) IgG	10	0	10
EBV IgM	10	0	10
Influenza A IgG	27	0	27
Influenza A IgM	1	0	1
Influenza B IgG	28	0	28
Influenza B IgM	6	0	6
Total	240	1	239

3) Clinical Performance

A. Thermo Fisher Scientific Clinical Agreement Study

Clinical Sensitivity:

Positive percent agreement (PPA) was determined by testing serum specimens collected at different times from 54 subjects who tested positive for SARS-CoV-2 by an EUA authorized PCR method (Mayo Clinic SARS-CoV-2 Molecular Detection Assay), and who also presented with COVID-19 symptoms. A total of 91 samples were collected from 54 subjects. The table below describes the PPA/sensitivity by days post-symptom onset, for the first sample per patient taken in each time bucket tested with the OmniPATH COVID-19 Total Antibody ELISA Test:

Table 1. Clinical sensitivity estimates for the first sample in each time bucket

		OmniPATH COVID-19 Total Antibody ELISA Test		
Days Post-Symptom Onset	***N***	**Positive**	**Negative**	**PPA (95% CI)**
≤ 7	21	4	17	19.0% (7.1, 40.6)
8 – 14	43	33	10	76.7% (62.1, 87.0)
≥ 15	27	27	0	100.0% (89.2, 100.0)

Clinical Specificity:

Negative percent agreement (NPA) was determined by testing 162 presumed SARS-CoV-2 negative samples from healthy donors collected during the year 2018, prior to the COVID-19 pandemic, resulting in 100% clinical specificity (95% CI: 98.02, 100.00). The table below describes NPA / specificity with the OmniPATH COVID-19 Total Antibody ELISA Test:

Table 2. Negative Agreement from healthy donors collected prior to COVID-19 pandemic

	OmniPATH COVID-19 Total Antibody ELISA Test		
Number of Samples Tested	**Total Antibody Positive results**	**Total Antibody Negative results**	**Overall NPA (95% CI)**
162	0	162	100.0% (98.0, 100.0)

Clinical agreement (PPA) for samples collected greater than 15 days after symptom o… 100% and overall NPA is 100%.

B. Independent Clinical Agreement Validation Study

The OmniPATH COVID-19 Total Antibody ELISA Test was tested on Septe…r 1, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored … National Cancer Institute (NCI). The test was validated against a panel o… viously … samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and … ntibody-ne… serum and anticoagulant citrate dextrose (ACD) plasma samples. Each o… 30 antibo… itive samples were confirmed with a nucleic acid amplification test (NAA… d both IgM … antibodies were confirmed to be present in all 30 samples. The presen… f antibodies in … samples was confirmed by several orthogonal methods prior to testin… th the OmniPATH COVID-19 Total Antibody ELISA Test. The presen… of IgM and IgG antibo… specifically was confirmed by one or more comparator metho… y-positive sample… re selected at different antibody titers.

All antibody-negative samples were … cted prior to 2020 and inc… ven… 0) samples selected without regard to clini… tus, "Negatives" and ii) ten (10) sa… cted from banked serum from HIV+ pa… , "HIV+". Testing was performed by one operator using 1 lot of OmniPATH COVID-19 … Antibody ELISA … Confidence intervals for sensitivity and specificity were calcul… r a score metho… cribed in CLSI EP12-A2 (2008).

For the evaluation of cross-re… y wi… +, it was determin… whether an increased false positive rate among antibody-ne… mples with HIV was … tically higher than the false positive rat… tibody-nega… mples without H… this, a confidence interval for the diffe… in fal… itive rates w… culated pe… ore method described by Altman). The r… s and data a… is are shown … table … ow.

… 3: Summary Res…

	…rator Method			Collected pre-2020		
	Antibody Positive			Antibody Negative		
OmniP… OVID-19 Total Antibody … Test	**IgM+, IgG+**	**IgM+, IgG-**	**IgM-, IgG+**	**Negative**	**HIV+**	**Total**
Pan Ig+	29			1	1	31
Pan Ig-	1			69	9	79
Total	30			70	10	110

Table 4: Summary Statistics

Measure	Estimate	Confidence Interval
Pan Ig Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
Pan Ig Specificity	97.5% (78/80)	(91.33%; 99.3%)
Combined Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
Combined Specificity	97.5% (78/80)	(91.33%; 99.3%)
Combined PPV for prevalence = 5.0%	67.1%	(33.6%; 88.4%)
Combined NPV for prevalence = 5.0%	99.8%	(99.0%; 100%)
Cross-reactivity with HIV+	10.0% (1… may b… ent	

Important limitations:

1. Samples were not randomly selected, and s… ity and specificity estimates … not be indicative of the real-world performance o… vice
2. These results are based on seru… nd ACD pl… samples only and may … be indicative of performance with … sample types, … as whole blood, … ding finger stick blood.
3. The number of samples in … anel is a minimally viable s… size tha… provides reasonable estimates … onfidence interv… for test perfo… the samples used may not be re… ntative of the anti… profile observed … nt populations.

4) Comparison or results bet… manual … utomated modes of operation

A total of 88 ser… specimens … and 45 negative) … ously determined to be positive or nega… for anti-SARS … ntibodies using th… A authorized Ortho-Clinical Diagnostics VIT… Anti-SARS-CoV … test, were t… by 1 operator using 1 kit lot. Automated proc… g was performed o… GILITY® … ated ELISA workstation. Manual testing was perf… d using an ELx50 micro… (BioTek Instruments, Inc., Winooski, VT) ELx800 micr… e reader with Gen5 softwa… on 1.11.5 (BioTek), and Thermo Isotemp … or. Resul… owed 100% agreement betw… en manual and automated modes in all 88 ser… mples … esent difference in OD values in positive specimens gener… y m… al and aut… ods was -11.0%, with minimum and maximum percent d… of -38.1% and 20.1%, respectively.

… 5. Results … mparison between results of manual vs automated modes of testing

		Manual Processing Method	
		Positive	**Negative**
Aut… ed Process… Method	**Positive**	43	0
	Negative	0	45

References

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