BIOMÉRIEUX

REF 423834-01

056098 - 03 - 2021-02

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VIDAS® SARS-COV-2 IgG

℞ only IVD

For prescription use only.

For *in vitro* diagnostic use only.

For use under an Emergency Use Authorization (EUA) only.

INTENDED USE

The VIDAS® SARS-COV-2 IgG is an automated assay using the ELFA (Enzyme Linked Fluorescent Assay) technique intended for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum or plasma (lithium heparin) on instruments of the VIDAS® family. The VIDAS® SARS-COV-2 IgG 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 VIDAS® SARS-COV-2 IgG 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 or high complexity tests.

Results are for the detection of IgG SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present 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 VIDAS® SARS-COV-2 IgG 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 VIDAS® SARS-COV-2 IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

Samples should only be tested from individuals that are 15 days or more post-symptom onset.

The VIDAS® SARS-COV-2 IgG is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a *Betacoronavirus* newly discovered in China in December 2019 which is responsible for an international outbreak of a respiratory illness termed coronavirus disease 19 (COVID-19), and whose manifestations range from a mild, self-limiting respiratory tract illness to severe progressive pneumonia, multiorgan failure, and death.[1]

Serology testing for specific immunoglobulins is an approach to identify individuals previously exposed to SARS-CoV-2.[2]

Indeed, most COVID-19 patients had an antibody response at ten days or later after onset of the symptoms.[3] This antibody response is characterized by the early rise of type M immunoglobulins (IgM), then followed by type G immunoglobulins (IgG).[4]

PRINCIPLE

The assay principle combines a two-step sandwich enzyme immunoassay method with a final fluorescence detection (ELFA).

The single-use Solid Phase Receptacle (SPR) serves as the solid phase as well as the pipetting device. Reagents for the assay are ready-to-use and pre-dispensed in the sealed single-use reagent strips.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR device several times.

After the sample dilution step, the SARS-CoV-2 IgG are captured by recombinant SARS-CoV-2 antigen coated into the interior of the SPR device wall. Unbound components are eliminated during washing steps.

During the second step, the IgG are specifically detected by anti-human IgG labeled with alkaline phosphatase. Unbound components are eliminated during washing steps.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR device. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm.

At the end of the assay, the results are automatically calculated by the instrument according to the S1 standard stored in memory and a test value is obtained.

The results can then be printed out.

CONTENT OF THE KIT (60 TESTS)

60 Strips[a] (9COG)	STR	Ready-to-use.
60 Solid Phase Receptacles (9COG) 2 x 30	SPR	Ready-to-use. Interior of SPR device coated with recombinant SARS-CoV-2 antigen (receptor binding domain (RBD) of the Spike SARS-CoV-2 protein).
Standard[b] (9COG) 1 x 0.5 mL (liquid)	S1	Ready-to-use. Buffer containing humanized recombinant anti-SARS-CoV-2 IgG antibody + stabilizer of animal origin + preservatives. MLE data indicate the acceptable range in "Relative Fluorescence Value" ("Standard (S1) RFV Range").
Positive control[b] (9COG) 1 x 0.5 mL (liquid)	C1	Ready-to-use. Buffer containing humanized recombinant anti-SARS-CoV-2 IgG antibody + stabilizer of animal origin + preservatives. MLE data indicate the acceptable range as an index ("Control C1 (+) Test Value Range").
Negative control[b] 1 x 0.5 mL (liquid)	C2	Ready-to-use. Buffer + stabilizer of animal origin + preservatives. MLE data indicate the acceptable range as an index ("Control C2 Test Value Range").
Specifications for the factory master data required to calibrate the assay: MLE barcode printed on the box label.		
1 package insert downloadable from www.biomerieux.com/techlib		

The product code (9COG) is unique to the product VIDAS® SARS-COV-2 IgG and is composed of an alphanumeric code representing the assay name. This product code enable the instrument to identify the test.

[a] **DANGER**

WARNING EUH208 / H317 / H318 / P261 / P280 / P302 + P352 / P305 + P351 + P338

[b] **WARNING** EUH208 / H317 / P261 / P280 / P302 + P352

Hazard statements

- EUH208: Contains 2-methyl-4-isothiazolin-3-one hydrochloride. May produce an allergic reaction.
- H317: May cause an allergic skin reaction.
- H318: Causes serious eye damage.

Precautionary statements

- P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280: Wear protective gloves/protective clothing/eye protection/face protection.
- P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
- P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

For further information, consult the Safety Data Sheet.

The SPR device
SPR devices are identified by the "9COG" code.

Only remove the required number of SPR devices from the pouch and carefully reseal the pouch after opening.

The Reagent Strip
The strip consists of 10 wells covered with a labeled foil seal. The label comprises a barcode which mainly indicates the assay code, kit lot number, and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

Description of the 9COG strip
The strip contains diethanolamine and sodium azide. Refer to the hazard statements “H” and precautionary statements “P” indicated above.[(a)]

Well	Reagents
1	Sample well: dispense 100 µL of standard, control or sample.
2	Sample diluent: buffer + detergent + stabilizer of animal origin + preservative.
3 - 4 - 5	Wash buffer: buffer + detergent + preservative.
6	Conjugate: mouse monoclonal anti-human IgG antibodies conjugated to alkaline phosphatase + stabilizer of animal origin + preservative.
7 - 8	Wash buffer: buffer + detergent + preservative.
9	Empty well
10	Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + preservative.

MATERIALS AND DISPOSABLES REQUIRED BUT NOT PROVIDED
- Single-use pipette and/or micropipettes to dispense the appropriate volumes.
- Powderless disposable gloves.
- For other specific materials and disposables, please refer to the Instrument User Manual.
- Instruments of the VIDAS® family: VIDAS®, MINI VIDAS® or VIDAS® 3.

WARNINGS AND PRECAUTIONS
- **For Emergency Use Authorization (EUA) only.**
- **For *in vitro* diagnostic use only.**
- This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- **For professional use only, by qualified laboratory personnel in clinical laboratories.**
- **Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- This test has been authorized only for detecting IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product 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 declaration is terminated or authorization is revoked sooner.
- Perform the procedure given in this package insert as described. Any deviation from the outlined protocols may result in assay failure or cause erroneous results. Modifications to assay reagents, assay protocol, or instrumentation is not permitted, and are in violation of the product Emergency Use Authorization.
- This kit does not contain products of human origin.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest; do not inhale), using safe laboratory procedures such as those outlined in CDC/ NIH Biosafety in Microbiological and Biomedical Laboratories, and in the CLSI Document M29 Protection of Laboratory Workers from Occupationally Acquired Infections..
- Do not use the SPR devices if the pouch is pierced or if the dot sealing a SPR device has come unstuck.
- Do not use visibly deteriorated strips (damaged foil or plastic).
- Do not use visibly deteriorated components.
- Do not use reagents after the expiration date indicated on the box label.

- Do not mix reagents (or disposables) from different lots.
- VIDAS® SARS-COV-2 assay reagents are only for use with the instruments of the VIDAS® family.
- Use powderless gloves, as powder has been reported to cause false results for certain enzyme immunoassay tests.
- Kit reagents contain sodium azide which can react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- Refer to the hazard statements “H” and precautionary statements “P” indicated above.
- Spills should be wiped up thoroughly after treatment with liquid detergent or a solution of household bleach containing at least 0.5% sodium hypochlorite. See the User Manual for cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
- The instrument should be regularly cleaned and decontaminated (refer to the User Manual for user and preventive maintenance operations).

STORAGE CONDITIONS

- Store the kit at +2°C/+8°C.
- **Do not freeze reagents.**
- **Store all unused reagents at +2°C/+8°C.**
- After opening the kit, check that the SPR pouches are correctly sealed and undamaged. If not, do not use the SPR devices.
- **After use, carefully reseal the pouch with the desiccant inside to maintain stability of the SPR devices, and return the complete kit to +2°C/+8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the box label.

SAMPLES

Specimen type and collection

Human serum or plasma (lithium heparin)

Note: Blood sampling tube results may vary from one manufacturer to another depending on the materials and additives used. Some collection tubes may contain substances which could interfere with test results.

Types of tubes validated

- Plastic tube with lithium heparin
- Plastic tube with clot activator

Sample preparation

The current WHO/DIL/LAB/99.1 document provides recommendations for sample preparation. [5]

For use of sample tubes, refer to the tube manufacturer’s recommendations for use.

The pre-analytical step, including the preparation of blood samples, is an essential first step when performing medical analyses. In accordance with Good Laboratory Practice, this step is performed under the responsibility of the laboratory manager.

Insufficient clot time can result in the formation of fibrin with micro-clots that are invisible to the naked eye. The presence of fibrin, red blood cells, or suspended particles can lead to erroneous results.

Samples containing suspended fibrin particles or erythrocyte stroma should be centrifuged before testing.

For serum samples, ensure that complete clot formation has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting times.

Preparation of frozen-stored samples

After thawing, all samples must be mixed before testing. Mix using a vortex-type mixer. If necessary, clarify the samples by centrifuging before testing (20 minutes at 2000 g or 10 minutes at 3900 g).

Sample stability

Samples can be stored in closed primary tubes at +18°C/+25°C for up to 6 hours or aliquoted at +2°C/+8°C for two days. If longer storage is required, freeze the serum or plasma at -19°C/-31°C.

These samples can be stored for 1 month at -19°C/-31°C, with up to three freeze/thaw cycles.

As an alternate to the above, the individual laboratory may determine specific specimen stability criteria for their laboratory per their laboratory workflow.

Sample-related interference

It is recommended not to use hemolyzed, lipemic, icteric samples, and, if possible, to collect a new sample.

Refer to the section **PERFORMANCE – Study of potentially interfering substances** for the compounds tested.

INSTRUCTIONS FOR USE

For complete instructions, see the Instrument User Manual.

Reading VIDAS® PTC (Protocol Test Change) data and MLE data

When using the assay for the first time

With the external instrument barcode reader, **scan the barcodes (PTC and MLE) in the following order**:

1. According to the instrument used, scan the PTC barcode(s) downloadable from www.biomerieux.com/techlib. This reading allows VIDAS® PTC protocol data to be transferred to the instrument software for its update.
2. Scan the MLE data on the box label.

When opening a new lot of reagents

With the external instrument barcode reader, scan the MLE data on the box label before performing the test.

Note: The master lot data need only be entered once for each lot.

It is possible to enter MLE data **manually or automatically** depending on the instrument (refer to the User Manual).

Calibration

Calibration, using the standard provided in the kit, must be performed each time a new lot of reagents is opened, after the MLE data have been entered, and then every 28 days.

This operation compensates for possible minor variations in assay signal throughout the shelf life of the kit.

The standard, identified by S1, must be tested in duplicate.

The standard value must be within the set RFV (Relative Fluorescence Value) range indicated in the MLE data. If this is not the case, recalibrate.

Kit controls

Two controls are included in this kit.

The kit controls must be used to validate each calibration. The kit controls must be performed immediately after opening a new kit to ensure that reagent performance has not been altered.

Note: Any other use of the kit control is under the customer's responsibility.

The instrument will check the control values only if the controls are identified by C1 or C2.

Results cannot be validated if the control values deviate from the expected values.

Procedure

1. **Remove the kit from storage at +2°C/+8°C and take out the required reagents. Carefully reseal the SPR pouch and return the kit to +2°C/+8°C.** The reagents can be used immediately.
2. Use one strip and one SPR device for each sample, control or standard to be tested. Make sure the SPR pouch has been carefully resealed after the required SPR devices have been removed.
3. The test is identified by the **9COG** code on the instrument. The standard, identified by S1, must be tested in duplicate. The controls, identified by C1 and C2, must be tested singly.
4. If necessary, clarify samples by centrifugation.
5. Mix the standard and controls using a vortex-type mixer.
6. For optimal results, refer to all the paragraphs in the **SAMPLES** section.
7. Before pipetting, ensure that the samples, standard and controls are free of bubbles.
8. **For this test, the standard, controls and sample test portion is 100 µL.**

   Caution: For the VIDAS® 3 instrument, standard and controls must be pipetted manually into the sample well.
9. Insert the SPR devices and the strips into the instrument.
10. Initiate the assay as directed in the User Manual. All the assay steps are performed automatically by the instrument.

    Caution: Initiate the assay within 10 minutes after the samples, standard and controls are dispensed into the strips
11. The assay will be completed within **approximately 27 minutes**. After the assay is completed, remove the SPR devices and strips from the instrument.
12. Close the vials and return them to the required temperature after pipetting.
13. Dispose of the used SPR devices and strips into an appropriate recipient.

QUALITY CONTROL

Additional quality controls can be performed in accordance with local regulations or requirements related to accreditation, as well as requirements defined in the laboratory's quality control procedure.

RESULTS AND INTERPRETATION

Once the assay is completed, results are analyzed automatically by the computer. Fluorescence is measured twice in the Reagent Strip's reading cuvette for each sample tested. The first reading is a background reading of the substrate cuvette before the SPR device is introduced into the substrate.

The second reading is taken after incubating the substrate with the enzyme that may be bound to the interior of the SPR device.

The RFV (Relative Fluorescence Value) is calculated by subtracting the background reading from the final result. This calculation appears on the result sheet.

The patient RFV is interpreted by the VIDAS® system as follows:

Test value = patient RFV / standard RFV

The test value and interpretation are also indicated on the result sheet.

Interpretation of results

Interpretation of results according to test value (i) is as follows:

Index	Test Result	Interpretation
i < 1.00	Negative	IgG antibodies to SARS-CoV-2 not detected
i ≥ 1.00	Positive	IgG antibodies to SARS-CoV-2 detected

LIMITATIONS OF THE METHOD

- SARS-CoV-2 antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days. Samples should only be tested from individuals that are 15 days or more post-symptom onset.
- The assay has only been validated using Lithium heparin plasma and serum.
- This test is for clinical laboratory use only. It is not for point of care or home use.
- 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.
- A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Patient specimens may be negative if collected during the early (pre-seroconversion) phase of illness or due to a decline in titer over time. In addition, the immune response may be depressed in elderly, immunocompromised, or immunosuppressed patients.
- Interference may be encountered with certain sera containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's clinical history and the results of any other tests performed.
- Two false positive (FP) results were observed while testing the cross-reactivity panel members—(1) HIV and (1) Rheumatoid Factor.
- Results obtained using samples from SARS-CoV-2 infected patients must be interpreted with caution.
- This assay is intended for qualitative detection only. Test value itself cannot be used to determine the quantity of SARS-CoV-2 IgG antibodies.
- The magnitude of the measured result above the threshold is not indicative of the total amount of antibody present in the sample.
- The individual immune response following SARS-CoV-2 infection varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably.
- This test should not be used to diagnose or exclude acute SARS-CoV-2 infection. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Testing with a molecular diagnostic should be performed to evaluate for active infection in symptomatic individuals.
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection. Results are not intended to be used as the sole basis for patient management decisions.
- The assay performance characteristics have not been established for matrices other than serum or plasma.

- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1 or OC43.
- Not for the screening of donated blood.
- The performance of this test has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

CONDITIONS OF AUTHORIZATIONS FOR THE LABORATORIES

The VIDAS® SARS-COV-2 IgG assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

Authorized laboratories using the VIDAS® SARS-COV-2 IgG (“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 must 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 must 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 must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must 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 bioMérieux local technical support center (800-682-2666 or CustomerService-ImmunoMolecular@biomerieux.com) any suspected occurrence of false positive or false nnegative 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 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 also be trained in and be familiar with the interpretation of results of the product.
- bioMérieux, authorized distributors, and authorized laboratories using your product must 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, to perform moderate and high complexity tests” as “authorized laboratories.”

PERFORMANCE

Studies performed using the VIDAS® SARS-COV-2 IgG assay gave the following results:

Precision

A precision study was performed according to CLSI EP05-A3 recommendations.

A panel of human samples representing index levels in the qualitative range of the assay was analyzed on the VIDAS® instrument to include the following main sources of variability: repeatability, run, calibration and day.

Four samples were tested in triplicate in two runs per day, over six days using one VIDAS® instrument (N=36 values for each sample). Repeatability (within-run precision) and total within-lot within-instrument precision were estimated for each sample.

The precision estimates obtained for each sample are reported in the following table, as a guide.

Sample	N	Mean index	Repeatability Within-run precision		Within-lot within-instrument total precision	
			Standard Deviation Index	CV (%)	Standard Deviation Index	CV (%)
Sample 1	36	0.03	0.00	14.80	0.01	23.70
Sample 2	36	0.89	0.04	4.00	0.04	4.50
Sample 3	36	1.45	0.08	5.90	0.09	6.40
Sample 4	36	8.15	0.50	6.10	0.56	6.80

Class Specificity

Antibody class specificity between IgG and IgM was tested for cross reactivity and competition on the VIDAS® instrument.

Cross reaction: 5 negative samples were tested in duplicate, then were spiked with 3 µg/mL of a recombinant human monoclonal IgM (rec Hu mAb IgM) anti SARS-CoV-2 and tested again in duplicate. All IgM spiked samples showed negative results with the VIDAS® SARS-CoV-2 IgG test.

Competition: 5 IgG positive samples with various levels of index values were tested in duplicate, then were spiked with 3 µg/mL of rec Hu mAb IgM anti SARS-CoV-2 and tested again in duplicate.

For both set of samples, i.e. negative and positive samples, an agreement of 100% was obtained between control and spiked samples.

Matrix Equivalency

Twenty (20) pairs of serum and lithium-heparin plasma samples were tested in duplicate on the VIDAS® instrument.

Matrix equivalency was determined according to the Deming linear regression model in accordance with CLSI Document EP09-A3.

N	Plasma index interval (y)	Serum index interval (x)	Slope	Intercept	r
20	[0.03;12.39]	[0.03;11.71]	1.0471	-0.0297	0.9991

Serum and lithium-heparin plasma matrices gave equivalent results with VIDAS® SARS-COV-2 IgG assay.

Analytical specificity

Cross-reactivity

The notion of cross-reactivity is the study of samples which are negative for the test to be evaluated and positive for the potentially interfering condition. The presence of these potentially interfering conditions must not modify the interpretation of the VIDAS® SARS-COV-2 IgG assay.

The results of the 134 samples tested on one lot and on the VIDAS® instrument are presented in the following table.

Sample category/ Antibody positive samples for	Number of samples tested	Number of positive
Anti-Nuclear Antibody	5	0
Rheumatoid factor	5	1*
Human Anti-Mouse Antibody	5	0
Borrelia burgdorferi	6	0
Haemophilus influenza B	5	0
Plasmodium falciparum	3	0
Toxoplasma gondii	6	0
Treponema pallidum	3	0
Trypanosoma cruzi	5	0
Hepatitis A Virus	3	0
Hepatitis B Virus	5	0
Hepatitis C Virus	5	0
Hepatitis E Virus	6	0

Sample category/ Antibody positive samples for	Number of samples tested	Number of positive
Herpes Simplex Virus	6	0
Human Immuno-deficiency Virus	5	1**
Cytomegalovirus	3	0
Measles Virus	3	0
Mumps Virus	3	0
Rubella Virus	6	0
Dengue Virus	3	0
West Nile Virus	3	0
Yellow Fever Virus	3	0
Zika Virus	5	0
Influenza A and B Virus	10	0
Respiratory Syncytial Virus	10	0
Coronavirus NL63	6	0
Coronavirus 229E	6	0
Total	**134**	**2**

* 1 out of 5 samples with Rheumatoid Factor showed a false positive result.

** 1 out of 5 samples with antibodies against the Human Immuno-deficiency Virus showed false positive results.

Study of Potentially Interfering Substances

Potential interference by commonly used substances was evaluated on 5 replicates of low and moderate SARS-CoV-2 IgG positive specimens on the VIDAS® instrument according to CLSI EP07-Ed3 recommendations.

No interference was detected up to the concentrations indicated below:

Tested substance	Concentration
Hemoglobin	10 g/L
Lipids	30 g/L
Albumin	60 g/L
Conjugated bilirubin	0.4 g/L
Unconjugated bilirubin	0.4 g/L

CLINICAL PERFORMANCE

Negative Percent Agreement (NPA)

A total of 989 samples collected from negative individuals before September 2019 were tested singly using the VIDAS® SARS-COV-2 IgG assay on the VIDAS® instrument. One false positive sample was detected.

The resulting overall NPA in the internal study was 99.9% [99.4-100.0].

Positive Percent Agreement (PPA)

The positive percent agreement was determined by evaluating the VIDAS® SARS-COV-2 IgG assay with samples collected from 120 SARS-COV-2 PCR positive patients. The 120 subjects were tested singly using the VIDAS® SARS-COV-2 IgG assay on the VIDAS® instrument.

The following table describes positive percent agreement by time of sampling after a PCR positive result.

Detection of IgG in 120 PCR Positive Subjects

Days from PCR Positive Result	Total PCR Positive Samples	VIDAS® SARS-COV-2 IgG Results		
		Number Reactive	Number Non-reactive	PPA (95% CI)
≤ 7	94	45	49	47.9% [38.1; 57.9]
8-14	9	9	0	100% [66.4; 100.0]
≥ 15	17	17	0	100% [80.5; 100.0]
Total Subjects	120			

For 67 out of the 120 patients, the number of days between specimen collection date and symptom onset was also provided. Positive percent agreement was calculated by time of sampling after symptom onset on these 67 subjects.

Detection of IgG in 67 Subjects from Symptom Onset

Days from Onset of Symptoms	Total PCR Positive Samples	VIDAS® SARS-COV-2 IgG Results		
		Number Reactive	Number Non-reactive	PPA (95% CI)
≤ 7	19	7	12	36.8% [19.1; 59.0]
8-14	19	16	3	84.2% [62.4; 94.5]
≥ 15	29	29	0	100% [88.1; 100.0]
Total Subjects	67			

For some of the 120 patients, different specimens were collected over time in a longitudinal study to evaluate seroconversion with the VIDAS® SARS-COV-2 IgG assay as shown below:

Detection of IgG in SARS-CoV-2 PCR Positive Samples from 120 Subjects Stratified by Days from PCR Positive Result across Different Bleeds

	First Serial Measurement		Second Serial Measurement		Third Serial Measurement		Fourth Serial Measurement		Fifth Serial Measurement	
Days from PCR Positive Result	Samples tested	Samples with IgG + Results	Samples tested	Samples with IgG + Results	Samples tested	Samples with IgG + Results	Samples tested	Samples with IgG + Results	Samples tested	Samples with IgG + Results
≤ 7 days	94	45/94	23	8/23	-	-	-	-	-	-
8-14 days	9	9/9	7	6/7	21	18/21	-	-	-	-
≥ 15 days	17	17/17	8	7/8	5	4/5	5	5/5	1	1/1
Total Subjects	120	-	38	-	26	-	5	-	1	-

Detection of IgG in Samples from 67 Subjects Stratified by Days Post-Symptom Onset across Different Bleeds

	First Serial Measurement		Second Serial Measurement		Third Serial Measurement		Fourth Serial Measurement		Fifth Serial Measurement	
Days Post Symptoms Onset	Samples tested	Samples with IgG + Results	Samples tested	Samples with IgG + Results	Samples tested	Samples with IgG + Results	Samples tested	Samples with IgG + Results	Samples tested	Samples with IgG + Results
≤ 7 days	19	7/19	-	-	-	-	-	-	-	-
8-14 days	19	16/19	6	3/6	1	1/1	-	-	-	-
≥ 15 days	29	29/29	10	9/10	6	5/6	3	3/3	1	1/1
Total Subjects	67	-	16	-	7	-	3	-	1	-

Longitudinal Studies

The following table shows SARS-CoV-2 IgG seroconversion based on the results of three patients tested with the VIDAS® SARS-COV-2 IgG assay.

	Number of Days after PCR Positive Results	IgG Index	IgG Interpretation
Patient 1	0	0.02	Negative
	7	0.44	Negative
	14	4.49	Positive
	20	5.75	Positive
Patient 2	0	0.01	Negative
	7	0.06	Negative
	14	3.70	Positive
	20	8.74	Positive
Patient 3	0	≤ 0.00	Negative
	5	0.17	Negative
	14	33.00	Positive
	26	34.33	Positive

WASTE DISPOSAL

Dispose of used or unused reagents, as well as any other contaminated disposable materials, following procedures for infectious or potentially infectious products.

It is the responsibility of each laboratory to handle waste and effluents produced, according to their nature and degree of hazardousness, and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. Huang C, Wang Y, Li X *et al.* - Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. - *Lancet* - 2020 Feb 15;395(10223):497-506.
2. Zou L, Ruan F, Huang M *et al.* - SARS-CoV-2 viral load in upper respiratory specimens of infected patients. - *N Engl J Med.* - 2020 Mar 19;382(12):1177-9.
3. Guo L, Ren L, Yang S *et al.* - Profiling early humoral response to diagnose novel coronavirus disease (COVID-19). - *Clin Infect Dis.* - 2020 March 21:ciaa310. doi: 10.1093/cid/ciaa310.
4. To KKW, Tsang OTY, Leung WS *et al.* - Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. - *Lancet Infect Dis.* - 2020 Mar 23: S1473-3099(20)30196-1.
5. World Health Organization, Use of anticoagulants in Diagnostic, Laboratory Investigation, 2002, WHO/DIL/LAB/99.1 Rev.2

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalogue number
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use

Symbol	Meaning
	Contains sufficient for <n> tests
	For US Only: Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner
	Date of manufacture

LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the "System") other than as set forth in the IFU.

REVISION HISTORY

Change type categories

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Note: *Minor typographical, grammar, and formatting changes are not included in the revision history.*

Release Date	Part Number	Change Type	Change Summary
2020-05	056098-01	N/A	First publication
2020-08	056098-02	Technical change	Limitations of the Method / Sample-related interference / Procedure / Performance / Clinical Performance
		Administrative	Intended Use / Summary and Explanation / Warnings and Precautions / Analytical specificity / Conditions of Autorizations of the Laboratories / Longitudinal Combined Studies
2021-02	056098-03	Technical change	Intended Use / Warnings and Precautions / Sample stability / Limitations of the Method / Conditions of Autorizations of the Laboratories

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REF **423834-01** 22118A – 2021-03-09

VIDAS® SARS-COV-2 IgG

IVD Rx only

EN

For use under the Emergency Use Authorization (EUA) only.

- This test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for detecting IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.

This is not the full instructions for use.
The instruction for use is downloadable from www.biomerieux.com/techlib

Please contact your local BIOMERIEUX representative if you require a printed copy of the instructions for use free of charge (Tel: +1 800 682 2666)