

INSTRUCTIONS FOR USE

CVGQN

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack

REF 619 9960

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrator

REF 619 9961

For emergency authorization use only.

Rx ONLY

For *in vitro* diagnostic use only.

The results of this quantitative test should not be interpreted as an indication or specific degree of immunity or protection from infection.

Intended Use

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack when used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrator is a chemiluminescent immunoassay test intended for the qualitative and quantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (dipotassium EDTA, tripotassium EDTA and lithium heparin). The VITROS Anti-SARS-CoV-2 IgG Quantitative 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 VITROS Anti-SARS-CoV-2 IgG Quantitative test should not be used to diagnose or exclude 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 the 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 the VITROS Anti-SARS-CoV-2 IgG Quantitative test in early 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 VITROS Anti-SARS-CoV-2 IgG Quantitative test 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 VITROS Anti-SARS-CoV-2 IgG Quantitative test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation of the Test

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a novel beta coronavirus that causes the CoronavirusDisease 2019 (COVID-19) and pandemic. SARS-CoV-2 is mainly transmitted through droplets and contact routes. ¹⁻² People who are infected with SARS-CoV-2 may express signs and symptoms of acute respiratory illness, such as fever, cough, shortness of breath, but can also be asymptomatic. Symptomatic, pre-symptomatic and asymptomatic SARS-CoV-2 carriers all can be potential sources for viral transmission. ³

Real-time reverse transcription polymerase chain reaction (rRT-PCR) detecting SARS-CoV-2 genes is considered the goldstandard for the diagnosis of COVID-19, and SARS-CoV-2 antigen assays have also been used to detect acute infection. ⁴ Upper respiratory specimen, such as nasopharyngeal swab and nasal swab, are commonly used for diagnostic testing. ⁴ Individuals infected with SARS-CoV-2 start to produce antibodies to the virus 1-2 weeks post symptom onset, and most individuals achieve seroconversion in week 3-4 after symptom onset. ⁵⁻⁶

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Principles of the Procedure

The World Health Organization (WHO) has established international standard and reference panel for anti-SARS-CoV-2 antibody, which is aimed to facilitate the standardization and harmonization of SARS-CoV-2 antibody tests.⁷ Quantitative SARS-CoV-2 IgG assays calibrated with a material traceable to the WHO international standard will allow data comparison among different SARS-CoV-2 IgG tests, which will help advance our knowledge of immune responses to SARS-CoV-2.

Principles of the Procedure

The VITROS Anti-SARS-CoV-2 IgG Quantitative test is performed using the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack and the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrator on the VITROS ECI/ ECIQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems. An immunometric technique is used; this involves a two stage reaction. In the first stage antibodies to SARS-CoV-2 present in the sample bind with SARS-CoV-2 spike protein S1 antigen coated on wells. Unbound sample is removed by washing. In the second stage horseradish peroxidase (HRP)-labeled murine monoclonal anti-human IgG antibodies are added in the conjugate reagent. The conjugate binds specifically to the antibody portion of the antigen-antibody complex. If complexes are not present, the unbound conjugate is removed by the subsequent wash step.

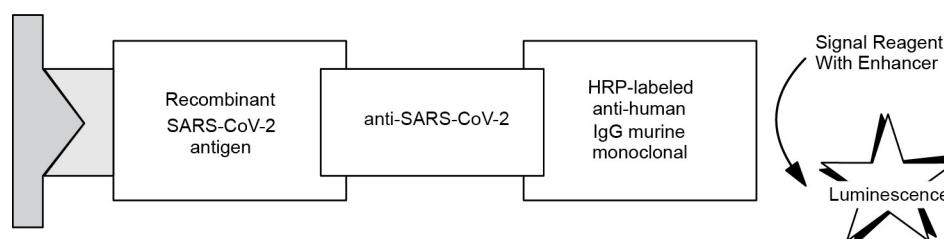
The bound HRP conjugate is measured by a luminescent reaction.⁸ A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP is directly proportional to the concentration (amount) of the SARS-CoV-2 IgG antibody present in the test sample.

Test Type	System *	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Immunometric	ECi/ECiQ**, 3600, 5600/XT 7600***	37 minutes	48 minutes	37° C	20 µL

* Not all products and systems are available in all countries.

** Software version 3.9.1 or later; ***Software version 3.6.1 or later

Reaction Scheme



Warnings and Precautions

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WARNING
:

Potentially Infectious Material

Treat as if capable of transmitting infection.

Use caution when handling material of human origin. Consider all samples potentially infectious. No test method can offer complete assurance that hepatitis B virus, hepatitis C virus (HCV), human immunodeficiency virus (HIV 1+2) or other infectious agents are absent. Handle, use, store and dispose of solid and liquid waste from samples and test components, in accordance with procedures defined by appropriate national biohazard safety guideline or regulation (e.g. CLSI document M29).⁹

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Reagents

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators contain: SARS-CoV-2 antibody positive plasma obtained from donors who were tested individually and who were found to be negative for hepatitis B surface antigen, and for antibodies to hepatitis C virus (HCV) and HIV, using approved methods (enzyme immunoassays).

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators in addition contain: SARS-CoV-2 IgG antibody. Handle as if capable of transmitting infection.

Quantitative Reagent Pack contains 1.0% ProClin 300. H317: May cause an allergic skin reaction. P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P280: Wear protective gloves/protective clothing and eye/face protection. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents/container to an approved waste disposal plant.

WARNING

*Contains ProClin 300
Contains ProClin 950¹⁰*

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators contain 0.5% ProClin950. H317: May cause an allergic skin reaction. P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P280: Wear protective gloves/protective clothing and eye/face protection. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents/container to an approved waste disposal plant.

Refer to www.orthoclinicaldiagnostics.com for the Safety Data Sheets and for Ortho Clinical Diagnostics contact information.

WARNING



Safe Disposal

Follow local disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

General

- For Emergency Use Authorization only.
- For *in vitro* diagnostic use only.
- For prescription use only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.

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- This product has been authorized only for detecting IgG antibodies to 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 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Reagents

Reagent Pack Contents

1 reagent pack containing:

- 100 coated wells (recombinant SARS-CoV-2 antigen derived from human cells, coated at 110 ng/well)
- 18.0 mL assay reagent (buffer with bovine protein stabilizers and antimicrobial agent)

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Specimen Collection, Preparation and Storage

- 20.4 mL conjugate reagent [anti-human IgG (murine monoclonal) conjugated to horseradish peroxidase, 5 ng/mL] in buffer with bovine protein stabilizers and antimicrobial agent

Reagent Pack Handling

- The reagent pack is supplied ready for use.
- The reagent pack contains homogeneous liquid reagents that do not require shaking or mixing prior to loading onto the system.
- Handle the reagent pack with care. Avoid the following:
 - allowing condensation to form on the pack
 - causing reagents to foam
 - agitation of the pack

Reagent Pack Storage and Preparation

Reagent	Storage Condition		Stability
Unopened	Refrigerated	2–8 ° C (36–46 ° F)	expiration date
Opened	On system	System turned on	≤8 weeks
Opened	Refrigerated	2–8 ° C (36–46 ° F)	≤8 weeks

- The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack is suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- Do not freeze reagent packs.
- Load reagent packs directly from refrigerated storage to minimize condensation.
- Opened reagent packs are moisture/humidity sensitive. Store opened refrigerated reagent packs in a sealed VITROS Immunodiagnostic Products Reagent Pack Storage Box with desiccant.

Calibrator Contents

- 2 sets of VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators 1, 2 and 3 (anti-SARS-CoV-2 IgG positive defibrinated plasma in anti-SARS-CoV-2 IgG negative protein-based matrix with antimicrobial agent, 1 mL)
- Lot calibration card
- Protocol card
- 24 calibrator bar code labels (8 for each calibrator)

Calibrator Handling

- Use only with reagent pack of the same lot number. Mix thoroughly by inversion and bring to 15–30 ° C (59–86 ° F) before use.
- Handle calibrators in original stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time the calibrators are on the system. Refer to the operating instructions for your system. Return to 2–8 ° C (36–46 ° F) as soon as possible after use, or load only sufficient volume for a single determination.

Calibrator Storage and Preparation

Calibrator	Storage Condition		Stability
Unopened	Frozen	≤-20 ° C (≤-4 ° F)	expiration date
Opened	Refrigerated	2–8 ° C (36–46 ° F)	≤24 hours

- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators are supplied frozen.
- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators are suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- **DO NOT REFREEZE.**
- The VITROS Anti-SARS-CoV-2 IgG Quantitative test uses 20 µL of calibrator for each determination. Transfer an aliquot of each calibrator into a sample container (taking account of the minimum fill volume of the container), which may be barcoded with the labels provided. For details on minimum fill volume of sample cups or containers, refer to the operating instructions for your system.

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Specimen Collection, Preparation and Storage

Patient Preparation

No special patient preparation is necessary.

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Testing Procedure

Specimens Recommended

- Serum
- EDTA Plasma
- Lithium Heparin Plasma

Specimens Not Recommended

No specimen limitations were identified. Refer to the Limitations of the Procedure section.

Special Precautions

IMPORTANT

Certain specimen collection tubes have been reported to affect other analytes and tests.¹¹ Owing to the variety of specimen collection tubes available, Ortho Clinical Diagnostics is unable to provide a definitive statement on the performance of its products with these devices. Confirm that your specimen collection tubes are compatible with this test.

Specimen Collection and Preparation

- Collect specimens using standard procedures.¹²
- Follow the instructions provided with your specimen collection tube for use and processing of the sample.¹³
- Samples should be thoroughly separated from all cellular material. Failure to do so may lead to an erroneous result.
- The VITROS Anti-SARS-CoV-2 IgG Quantitative test uses 20 µL of sample for each determination. This does not take account of the minimum fill volume of the chosen sample container. For details on minimum fill volume of sample cups or containers, refer to the operating instructions for your system.

Handling and Storage Conditions

- Handle samples in stoppered containers to avoid contamination and evaporation.
- Follow procedures within your laboratory to avoid cross contamination of patient specimens.
- The amount of time samples are on the system prior to analysis should be limited to avoid evaporation. Refer to the operating instructions for your system.
- Return to 2–8 °C (36–46 °F) as soon as possible after use or load sufficient volume for a single determination.
- Samples may be stored for up to 24 hours at room temperature (up to 30 °C [86 °F]) or 7 days at 2–8 °C (36–46 °F).
- Samples that will not be tested within the time frames outlined above should be stored at ≤ -20 °C [≤ -4 °F] and may be subjected to 1 freeze-thaw cycle
- As an alternative to the above, sample stability may be established by each laboratory.

Testing Procedure

Materials Provided

- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack
- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators

Materials Required but Not Provided

- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent
- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls
- VITROS Immunodiagnostic Products Reagent Pack Storage Box with desiccant

Operating Instructions

Check the inventory regularly to aid the management of reagents and ensure that sufficient VITROS Immunodiagnostic Products Signal Reagent, VITROS Immunodiagnostic Products Universal Wash Reagent and calibrated reagent lots are available for the work planned. When performing panels of tests on a single sample, ensure that the sample volume is sufficient for the tests ordered. For detailed information refer to the operating instructions for your system.

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Note:

Do not use visibly damaged product.

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CVGQN Calibration

Default Test Name

The default test name which will appear on patient reports is SARS CV2 IgG QN. The default short name that will appear on the test selection menus and laboratory reports is CVGQN. These defaults may be reconfigured, if required. For detailed information refer to the operating instructions for your system.

Calibration

Calibration Procedure

- Calibration is lot specific; reagent packs and calibrator are linked by lot number. Reagent packs from the same lot may use the same calibration.
- A Master Calibration (a dose response curve covering the full calibration range) is established for each new reagent lot. Concentrations for the linked lot of calibrators are determined from the Master Calibration.
- Ensure that the Master Calibration for each new reagent lot is available on your system.
- Process calibrators in the same manner as samples. Calibration need not be programmed if bar code labels are used; load the calibrators in any order, calibration will be initiated automatically.
- When the calibrators are processed, the signal expected for each calibrator is compared against the actual signal obtained. The Master Calibration is then rescaled to reflect the differences between the actual and expected signals. The validity of this calibration curve is assessed against a range of quality parameters, and if acceptable, it is stored for use with any reagent pack of that lot.
- The quality of calibration cannot be completely described by a single parameter. The calibration report should be used in conjunction with acceptable control values to determine the validity of the calibration.
- Recalibration is required after a pre-determined calibration interval, or when a different reagent lot is loaded.
- Calibration results are assessed against a range of quality parameters. Failure to meet any of the defined quality parameter ranges will be coded in the calibration report. For actions to be taken following a failed calibration refer to the operating instructions for your system.
- Refer to the operating instructions for your system for detailed instructions on the calibration process.

When to Calibrate

- Calibrate when the reagent pack and calibrator lot changes.
- Calibrate every 28 days.
- After specified service procedures have been performed.
- If quality control results are consistently outside of your acceptable range.

For additional information on when to calibrate, refer to the operating instructions for your system.

Traceability of Calibrators to the CRM (Certified Reference Material)

The VITROS Anti-SARS-CoV-2 IgG Quantitative test results are traceable to the First WHO International Standard Anti-SARS-CoV-2 Immunoglobulin (Human), NIBSC 20/136. ⁷

The assignment of the working calibrator values (0 calibrator and 8 positive calibrators) was completed in a traceability procedure using the WHO standard for Anti-SARS-CoV-2 Immunoglobulin 20/136. Four parameter logistic curve (master calibration curve) is constructed using the working calibrators. For each Reagent Lot, a set of three end-user IVD MD calibrators targeted at 0, 15 and 180 BAU/mL are assigned lot specific values using a measurement procedure calibrated with the Working Calibrators which are traceable to WHO Reference Standard 20/136. The three End-User IVD MD Calibrators together with specific electronic coded assay data or encoded magnetic card (with Master Calibration) are used to scale the master calibration curve to the laboratory's instrument that the resulting calibration curve is specific for that analyzer and reagent lot.

Working Calibrators are used to define the calibration curve for the VITROS Anti-SARS-CoV-2 IgG Quantitative assay to assure consistent assay performance over the life of the product (i.e. from lot to lot).

Quality Control

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Measuring (Reportable) Range

System	Measuring (Reportable) Range**
ECi/ECiQ, 3600, 5600, XT 7600	2.00–200 BAU/mL*

* BAU = Binding Antibody Units

** Lower limit of measuring range is based on the Limit of Quantitation. Values between 2.00 BAU/mL and <17.8 BAU/mL should be interpreted as not having detectable anti-SARS-CoV-2 IgG antibodies and are reported as Non-reactive (Negative).

Quality Control

Quality Control Material

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. There are 3 VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls.

Appropriate quality control value ranges are provided for the VITROS Anti-SARS-CoV-2 IgG Quantitative Controls.

Quality Control Procedure Recommendations

- Good laboratory practice requires that controls be processed to verify the performance of the test.
- If control results fall outside the acceptable range, the results are invalid. Do not report invalid results. Samples should be retested, and valid results should be reported.
- To verify system performance, analyze control materials:
 - After calibration
 - If the system is turned off for more than 2 hours
 - After reloading reagent packs that have been removed from the MicroWell Supply and stored for later use
 - According to local regulations or at least once each day that the test is being performed
 - After specified service procedures are performed

If quality control procedures within your laboratory require more frequent use of controls, follow those procedures.

- Analyze quality control materials in the same manner as patient specimens.
- Refer to published guidelines for general quality control recommendations. ¹⁴

For more detailed information, refer to the operating instructions for your system.

Quality Control Material Preparation and Storage

Refer to the manufacturer's product literature for preparation, storage, and stability information.

Results

Results are automatically calculated by the VITROS Immunodiagnostic and VITROS Integrated Systems.

Placement of the cut-off for a reactive sample is set to ≥ 17.8 BAU/mL and was based on a panel of 120 presumed anti-SARS-CoV-2 negative samples collected prior to December 2019. A placement of the cut-off to correctly classify all samples was determined across multiple calibration events and the average placement determined to be ≥ 17.8 BAU/mL.

Interpretation of Results

Patient sample results will be displayed with a numerical result in Binding Antibody Units (BAU) per mL and with a Non-reactive (negative) or Reactive (positive) label.

Numerical Result (BAU/mL*)	Results	Total Result Interpretation
X <17.8	Non-reactive (Negative) Numerical result is not reported outside the laboratory	IgG Antibodies for SARS-CoV-2 are not detected

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$200 \geq X \geq 17.8$	Reactive (Positive); Numerical result is reported outside the laboratory	CVGQN IgG Antibodies for SARS-CoV-2 are detected
>200	Reactive (Positive); Report outside the laboratory indicates that the result is above 200 BAU/mL (ULMI **)	

*BAU/mL – Binding Antibody Units/mL

**Upper limit of measuring interval (ULMI)

CVGQN**INSTRUCTIONS FOR USE****Limitations of the Procedure****Limitations of the Procedure****Limitations**

- Samples should only be tested from individuals that are 15 days or more post-symptom onset.
- Heterophilic antibodies in serum samples may cause interference in immunoassays.¹⁵ 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.
- Samples around the cutoff with total protein concentrations above 10 g/dL demonstrated a positive bias in analytical studies that ranged from 12.5% to 17.1%.
- Samples with rheumatoid factor concentrations above 800 IU/mL demonstrated 12.1% negative bias in analytical studies.
- A non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody detected by the test.
- The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.
- Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection.
- This test should not be used for screening of donated blood for the purpose of preventing COVID-19 transmission.
- 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.
- 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.
- It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to infection.
- The PPA performance of this test was established based on the evaluation of a limited number of clinical specimens collected between April 2020 and January 2021 in different locations in the US and Colombia. 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 may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Conditions of Authorization for the Laboratory

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack when used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrators Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, 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/in-vitro-diagnostics-euas>. However, to assist clinical laboratories using the VITROS Anti-SARS-CoV-2 IgG Quantitative test ("your product" in the conditions below), the relevant Conditions of Authorization are 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.

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- 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.

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- 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 Ortho-Clinical Diagnostics, Inc. (OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.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 also be trained in and be familiar with the interpretation of results of the product
- Ortho-Clinical Diagnostics, Inc., 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 or high complexity tests" as "authorized laboratories."

Performance Characteristics

Limit of Detection

The Limit of Detection (LoD) for VITROS Anti-SARS-CoV-2 IgG Quantitative assay is 0.54 BAU/mL, determined consistent with CLSI document EP17, ¹⁶ as the concentration with proportions of false positives (α) less than 5% and false negatives (β) less than 5%; based on at least sixty determinations, with 5 blank and 5 low-level samples. The Limit of Quantitation (LoQ) is 2.00 BAU/mL as determined by the lowest concentration at which precision and accuracy design requirements are still met and within the linear range of the test.

Limit of Detection and Limit of Quantitation

LoB	LoD	LoQ
0.26 BAU/mL	0.54 BAU/mL	2.00 BAU/mL

Linearity

Linearity testing was performed in accordance with CLSI Document EP06 A. ¹⁷ High titer reactive pools used for these studies consisted of two high-titer clinical specimens, a preparation of the First WHO standard for Anti-SARS-CoV-2 Immunoglobulin 20/136, and an assay reference calibrator which is a pool of high-titer clinical specimens assigned a value (BAU/mL) that is directly traceable to the WHO standard 20/136. Dilutions of each clinical specimen were made using a pool of non-reactive claimed matrix (serum or plasma) to generate a 12 member dilution series that spanned the linear range of the assay and at least 10% beyond the upper and lower limits of this interval. Linearity was demonstrated throughout the measuring interval of 2.00 – 200 BAU/mL

Recovery

A recovery study was performed and established the accurate recovery of the First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (20/136) standard using the VITROS Anti-SARS-CoV-2 IgG Quantitative test. In the study, the WHO standard 20/136 was diluted with non-reactive clinical samples to generate 6 samples with known levels of analyte to demonstrate accurate recovery across the assay range in these samples. The study examined the First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (20/136) using 6 levels across 10 repetitions to demonstrate accurate recovery of the certified reference material (CRM) in these specimens.

Level	Target concentration CRM (BAU/mL)	Average (BAU/mL)	SD (BAU/mL)	%CV	% Recovery
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1	200	199	14.7	7.39	99.5
2	100	91.3	2.04	2.23	91.3
3	70.0	67.7	2.21	3.26	96.7
4	50.0	48.6	1.16	2.39	97.2
5	35.0	36.3	2.31	6.36	103.7
6	17.5	19.1	0.88	4.61	109.1

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Performance Characteristics

Clinical Performance Characteristics

Positive Percent Agreement

Samples were retrospectively collected between April 2020 and January 2021 from 236 individual patients confirmed to be SARS-CoV-2 positive by RT-PCR and tested with the VITROS Anti-SARS-CoV-2 Quantitative test. All positive samples were collected at least after 15 days from symptoms onset. Of the 236 PCR positive samples, 217 were Reactive in the VITROS Anti-SARS-CoV-2 IgG Quantitative test and 19 were Non-reactive. Positive Percent Agreement and the 95% confidence intervals were calculated. The results are summarized in the table below.

Days between Symptom Onset and Serum Collection	Number of Subjects Tested	IgG Reactive Results	IgG PPA	(95% CI)
≥15	236	217	91.9%	87.7-95.1%

Negative Percent Agreement

Five hundred and thirty-three presumed SARS-CoV-2 negative samples retrospectively collected prior to the COVID-19 pandemic were tested (Out of 533 samples evaluated, 337 were collected from healthy donors) resulting in 100% negative percent agreement (95% CI: 99.3–100.0%).

Number of Subjects Tested	IgG Non-reactive Results	IgG NPA	IgG NPA (95% CI)
533	533	100.0%	99.3-100.0%

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Potentially Cross-reacting Subgroups

96 samples containing antibodies to one or more of the following potentially cross-reacting sub-groups were tested with the VITROS Anti-SARS-CoV-2 IgG Quantitative test producing a total of 334 results. Of these samples tested, none were found to be reactive with the VITROS Anti-SARS-CoV-2 IgG Quantitative test. The results are summarized in the table below.

Sample Category	Number of Samples per condition	Non-reactive	Reactive
anti-influenza A IgG	5	5	0
anti-influenza A IgM	19	19	0
anti-influenza A IgA	6	6	0
anti-influenza B IgG	17	17	0
anti-influenza B IgM	15	15	0
anti-influenza B IgA	3	3	0
anti-HCV	5	5	0
anti-HBV	9	9	0
anti- <i>Haemophilus influenzae</i>	25	25	0
anti-229E (alpha coronavirus)	24	24	0
anti-NL63 (alpha coronavirus)	10	10	0
anti-OC43 (beta coronavirus)	21	21	0
anti-HKU1 (beta coronavirus)	11	11	0
anti-nuclear antibodies	5	5	0
anti-respiratory syncytial virus	20	20	0
anti-HIV	5	5	0
Adenovirus	6	6	0

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Performance Characteristics

Sample Category	Number of Samples	Non-reactive	Reactive
Virus parainfluenza 1-4	22	22	0
Human Metapneumovirus	5	5	0
Enterovirus	12	12	0
Rhinovirus	5	5	0
Epstein-Barr Virus	21	21	0
Legionella	5	5	0
B. pertussis	9	9	0
M. pneumonia	26	26	0
C. pneumonia	13	13	0
Anti-CMV IgG	10	10	0
Total Results	334		

Precision

Precision of the VITROS Anti-SARS-CoV-2 IgG Quantitative test was evaluated.¹⁷ Two replicates each of six samples were tested on two separate occasions per day on at least three different days. The experiment was performed using two reagent lots on two different systems. The experiment was performed using one reagent lot on each system. The data presented are a representation of the product performance.

Units = BAU/mL												
Mean Conc.	Repeatability**		Between-Run***		Between-Day****		Between-Site/instrument/lot#		Reproducibility (Total)##		No Obs.	No Days
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV		
5.46	0.1	2.7	0.2	3.3	0.0	0.7	0.5	9.5	0.6	10.4	24	3
53.5	0.6	1.2	1.4	2.6	1.0	1.9	4.0	7.5	4.4	8.3	24	3
157	5.4	3.5	9.5	6.0	8.2	5.2	18.5	11.7	23.0	14.6	24	3
2.67	0.1	2.7	0.1	4.3	0.0*	0.0	0.4	14.0	0.4	14.9	24	3
15.0	0.19	1.3	0.48	3.2	0.00*	0.0	1.31	8.7	1.40	9.3	24	3
67.1	1.31	2.0	2.11	3.1	1.44	2.1	6.12	9.1	6.76	10.1	24	3

* Analysis of variance yielded a negative variance for these values which was approximated to zero.

** **Repeatability.** Between Duplicate precision averaged over all runs, or with-in run precision.

*** **Between-Run.** Total precision with weighted components of repeatability.

**** **Between-Day** is equivalent to the within-laboratory precision as each lab only consisted of one lot and instrument.

Between-Site/instrument/lot. Total precision with weighted components of repeatability, between-run and between-day variation.

Reproducibility. Total precision with weighted components of repeatability, between-run, between-site/instrument/lot, and between-day variation.

Analytical Specificity

Potential Interference

The VITROS Anti-SARS-CoV-2 IgG Quantitative test was evaluated for potential interference.¹⁸ Commonly encountered substances were tested on a single lot of reagents as listed in the following two tables.

The first table below contains the potential interferent substances and the concentration tested that showed no interference with the VITROS Anti-SARS-CoV-2 IgG Quantitative test.

CVGQN

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Compound	Concentration
Hemoglobin	>1000 mg/dL
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Intralipid	2000 mg/dL
Biotin	3510 ng/mL
EDTA	99.0 μ g/dL
Lithium Heparin	330 U/dL

In addition to the substances listed above, total protein and rheumatoid factor were evaluated and showed interference with the VITROS Anti-SARS-CoV-2 IgG Quantitative Test. Rheumatoid factor and total protein that were found to interfere with the test at the concentrations indicated in the tables below when present in samples containing Anti-SARS-CoV-2 IgG antibody levels of approximately 0, 10, and 170 BAU/mL. Rheumatoid Factor, when tested at concentrations between 800 and 1200 IU/mL, showed a negative bias on assay performance between -12.1% and -21.9%, (see table below).

Interferent	Interferent Concentration	Units = BAU/mL		% Bias
		CVGQN Numerical Result*	Bias**	
Rheumatoid Factor	1200 IU/mL	11.8	-0.2	-1.7
		160	-35	-21.9
	800 IU/mL	149	-18	-12.1

* Average test concentration of replicate determinations using a single lot of reagent.

** Estimate of the average difference observed.

Total protein was evaluated at concentrations from 6 – 15 g/dL with the VITROS Anti-SARS-CoV-2 IgG Quantitative test using negative, high negative and high positive SARS-CoV-2 IgG antibodies samples. Samples with total protein concentrations up to 9 g/dL demonstrated $\leq 10\%$ bias in SARS-CoV-2 IgG antibodies numerical results, while total protein concentrations between 10 and 15 g/dL, showed positive bias ranging from 12.5% to 17.1% in high negative samples, and up to -14.4% negative bias in high positive samples. The results are summarized in the following table:

Samples		Bias Observed	Total Protein Concentration (Mean g/dL)						
SARS-CoV-2 IgG Levels	Target BAU/mL*		6 (Baseline)	8	9	10	11	13	15
Negative	< 2.00	Absolute Bias	0	NA	NA	NA	0.5	0.9	0.5
High negative	12.5	Relative Bias (%)	0	3.2	7.2	12.5	12.8	12.8	17.1
High positive	139		0	-1.4	-4.3	-0.7	-7.2	-7.2	-14.4

*Device cutoff 17.8 BAU/mL

INSTRUCTIONS FOR USE

Performance Characteristics

CVGQN

References

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
































INSTRUCTIONS FOR USE

CVGQN

Glossary of Symbols

Glossary of Symbols

The following symbols may have been used in the labeling of this product.

	Do Not Reuse		Upper Limit of Temperature		Range
	Use by or Expiration Date (Year-Month-Day)		Lower Limit of Temperature		Range of Means
	Batch Code or Lot Number		Temperature Limitation		Midpoint
	Serial Number		Consult Instructions for Use		Revised
	Catalog Number or Product Code		Attention: The Instructions for Use (IFU) has been updated		Supersedes
	Caution		For use in Slide Supply 1		Contains Sufficient for "n" Tests
	Keep Dry (Protect from Moisture/Humidity)		For use in Slide Supply 2		<i>in vitro</i> Diagnostic Medical Device
	Manufacturer		SI Units		Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations
	Date of Manufacture		Conventional Units		Estimated within-lab SD
	Authorized Representative in the European Community		Value		Serious Health Hazards
	Corrosive		Flammable		Environmental or Aquatic Toxicity
	Health Hazards		Acute Toxicity		

Revision History

Date of Revision	Version	Description of Technical Changes*
2021-05-27	1.0	Initial version of Instructions for Use

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

Signatur

Obsolete

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INSTRUCTIONS FOR USE

Revision History

Conditions of supply: all supplies are made subject to the standard terms and conditions of Ortho ClinicalDiagnostics or its distributors. Copies of these are available on request.



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Ortho Clinical Diagnostics

INSTRUCTIONS FOR USE

CVGQN

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls

REF 619 9966

For emergency authorization use only. Rx ONLY

For in vitro diagnostic use only.

Intended Use

For *in vitro* diagnostic and laboratory professional use.

For use in monitoring the performance of the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS5600/XT 7600 Integrated Systems when used with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Calibrator for the determination of IgG antibodies to SARS-CoV-2.

Warnings and Precautions

WARNING

Potentially Infectious Material

Treat as if capable of transmitting infection.

Use caution when handling material of human origin. Consider all samples potentially infectious. No test method can offer complete assurance that hepatitis B virus, hepatitis C virus (HCV), human immunodeficiency virus (HIV 1+2) or other infectious agents are absent. Handle, use, store and dispose of solid and liquid waste from samples and test components, in

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls 1, 2 and 3 in addition contains: SARS-CoV-2 IgG.

WARNING

Contains ProClin 950 (CAS 2682-20-4) ²

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls contain 0.5% ProClin950. H317: May cause an allergic skin reaction. P280: Wear protective gloves. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P262: Wash. Refer to www.orthoclinicaldiagnostics.com for the Safety Data Sheets and for Ortho contact information.

WARNING



- For Emergency Use Authorization only
- For *in vitro* diagnostic use only
- For prescription use only
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- •This product has been authorized for use with a test authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens

Materials Provided

- 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 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Materials Provided

3 sets of VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls 1, 2 and 3 (matrix with anti-microbial agent, 2 mL)

Materials Required but Not Provided

Pipette, sample containers.

Control Storage, Preparation and Handling

Control	Storage Condition	Stability
Unopened	Frozen $\leq -20^{\circ}\text{C}$ ($\leq -4^{\circ}\text{F}$)	expiration date
Opened	Refrigerated $2-8^{\circ}\text{C}$ ($36-46^{\circ}\text{F}$)	≤ 7 days

- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls are supplied frozen.
- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Controls are suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- DO NOT REFREEZE.**
- Thoroughly mix controls by inversion and bring to $15-30^{\circ}\text{C}$ ($59-86^{\circ}\text{F}$) before use.
- Handle controls in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time controls are on the system. Refer to the operating instructions for your system.
- Return to $2-8^{\circ}\text{C}$ ($36-46^{\circ}\text{F}$) as soon as possible after use, or load only sufficient for a single determination.
- The expiration date for the controls must be entered onto the system. For further information, refer to the operating instructions for your system.

Testing Procedure

Load each control onto the system by transferring an aliquot into a sample container (taking account of the volume required by the test and the minimum fill volume of the container). Process in the same manner as samples, according to the instructions in the appropriate VITROS Immunodiagnostic Products Reagent Pack and Calibrator instructions for use.

Please refer to the Control Value Booklet provided with these controls for expected results. If control results fall outside the acceptable range, the results are invalid. Do not report invalid results. Samples should be retested, and valid results should be reported.

Note: Do not use visibly damaged product.

For further information on quality control procedures refer to the operating instructions for your system. Not all products and systems are available in all countries.

Baseline Statistics

For lot specific values, refer to the Controls Values booklet provided with the product.

References

CVGQN

INSTRUCTIONS FOR USE

1. CLSI. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Fourth Edition*. CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
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





























INSTRUCTIONS FOR USE

CVGQN

Glossary of Symbols

Glossary of Symbols

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	Use by or Expiration Date (Year-Month-Day)		Lower Limit of Temperature		Range of Means
	Batch Code or Lot Number		Temperature Limitation		Midpoint
	Serial Number		Consult Instructions for Use		Revised
	Catalog Number or Product Code		Attention: The Instructions for Use (IFU) has been updated		Supersedes
	Caution		For use in Slide Supply 1		Contains Sufficient for "n" Tests
	Keep Dry (Protect from Moisture/Humidity)		For use in Slide Supply 2		<i>in vitro</i> Diagnostic Medical Device
	Manufacturer		SI Units		Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations
	Date of Manufacture		Conventional Units		Estimated within-lab SD
	Authorized Representative in the European Community		Value		Serious Health Hazards
	Corrosive		Flammable		Environmental or Aquatic Toxicity
	Health Hazards		Acute Toxicity		

Revision History

Date of Revision	Version	Description of Technical Changes*
2021-04-13	1.0	Initial version of Instructions for Use

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

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INSTRUCTIONS FOR USE

Revision History

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Rx Only

For EUA Only

IVD

Printed Instructions for Use may be requested
at no charge at 1 800 421 3311.

This is not the full Instructions for Use.
The full Instructions for Use are available on
[https://techdocs.orthoclinicaldiagnostics.com/
TechDocs/TechDocSearch.aspx?tID=0](https://techdocs.orthoclinicaldiagnostics.com/TechDocs/TechDocSearch.aspx?tID=0)

This product 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 product has been authorized for use with a test authorized only for the
determination of IgG antibodies to 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 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
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Issued July 2021
PIGEM5262EUA

Product codes: 6199966

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This product has been authorized only for measuring IgG antibodies against SARS-
CoV-2, not for any other viruses or pathogens.

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Issued July 2021
PIGEM1262EUA

Product codes: 6199960, 6199961