

INSTRUCTIONS FOR USE

CV2Ag

VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack

REF 619 9949

VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator

REF 619 9950

Rx ONLY

For *in vitro* diagnostic and laboratory professional use. For emergency authorization use only.

Intended Use

The VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack when used in combination with the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator is a chemiluminescent immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in nasopharyngeal (NP) specimens collected in CDC's formulation of VTM, COPAN Universal Transport Media (UTM)[®], Remel M4RT[®] VTM, or Hardy R99 VTM from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms using the VITROS 3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems. 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.

The VITROS SARS-CoV-2 Antigen test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The VITROS SARS-CoV-2 Antigen test is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of *in vitro* diagnostic procedures, and proper infection control procedures. In the United States, the VITROS SARS-CoV-2 Antigen 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 and is the causative agent of Coronavirus Disease 2019 (COVID-19) and the pandemic. SARS-CoV-2 is mainly transmitted through droplets and contact routes, and people who are infected with SARS-CoV-2 may express signs and symptoms of acute respiratory illness, such as fever, cough, shortness of breath, etc., but can also be asymptomatic.¹⁻² The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.³ Symptomatic, pre-symptomatic and asymptomatic SARS-CoV-2 carriers all can be potential sources for viral transmission.⁴

Real-time reverse transcription polymerase chain reaction (rRT-PCR) detecting viral genes is the current gold standard for the diagnosis of COVID-19. Upper respiratory specimen, such as nasopharyngeal swab and oropharyngeal swab, are commonly used for diagnostic testing.² SARS-CoV-2 produces multiple viral antigens with the nucleocapsid antigens being the most abundant.⁵ Immunoassays detect the SARS-CoV-2 nucleocapsid antigen and are also used for the diagnosis of active infection.⁶

Principles of the Procedure

The VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test is performed using the VITROS SARS-CoV-2 Antigen Reagent Pack and the VITROS SARS-CoV-2 Antigen Calibrator on the VITROS 3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems. An immunometric technique is used; this involves a two stage reaction. In the first stage SARS-CoV-2 nucleocapsid antigen present in the sample binds with monoclonal anti-SARS-CoV-2 coated on the well. Unbound sample is removed by washing. In the second stage horseradish peroxidase (HRP)-labeled monoclonal anti-

CV2Ag

INSTRUCTIONS FOR USE

Warnings and Precautions

SARS-CoV-2 is added in the conjugate reagent. The conjugate binds specifically to any SARS-CoV-2 nucleocapsid captured on the well in the first stage. Unbound conjugate is removed by the subsequent wash step.

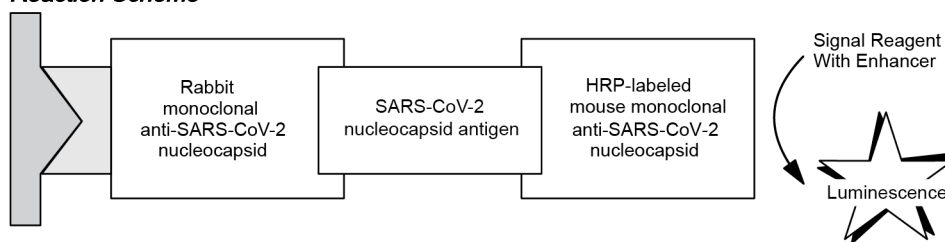
The bound HRP conjugate is measured by a luminescent reaction.⁷ A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. Signal to cutoff numerical values will increase as the amount of SARS-CoV-2 antigen present in the sample increases.

Test Type	System*	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Immunometric	3600, 5600, XT 7600	37 minutes	48 minutes	37 °C	Extracted 80 µL**

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

** 80 µL of extracted sample (see Specimen Collection and Preparation)

Reaction Scheme



Warnings and Precautions

1. For *in vitro* diagnostic use. For prescription use only. In the USA, only for use under an Emergency Use Authorization.
2. This test has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under CLIA that meet the requirements to perform moderate or high complexity tests.
3. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
4. 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* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
5. Do not use the kit contents beyond the expiration date.
6. Calibration is lot specific; reagent packs and calibrator are linked by lot number.
7. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
8. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
9. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
10. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Proper handling and disposal methods should be established by the laboratory in accordance with local, state and federal regulations.
11. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS)⁸ located at www.orthoclinicaldiagnostics.com.

WARNING:

Potentially Infectious Material

Treat as if capable of transmitting infection.

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

WARNING:

Contains EDTA (CAS 10378-23-1) and ProClin 300⁸

INSTRUCTIONS FOR USE

CV2Ag

Reagents

The VITROS SARS-CoV-2 Antigen Reagent Pack contains 1.9% EDTA and 1.0% ProClin 300. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. P280: Wear protective gloves, Eye Protection. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash before reuse.

WARNING:

Contains ProClin 950[®]

The VITROS SARS-CoV-2 Antigen Calibrator contains 0.5% ProClin 950. H317: May cause an allergic skin reaction. P280: Wear protective gloves. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash before reuse.

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.

Reagents

Reagent Pack Contents

1 reagent pack containing:

- 100 coated wells (rabbit monoclonal anti-SARS-CoV-2 nucleocapsid, 1.0 µg/mL)
- 6.0 mL assay reagent (buffer with bovine protein stabilizers and antimicrobial agent)
- 16.2 mL conjugate reagent (HRP-mouse monoclonal anti-SARS-CoV-2 nucleocapsid, 2.0 µg/mL) in buffer with 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	≤4 weeks
Opened	Refrigerated	2–8 °C (36–46 °F)	≤4 weeks

- The VITROS SARS-CoV-2 Antigen 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.

CV2Ag

INSTRUCTIONS FOR USE

Specimen Collection, Preparation and Storage

Calibrator Contents

- 2 vials of VITROS SARS-CoV-2 Antigen Calibrator (recombinant SARS-CoV-2 nucleocapsid antigen in buffer with bovine serum albumin and antimicrobial agent, 1.0 mL)
- 8 calibrator bar code labels

Calibrator Handling

- Use only with reagent packs 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 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 SARS-CoV-2 Antigen Calibrator is supplied frozen. DO NOT REFREEZE.
- The VITROS SARS-CoV-2 Antigen Calibrator is suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- The VITROS SARS-CoV-2 Antigen test uses 80 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). For details on minimum fill volume of sample cups or containers, refer to the operating instructions for your system.

Caution: Do not add extraction buffer to calibrator.

- The VITROS SARS-CoV-2 Antigen Calibrator is automatically processed in duplicate.

Specimen Collection, Preparation and Storage

Patient Preparation

No special patient preparation is necessary.

Specimens Recommended

- Nasopharyngeal specimen stored in CDC viral transport media
- Nasopharyngeal specimen stored in Hardy R99 viral transport media
- Nasopharyngeal specimen stored in COPAN[®] UTM[®] Universal transport media
- Nasopharyngeal specimen stored in Remel M4RT[®] viral transport media

^{*}COPAN UTM[®] is also distributed as Becton Dickinson UVT and other brands.

Special Precautions

IMPORTANT: *Certain transport media have been reported to affect other analytes and tests.¹⁰ False positive results for SARS-Co-2 have been observed in some tests with use of some transport media.*

Specimen Collection and Preparation

- Collect nasopharyngeal (NP) specimens by a trained healthcare provider with proper infection control and personal protective equipment (PPE).¹⁰
- Follow the instructions provided with your transport media for use and processing of the sample.¹⁰
- The VITROS SARS-CoV-2 Antigen test uses 80 µL of extracted sample for each determination. This is in addition to 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.
- Sample Preparation and Testing:

INSTRUCTIONS FOR USE

CV2Ag

Testing Procedure

1. Prepare Sample for Extraction
 - Receive sample swab in transport media.
 - Mix transport tube well (e.g., vortex approx. 3-5 seconds).
2. Add Extraction Buffer to Sample
 - Transfer 100 µL VITROS SARS-CoV-2 Antigen Extraction Buffer into a labeled new sample tube.
 - Add 400 µL viral sample into the same sample tube.
 - Mix well (e.g. cover sample container with cap/plug and vortex approx. 3-5 seconds).

IMPORTANT: Care should be taken when handling sample tubes as the sample should be considered potentially infectious.

3. Load to Instrument
 - Load and process samples in the same manner as other testing on your VITROS System.
 - Refer to the operating instructions for your system.

Note: An alternate sample volume may be used if desired, using 4 parts media to 1 part VITROS SARS-CoV-2 Antigen Extraction Buffer. It is recommended to have a minimum of 250 µL of sample/extraction buffer loaded on the VITROS system.

If programming samples on the system manually, process samples by selecting the CV2Ag test button on system.

Handling and Storage Conditions

Extraction	Storage Condition	Stability
Pre- or Post-	Room Temperature (up to 30 °C [86 °F])	24 hours
Pre- or Post-	Refrigerated 2–8 °C (36–46 °F)	48 hours

- 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 unused sample (pre- or post-extraction) to 2–8 °C (36–46 °F) as soon as possible after use or load sufficient volume for a single determination.
- Samples (pre- or post-extraction) that will not be tested within the time frames outlined above should be stored at ≤-20 °C [≤-4 °F].

Testing Procedure

Materials Provided

- VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack
- VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator

Materials Required but Not Provided

- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent
- Quality control materials such as VITROS Immunodiagnostic Products VITROS SARS-CoV-2 Antigen Controls
- VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Extraction Buffer
- VITROS Immunodiagnostic Products Reagent Pack Storage Box (optional) with desiccant
- Appropriate volume pipette and sample containers for extraction

Operating Instructions

Check the inventory regularly to aid the management of reagents and ensure that sufficient VITROS Signal Reagent, VITROS 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.

Note: Do not use visibly damaged product.

CV2Ag

INSTRUCTIONS FOR USE

Calibration

Default Test Name

The default test name which will appear on patient reports is SARS-CoV-2 Ag. The default short name that will appear on the test selection menus and laboratory reports is CV2Ag. 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 is established for each new reagent lot by performing multiple tests. This is the process by which a lot-specific parameter [a] which links the signal at the cutoff (cutoff value) to the calibrator signal is determined.
- Cutoff value = (a x Signal of Cal 1)
- Ensure that the Master Calibration for each new reagent lot is available on your system.
- Load sufficient volume for the automatic duplicate determination. Calibration need not be programmed if bar code labels are used; calibration will be initiated automatically.
- When the calibrator is processed, the validity of the calibration is assessed against quality parameters which compare the actual signal of the calibrator with the expected signal. If the calibration is acceptable the cutoff value is calculated and 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 Calibration

Calibration of the VITROS SARS-CoV-2 Antigen test is traceable to an in-house reference calibrator which has been value assigned to optimize clinical sensitivity and specificity.

Calibration Model

Results are calculated as a normalized signal, relative to a cutoff value. During the calibration process a lot-specific parameter is used to determine a valid stored cutoff value for the VITROS Immunodiagnostic and VITROS Integrated Systems.

Quality Control**Quality Control Material Selection**

VITROS SARS-CoV-2 Antigen Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. There are 2 VITROS SARS-CoV-2 Antigen Controls (SARS-CoV-2 Ag negative and SARS-CoV-2 Ag positive).

Appropriate quality control value ranges must be established for all quality control materials used with the VITROS SARS-CoV-2 Antigen test.

Quality Control Procedure Recommendations

- Good laboratory practice requires that controls be processed to verify the performance of the test.

INSTRUCTIONS FOR USE

CV2Ag

Results

- 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.
- If control results fall outside your acceptable range, investigate the cause before deciding whether to report patient results.
- Refer to published guidelines for general quality control recommendations. ¹¹

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.

Result Calculation

$$\text{Result} = \frac{\text{Signal for test sample}}{\text{Signal at Cutoff (Cutoff value)}}$$

Interpretation of Results*

Sample results will be displayed with a numerical signal to cutoff (S/C) value and a "Non-reactive" (negative) or "Reactive" (positive) label.

Result (S/C)	<1.00	≥1.00
Result Text	Non-reactive (negative)	Reactive (positive)

*Quantitative values should not be reported to health care providers.

Limitations of the Procedure

Known Interferences

The VITROS SARS-CoV-2 Antigen test was evaluated for interference. Commonly encountered substances were tested on one lot of reagent. Of the compounds tested, none was observed to interfere with the clinical interpretation of the test. SARS-CoV was not tested using the VITROS assay however it does cross-react in the VITROS SARS-CoV-2 Antigen assay. Refer to "Substances that do not Interfere" for a list of compounds tested that did not show interference.

Other Limitations

- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasopharyngeal swab specimens only.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.
- Performance has only been established with nasopharyngeal specimens. Other specimen types have not been evaluated and should not be used with this assay. Performance in fresh specimens has not been established and may differ.
- Only qualitative results should be reported. Semi-quantitative numerical results have not been clinically or analytically validated and may not correlate with patient disease status, duration of illness or severity of illness. Semi-quantitative results have not been demonstrated to correlate with the success or failure of any therapeutic interventions and should not be used to guide clinical management.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Positive test results do not rule out co-infections with other pathogens.

CV2Ag

INSTRUCTIONS FOR USE
Performance Characteristics

- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
- The VITROS SARS-CoV-2 Antigen test can detect both viable and non-viable SARS-CoV-2 material. The VITROS SARS-CoV-2 Antigen test performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection. Decreased clinical sensitivity was observed for mid-turbinate swabs collected from asymptomatic individuals.

Conditions of Authorization for the Laboratory

The VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test 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#individual-serological>. However, to assist clinical laboratories using the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack 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 VITROS SARS-CoV-2 Antigen Instructions for Use. 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 Ortho-Clinical Diagnostics, Inc. at OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.com or via phone by contacting Ortho Customer Support Services at 1-800-421-3311 any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Ortho-Clinical Diagnostics, Inc., 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," that meet the requirements to perform high or moderate complexity tests.

Performance Characteristics**Limit of Detection**

The Limit of Detection (LoD) was determined by evaluating different dilutions of heat inactivated SARS-CoV-2 virus added to pooled nasal wash. 50 µL of the viral particle solution was added to dry swabs and the swab was then placed into 2 mL of transport media. The transport media with eluted viral particles was tested repeatedly using the VITROS SARS-CoV-2 Antigen test (n=20). LoD is defined as the lowest virus concentration at which a minimum of 19 replicates out of 20 generate a Reactive result. Testing was performed across four transport media types and the resulting LoD ranged from 5.0 x 10² TCID₅₀ per mL to 1.5 x 10³ TCID₅₀ per mL.

INSTRUCTIONS FOR USE

CV2Ag

Performance Characteristics

LoD Determinations

Swab Type	Transport Medium	TCID ₅₀ per mL
Nasopharyngeal	CDC Viral Transport Medium	5.0 x 10 ²
Nasopharyngeal	COPAN Universal Transport Medium	5.0 x 10 ²
Nasopharyngeal	Hardy Viral Transport Medium	1.5 x 10 ³
Nasopharyngeal	Remel M4RT Viral Transport Medium	7.5 x 10 ²

Clinical Performance Characteristics

Clinical performance characteristics of the VITROS SARS-CoV-2 Antigen test was evaluated using residual samples from patients suspected of having contracted the SARS-CoV-2 virus within seven days of symptom onset. Samples were collected from 69 female patients and 36 male patients. Seven samples were from patients less than 21 years of age, 47 were from patients 21 to 60 years of age and 51 were from patients over the age of 60.

Nasopharyngeal samples were stored frozen between the time of collection and the time of testing. FDA Emergency Use Authorized high sensitivity real-time Polymerase Chain Reaction (RT-PCR) assays for the detection of SARS-CoV-2 were utilized as the comparator methods for this study.

Testing was performed by operators who were blinded to the RT-PCR test result. External control testing, using VITROS SARS-CoV-2 Antigen Controls was performed on each day of VITROS testing.

The performance of VITROS SARS-CoV-2 Antigen test was established with 105 nasopharyngeal specimens collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

VITROS SARS-CoV-2 Antigen Performance in RT-PCR Positive Samples Collected Within 7 Days of Symptom Onset Against the Comparator Method

VITROS SARS-CoV-2 Antigen Test	RT-PCR Comparator Method		
	Detected	Not Detected	Total
Reactive	24	0	24
Non-reactive	6	75	81
Total	30	75	105
Positive Percent Agreement: 80.0% (95% CI: 56.6–88.5%)			
Negative Percent Agreement: 100.0% (95% CI: 95.2–100.0%)			

Positive results broken down by days since symptom onset.

Days Since Symptom Onset	Cumulative VITROS PCR Positive (+)	Cumulative VITROS Reactive (+)	PPA
0	8	4	50.0%
1	10	6	60.0%
2	14	10	71.4%
3	20	16	80.0%
4	20	16	80.0%
5	22	18	81.8%
6	26	21	80.8%
7	30	24	80.0%

Potentially Cross-reacting Subgroups

The VITROS SARS-CoV-2 Antigen test was evaluated for potential microbial cross-reactivity and interference using contrived samples in the absence and presence of SARS-CoV-2. Potentially cross-reactive organisms were spiked into solution at concentrations of greater than or equal to 10⁶ CFU/mL for bacteria and greater than or equal to 10⁵ pfu/mL for viruses. The results are summarized in the table below.

Sample Category	Non-Reactive Sample	Spiked Reactive Sample	Cross-Reactivity (Y/N)
Human coronavirus 229E	Non-Reactive	Reactive	N
Human coronavirus OC43	Non-Reactive	Reactive	N
Human coronavirus NL63	Non-Reactive	Reactive	N
Influenza A	Non-Reactive	Reactive	N
Influenza B	Non-Reactive	Reactive	N
Adenovirus (e.g., C1 Ad. 71)	Non-Reactive	Reactive	N

CV2Ag

INSTRUCTIONS FOR USE

Performance Characteristics

Sample Category	Non-Reactive Sample	Spiked Reactive Sample	Cross-Reactivity (Y/N)
Human Metapneumovirus (hMPV)	Non-Reactive	Reactive	N
Parainfluenza virus 1-4	Non-Reactive	Reactive	N
Enterovirus	Non-Reactive	Reactive	N
Respiratory syncytial virus	Non-Reactive	Reactive	N
Rhinovirus	Non-Reactive	Reactive	N
<i>Hemophilus influenzae</i>	Non-Reactive	Reactive	N
<i>Streptococcus pneumoniae</i>	Non-Reactive	Reactive	N
<i>Streptococcus pyogenes</i>	Non-Reactive	Reactive	N
<i>Candida albicans</i>	Non-Reactive	Reactive	N
<i>Bordetella pertussis</i>	Non-Reactive	Reactive	N
<i>Mycoplasma pneumoniae</i>	Non-Reactive	Reactive	N
<i>Legionella pneumophila</i>	Non-Reactive	Reactive	N
MERS-coronavirus	Non-Reactive	Reactive	N
<i>Chlamydomphila pneumoniae</i>	Non-Reactive	Reactive	N
<i>Staphylococcus epidermidis</i>	Non-Reactive	Reactive	N
<i>Staphylococcus aureus</i>	Non-Reactive	Reactive	N

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing, *In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- No protein sequence homology was found between *M. tuberculosis*, *P. jirovecii* or HCov-HKU1, thus cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein and SARS-CoV shows homology of 90.52% and suggests that there will be significant cross reactivity in this test.

Specificity

Substances that do not interfere

The VITROS SARS-CoV-2 Antigen test was evaluated for interference. Of the compounds tested, none was found to interfere with the clinical interpretation of the test in Non-reactive and weakly Reactive samples at the concentrations indicated.

Interfering Substance	Active Ingredient	Concentration
Human Blood	Blood	4%
Hemoglobin	Hemolysate	1000 mg/dL
Purified mucin protein	Mucin protein	5.0 mg/mL (5%)
OTC Nasal Spray 1	Oxymetazoline	15%
OTC Nasal Spray 2	Fluticasone	5%
OTC Nasal Spray 3	Triamcinolone	5%
OTC Nasal Spray 4	Phenylephrine hydrochloride	15%
OTC Nasal Spray 5	Budesonide (Glucocorticoid)	5%
OTC Nasal Spray 6	Saline	15%
OTC Nasal Spray 7	Cromolyn	15%
OTC Nasal Wash	Alkolol	10%
OTC Nasal Gel	Sodium Chloride (NeilMed)	5%
Sore Throat Spray	Benzocaine, Menthol, Phenol	0.7 g/mL (70%)
Throat Lozenge	Menthol	0.8 g/mL (80%)
Anti-viral Drug 1	Oseltamivir	5.0 µg/mL
Anti-viral Drug 2	Zanamivir	282.0 ng/mL
Anti-bacterial, Systemic	Tobramycin	1.25 mg/mL
Hemeopathic Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5%
Antibacterial	Mupirocin	10 mg/mL

INSTRUCTIONS FOR USE

CV2Ag

References

References

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4. Lai et al. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges. *International Journal of Antimicrobial Agents.* 55:3; 2020.
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7. Summers M. et al. Luminogenic Reagent Using 3-Chloro 4-Hydroxy Acetanilide to Enhance Peroxidase/Luminol Chemiluminescence. *Clinical Chemistry.* 41. S73; 1995.
8. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
9. 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.
10. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. (<https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>)
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CV2Ag

INSTRUCTIONS FOR USE

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*
2021-01-11	1.6	<ul style="list-style-type: none"> Intended Use: updated Warnings and Precautions: amended warning 2-4 Other Limitations: amended third bullet Conditions of Authorization for the Laboratory: updated FDA website address
2021-01-08	1.5	<ul style="list-style-type: none"> Intended Use: updated Warnings and Precautions: added #6 Specimens Recommended: updated Important statement Specimen Collection and Preparation: updated first bullet Interpretation of Results: added footnote Other Limitations: added new limitations Limit of Detection: updated Clinical Performance Characteristics: updated data Back page: added website and phone number

INSTRUCTIONS FOR USE

CV2Ag

Revision History

Date of Revision	Version	Description of Technical Changes*
2021-01-07	1.4	<ul style="list-style-type: none"> • Handling and Storage Conditions: <ul style="list-style-type: none"> – removed freeze-thaw cycle – removed last bullet
2020-12-07	1.3	<ul style="list-style-type: none"> • Intended Use: updated • Calibrator Storage and Preparation: Opened - changed from 5 days to 24 hours • Specimens Recommended: removed NewProv viral transport media • Specimen Collection and Preparation: updated Important statement • Known Interferences: added statement • Limit of Detection: updated table • Clinical Performance Characteristics: updated tables • Potentially Cross-reacting Subgroups: updated table • Substances that do not Interfere: updated table
2020-11-20	1.2	<ul style="list-style-type: none"> • Intended Use: updated • Handling and Storage Conditions: updated bullets • Quality Control Material Selection: updated • Quality Control Procedure Recommendations: removed second bullet • Clinical Performance Characteristics: <ul style="list-style-type: none"> – updated tables – Specificity table updated
2020-11-03	1.1	Calibrator Storage and Preparation: Updated
2020-10-26	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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Ortho Clinical Diagnostics

INSTRUCTIONS FOR USE

VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Extraction Buffer

REF 619 9944

Rx ONLY, IVD, EUA Only

Intended Use

For *in vitro* diagnostic and laboratory professional use.

For use to extract the viral materials from nasopharyngeal swab samples placed in CDC's formulation of VTM, COPAN Universal Transport Media (UTM)[®], Remel M4RT[®] VTM, or Hardy R99 VTM for use on the VITROS 3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems.

This test has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under CLIA that meet the requirements to perform moderate or high complexity tests.

This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this test is 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Warnings and Precautions

WARNING:

Potentially Infectious Material

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).¹

WARNING:

Contains Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (CAS 55965-84-9)²

The VITROS SARS-CoV-2 Antigen Extraction Buffer contains ≥0.0015–<0.06% of Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone. H317: May cause an allergic skin reaction. P280: Wear protective gloves. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash before reuse.

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

WARNING



Materials Provided

1 extraction buffer pack containing:

- 4 bottles of VITROS SARS-CoV-2 Antigen Extraction Buffer (28 mL) with antimicrobial agent

INSTRUCTIONS FOR USE

Materials Required but Not Provided

Materials Required but Not Provided

- Appropriate volume pipette and sample containers for extraction

Refer to the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack and Calibrator instructions for use.

Storage, Preparation and Handling

- The VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Extraction Buffer is supplied ready to use.
- Store unopened at 2–8 °C (36–46 °F).
- Do not freeze.
- Use opened vial within 4 weeks of opening.
- Do not use beyond the expiration date.

Testing Procedure

Refer to the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack and Calibrator instructions for use.

Note: Do not use visibly damaged product.

Not all products and systems are available in all countries.

References




































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.
2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

INSTRUCTIONS FOR USE

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*
2021-01-11	1.1	Intended Use: added statements for Emergency Use Authorization (EUA)
2020-10-22	1.0	Initial version of document

* 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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Ortho Clinical Diagnostics

INSTRUCTIONS FOR USE

CV2Ag

VITROS Immunodiagnostic Products
SARS-CoV-2 Antigen Controls

REF 619 9943

Rx ONLY, IVD, EUA Only

Intended Use

For *in vitro* diagnostic and laboratory professional use.

For use in monitoring the performance of the VITROS 3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems for the qualitative detection of the SARS-CoV-2 nucleocapsid antigen.

This test has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under CLIA that meet the requirements to perform moderate or high complexity tests.

This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this test is 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Warnings and Precautions

WARNING:

Potentially Infectious Material

Treat as if capable of transmitting infection.

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).¹

WARNING:

Contains ProClin 950²

The VITROS SARS-CoV-2 Antigen Controls contain 0.5% ProClin 950. H317: May cause an allergic skin reaction. P280: Wear protective gloves. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash before reuse.

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

WARNING



Materials Provided

3 sets of VITROS SARS-CoV-2 Antigen Controls 1 and 2 (recombinant SARS-CoV-2 nucleocapsid antigen in buffer with bovine serum albumin and antimicrobial agent, 3 mL)

CV2Ag

INSTRUCTIONS FOR USE
 Materials Required but Not Provided

Materials Required but Not Provided

- Pipette, sample containers
- VITROS Immunodiagnostic Products SARS-COV-2 Antigen Extraction Buffer

Control Storage, Preparation and Handling

Control	Storage Condition		Stability
Unopened	Frozen	≤-20 °C (≤-4 °F)	expiration date
Opened	Refrigerated	2–8 °C (36–46 °F)	≤5 days

- VITROS SARS-CoV-2 Antigen Controls are supplied frozen. DO NOT REFREEZE.
- VITROS SARS-CoV-2 Antigen 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.
- Thoroughly mix controls by inversion and bring to 15–30 °C (59–86 °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 °C (36–46 °F) as soon as possible after use, or load only sufficient volume for a single determination.
- Baseline statistics for controls should be entered onto the system. For further information, refer to the operating instructions for your system.
- 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

For each control:

- Combine 100 µL VITROS SARS-CoV-2 Extraction Buffer and 400 µL of control into a sample container.
- Mix well (e.g. cover sample container with cap/plug and vortex approx. 3-5 seconds).

Load each control onto the system by transferring an aliquot into a sample container, if needed (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.

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

VITROS SARS-CoV-2 Antigen Control 1 should generate Non-reactive results.
 VITROS SARS-CoV-2 Antigen Control 2 should generate Reactive results.

References

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

CV2Ag

Glossary of Symbols

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Revision History

Date of Revision	Version	Description of Technical Changes*
2021-01-11	1.2	Intended Use: added statements for Emergency Use Authorization (EUA)
2020-11-03	1.1	Control Storage, Preparation and Handling: Updated
2020-10-23	1.0	Initial version of document.

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