INSTRUCTIONS FOR USE

CoV2T

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator

Rx ONLY

For in vitro diagnostic and Laboratory Professional use. For emergency authorization use only.

Intended Use

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test is used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator on the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems. An immunometric technique is used, which 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 the well. Unbound sample is removed by washing. In the second stage, horseradish peroxidase (HRP)-labeled recombinant SARS-CoV-2 spike protein S1 antigen is added in the conjugate reagent. The conjugate binds specifically to any anti-SARS-CoV-2 captured on the well in the first stage. Unbound conjugate is removed by the subsequent wash step.

Summary and Explanation of the Test

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a beta coronavirus that causes the Coronavirus Disease 2019 (COVID-19) and pandemic. SARS-CoV-2 is mainly transmitted through droplets and contact routes, and the virus infects human cells via binding to angiotensin converting enzyme 2 (ACE2). 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 can all be potential sources for viral transmission. Currently, no specific treatments or vaccines are available for COVID-19.

Real-time reverse transcription polymerase chain reaction (rt-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.

Principles of the Procedure

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack and the VITROS Anti-SARS-CoV-2 Total Calibrator on the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems. An immunometric technique is used, which 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 the well. Unbound sample is removed by washing. In the second stage, horseradish peroxidase (HRP)-labeled recombinant SARS-CoV-2 spike protein S1 antigen is added in the conjugate reagent. The conjugate binds specifically to any anti-SARS-CoV-2 captured on the well in the first stage. Unbound conjugate is removed by the subsequent wash step.
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Warnings and Precautions

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peroxidase) 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 acetylhydride) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the amount of SARS-CoV-2 antibody present.

<table>
<thead>
<tr>
<th>Test Type</th>
<th>System*</th>
<th>Incubation Time</th>
<th>Time to first result</th>
<th>Test Temperature</th>
<th>Reaction Sample Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunometric</td>
<td>ECI/ECIQ, 3600, 5600, XT 7600</td>
<td>37 minutes</td>
<td>48 minutes</td>
<td>37 °C</td>
<td>80 μL</td>
</tr>
</tbody>
</table>

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

Reaction Scheme

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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).

VITROS Anti-SARS-CoV-2 Total Calibrator contains: SARS-CoV-2 antibody negative 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 Anti-SARS-CoV-2 Total Calibrator in addition contains: SARS-CoV-2 antibody. Handle as if capable of transmitting infection.

**WARNING:**

Contains ProClin 300 (CAS 55965-84-9)

P302: If on skin: Wash with plenty of soap and water.

**WARNING:**

Contains ProClin 950 (CAS 2682-20-4)

P317: May cause an allergic skin reaction. P280: Wear protective gloves. P332 + P313: If skin irritation or rash occurs: Get medical advice/attention. P333: Wash contaminated clothing before reuse.
INSTRUCTIONS FOR USE

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Reagents

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.
• This test has not been FDA cleared or approved.
• This test has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests.
• This test has been authorized only for the detection of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
• This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Reagents

Reagent Pack Contents

1 reagent pack containing:
• 100 coated wells (streptavidin, bacterial; binds ≥ 3 ng biotin per well; biotin recombinant SARS-CoV-2 antigen 0.1 μg/mL)
• 6.0 mL assay reagent (buffer with bovine protein stabilizers and antimicrobial agent)
• 16.2 mL conjugate reagent (HRP-recombinant SARS-CoV-2 antigen, 0.5 μg/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

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Storage Condition</th>
<th>Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened</td>
<td>Refrigerated</td>
<td>2–8 °C (36–46 °F)</td>
</tr>
<tr>
<td>Opened</td>
<td>On system</td>
<td>System turned on</td>
</tr>
<tr>
<td>Opened</td>
<td>Refrigerated</td>
<td>2–8 °C (36–46 °F)</td>
</tr>
</tbody>
</table>

• The VITROS Anti-SARS-CoV-2 Total 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 vials of VITROS Anti-SARS-CoV-2 Total Calibrator (anti-SARS-CoV-2 in anti-SARS-CoV-2 negative human plasma with antimicrobial agent, 1 mL)

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.
INSTRUCTIONS FOR USE CoV2T

Specimen Collection, Preparation and Storage

Calibrator Storage and Preparation

<table>
<thead>
<tr>
<th>Calibrator</th>
<th>Storage Condition</th>
<th>Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened</td>
<td>Frozen</td>
<td>≤-20 °C (≤-4 °F) expiration date</td>
</tr>
<tr>
<td>Opened</td>
<td>Refrigerated</td>
<td>2-8 °C (36-46 °F) &lt;24 hours</td>
</tr>
</tbody>
</table>

- VITROS Anti-SARS-CoV-2 Total Calibrator is supplied frozen.
- The VITROS Anti-SARS-CoV-2 Total 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.
- DO NOT REFREEZE.
- The VITROS Anti-SARS-CoV-2 Total 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.
- The VITROS Anti-SARS-CoV-2 Total Calibrator is automatically processed in duplicate.

Specimen Collection, Preparation and Storage

Patient Preparation

No special patient preparation is necessary.

Specimens Recommended

- Serum
- K2 EDTA Plasma

Specimens Not Recommended

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

Special Precautions

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

Specimen Collection and Preparation

- Collect specimens using standard procedures.
- Follow the instructions provided with your collection device for use and processing of the sample.
- 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 Total test uses 80 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 VITROS Anti-SARS-CoV-2 Total Reagent Pack
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 = \( (a \times \text{Signal of Cal}) \)
- Ensure that the Master Calibration for each new reagent lot is available on your system.
- Process calibrator in the same manner as samples. Load sufficient 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 Anti-SARS-CoV-2 Total 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.
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Quality Control

Quality Control Material Selection

VITROS Anti-SARS-CoV-2 Total Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. There are 2 VITROS Anti-SARS-CoV-2 Total Controls (anti-SARS-CoV-2 Total negative and anti-SARS-CoV-2 Total positive). The performance of other commercial control fluids should be evaluated for compatibility with this test before they are used for quality control.

Control materials may show a difference when compared with other anti-SARS-CoV-2 Total antibody methods if they contain high concentrations of preservatives, stabilizers, or other non-physiological additives, or otherwise depart from a true human sample matrix.

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

Quality Control Procedure Recommendations

- Good laboratory practice requires that controls be processed to verify the performance of the test.
- Choose control levels that check the clinically relevant concentrations.
- To verify system performance, analyze control materials:
  - After calibration
  - If the system is turned off for more than 2 hours
  - After reloading reagent packets 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.

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.

Result

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

Patient sample results will be displayed with a “Non-reactive” or “Reactive” label. Results reported outside the laboratory should be reported as only “Non-reactive” or “Reactive”. Numerical results should not be reported outside the laboratory to individual patients or their physicians.

<table>
<thead>
<tr>
<th>Result (S/C)</th>
<th>&lt;1.00</th>
<th>≥1.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result Text</td>
<td>Non-reactive (negative)</td>
<td>Reactive (positive)</td>
</tr>
</tbody>
</table>

The following table summarizes the interpretation of results obtained with the VITROS Anti-SARS-CoV-2 Total test on the VITROS Immunodiagnostic and VITROS Integrated Systems. The magnitude of the measured result above the cutoff is not indicative of the total amount of antibody present in the sample and no clinical utility of significance has been validated for the magnitude of the measure result above the cutoff. Linearity of results has not been demonstrated (for example: a S/C result of 20 does not necessarily contain twice as much antibody as a result of 10 S/C)
Limitations of the Procedure

Known Interferences
The VITROS Anti-SARS-CoV-2 Total test was evaluated for interference. Commonly encountered substances were tested on one lot of reagent. Of the compounds tested, none was found to interfere with the clinical interpretation of the test. Refer to “Substances that do not interfere” for a list of compounds tested that did not show interference.

Other Limitations
- Heterophilic antibodies in serum or plasma samples may cause interference in immunoassays. These antibodies may be present in blood samples from individuals exposed to animals or even after being treated with animal serum products. Results that are inconsistent with clinical observations indicate the need for additional testing.
- A negative or 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 if 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.
- 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.

Conditions of Authorization for the Laboratory

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test 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/vitro-diagnostic-tests. However, to assist clinical laboratories using the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test (“your product” in the conditions below), the relevant Conditions of Authorization are listed below:
- Authorized laboratories using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product will use your product as outlined in the 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 will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Ortho-Clinical Diagnostics, Inc (OrthoCareTechnicalSolution@orthoclinicaldiagnostics.com) 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 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

Clinical Performance Characteristics

Sensitivity
Samples collected from 86 individual patients confirmed to be SARS-CoV-2 positive by PCR were tested. Of the 86 PCR positive samples, 80 were Reactive in the VITROS Anti-SARS-CoV-2 Total assay and 6 were Non-reactive. For 69 of the 86 samples, the date of sample collection and date of onset of symptoms were provided. Reactivity was correlated with elapsed days after onset of symptoms. Positive Percent Agreement and the 95% confidence intervals were calculated.
The results are summarized in the table below.

<table>
<thead>
<tr>
<th>Days Since Symptoms Reported</th>
<th>Number Reactive</th>
<th>Number Non-Reactive</th>
<th>Total</th>
<th>PPA (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤8</td>
<td>16</td>
<td>4</td>
<td>20</td>
<td>80.0% (56.3–94.3%)</td>
</tr>
<tr>
<td>&gt;8</td>
<td>49</td>
<td>0</td>
<td>49</td>
<td>100.0% (92.7–100.0%)</td>
</tr>
</tbody>
</table>

*An additional 17 samples were tested but information about date of symptom onset was not available. Of those 17 samples, 15 were Reactive.

**Clinical Specificity**

Four hundred presumed SARS-CoV-2 negative samples from healthy blood donors collected prior to COVID-19 pandemic were tested resulting in 100% clinical specificity (95% CI: 99.1–100.0%).

**Potentially Cross-reacting Subgroups**

The VITROS Anti-SARS-CoV-2 Total test was evaluated for potential cross-reactivity in anti-SARS-CoV-2 negative samples from medical conditions unrelated to SARS-CoV-2 infection. The results are summarized in the table below.

<table>
<thead>
<tr>
<th>Sample Category</th>
<th>Number of Samples</th>
<th>Non-reactive</th>
<th>Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus Antibody</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Influenza A Antibody</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Influenza B Antibody</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Coxsackie Virus Antibody</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Echovirus Antibody</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>HCV Antibody</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Anti Nuclear Antibody</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>

A large proportion of healthy general population have been exposed to common coronaviruses causing respiratory infections (beta-coronavirus OC43 and HKU1 and alpha-coronavirus NL63 and 229E). 1 400 healthy blood donors were tested with VITROS Anti-SARS-CoV-2 Total with no reactivity observed.

**Specificity**

**Substances that do not Interfere**

The VITROS Anti-SARS-CoV-2 Total 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.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin, conjugated</td>
<td>40.0 mg/dL, 475 μmol/L</td>
</tr>
<tr>
<td>Bilirubin, unconjugated</td>
<td>40.0 mg/dL, 684 μmol/L</td>
</tr>
<tr>
<td>Biotin</td>
<td>3510 ng/mL, 14.3 μmol/L</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1000 mg/dL, 0.156 mmol/L</td>
</tr>
<tr>
<td>Intralipid</td>
<td>2000 mg/dL, N/A</td>
</tr>
</tbody>
</table>

N/A = Not Applicable (alternate units are not provided)

**References**


### Glossary of Symbols

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="symbol1.png" alt="Image" /></td>
<td>Do Not Reuse</td>
</tr>
<tr>
<td><img src="symbol2.png" alt="Image" /></td>
<td>Use by or Expiration Date (Year-Month-Day)</td>
</tr>
<tr>
<td><img src="symbol3.png" alt="Image" /></td>
<td>Batch Code or Lot Number</td>
</tr>
<tr>
<td><img src="symbol4.png" alt="Image" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="symbol5.png" alt="Image" /></td>
<td>Catalog Number or Product Code</td>
</tr>
<tr>
<td><img src="symbol6.png" alt="Image" /></td>
<td>Caution</td>
</tr>
<tr>
<td><img src="symbol7.png" alt="Image" /></td>
<td>Keep Dry (Protect from Moisture/Humidity)</td>
</tr>
<tr>
<td><img src="symbol8.png" alt="Image" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="symbol9.png" alt="Image" /></td>
<td>Date of Manufacture</td>
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<td><img src="symbol10.png" alt="Image" /></td>
<td>Authorized Representative in the European Community</td>
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<td><img src="symbol11.png" alt="Image" /></td>
<td>Corrosive</td>
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<td><img src="symbol12.png" alt="Image" /></td>
<td>Flammable</td>
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<td><img src="symbol13.png" alt="Image" /></td>
<td>Health Hazards</td>
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<tr>
<td><img src="symbol14.png" alt="Image" /></td>
<td>Upper Limit of Temperature</td>
</tr>
<tr>
<td><img src="symbol15.png" alt="Image" /></td>
<td>Lower Limit of Temperature</td>
</tr>
<tr>
<td><img src="symbol16.png" alt="Image" /></td>
<td>Temperature Limitation</td>
</tr>
<tr>
<td><img src="symbol17.png" alt="Image" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="symbol18.png" alt="Image" /></td>
<td>Attention: The Instructions for Use (IFU) has been updated</td>
</tr>
<tr>
<td><img src="symbol19.png" alt="Image" /></td>
<td>S1</td>
</tr>
<tr>
<td><img src="symbol20.png" alt="Image" /></td>
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<td><img src="symbol22.png" alt="Image" /></td>
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<td><img src="symbol23.png" alt="Image" /></td>
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<tr>
<td><img src="symbol24.png" alt="Image" /></td>
<td>Range</td>
</tr>
<tr>
<td><img src="symbol25.png" alt="Image" /></td>
<td>Range of Means</td>
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<tr>
<td><img src="symbol26.png" alt="Image" /></td>
<td>Midpoint</td>
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<tr>
<td><img src="symbol27.png" alt="Image" /></td>
<td>Revised</td>
</tr>
<tr>
<td><img src="symbol28.png" alt="Image" /></td>
<td>Supersedes</td>
</tr>
<tr>
<td><img src="symbol29.png" alt="Image" /></td>
<td>Contains Sufficient for &quot;n&quot; Tests</td>
</tr>
<tr>
<td><img src="symbol30.png" alt="Image" /></td>
<td>In vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td><img src="symbol31.png" alt="Image" /></td>
<td>Der Grüne Punkt (the Green Dot) Manufacturer follows certain packaging material waste disposal management regulations</td>
</tr>
<tr>
<td><img src="symbol32.png" alt="Image" /></td>
<td>Estimated within-lab SD</td>
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<tr>
<td><img src="symbol33.png" alt="Image" /></td>
<td>Serious Health Hazards</td>
</tr>
<tr>
<td><img src="symbol34.png" alt="Image" /></td>
<td>Environmental or Aquatic Toxicity</td>
</tr>
<tr>
<td><img src="symbol35.png" alt="Image" /></td>
<td>Acute Toxicity</td>
</tr>
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## Revision History

<table>
<thead>
<tr>
<th>Date of Revision</th>
<th>Version</th>
<th>Description of Technical Changes*</th>
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<tr>
<td>2020-10-26</td>
<td>3.3</td>
<td>• Added “Lot 500 and above”</td>
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<td></td>
<td></td>
<td>• Calibrator Storage and Preparation: changed to frozen</td>
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<tr>
<td>2020-10-16</td>
<td>3.2</td>
<td>• Warnings and Precautions: added new section</td>
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<td>• Conditions of Authorization for the Laboratory: updated email address</td>
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<tr>
<td>2020-09-04</td>
<td>3.1</td>
<td>• Other Limitations: added new limitation</td>
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<td>2020-04-30</td>
<td>3.0</td>
<td>• Intended Use: added IgA</td>
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<tr>
<td></td>
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<td>• Principles of the Procedure: updated</td>
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<td></td>
<td></td>
<td>• Handling and Storage Condition: added bullet</td>
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<td>• Limitations of the Procedure: updated email address</td>
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<td>• Sensitivity: updated table</td>
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<tr>
<td></td>
<td></td>
<td>• Substances that do not interfere: corrected typographical errors</td>
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</table>

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

________________________

Signature

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

Ortho Clinical Diagnostics

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INSTRUCTIONS FOR USE

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Controls

Rx ONLY

Intended Use
For use under Emergency Use Authorization (EUA) only
For in vitro diagnostic and Laboratory Professional use.
For use in monitoring the performance of the VITROS Immunodiagnostic and Integrated Systems when used for the determination of 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. Notes: method can offer complete assurance that hepatitis B virus, hepatitis C virus (HCV), human immunodeficiency virus (HIV1+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).

VITROS Anti-SARS-CoV-2 Total Controls 1 and 2 contain: SARS-CoV-2 antibody negative 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 Anti-SARS-CoV-2 Total Control 2 in addition contains: SARS-CoV-2 antibody. Handle as if capable of transmitting infection.

WARNING: Contains ProClin 950 (CAS 2682-20-4)

The VITROS Anti-SARS-CoV-2 Total Controls contain 0.5% ProClin 950. P245: Use protective clothing. P280: Wear protective gloves. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P363: Wash contaminated clothing before reuse.

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

WARNING

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

Materials Provided

3 sets of VITROS Anti-SARS-CoV-2 Total Controls 1 and 2 (human matrix with anti-microbial agent, 2 mL)

Materials Required but Not Provided

Pipette, sample containers.

Control Storage, Preparation and Handling

<table>
<thead>
<tr>
<th>Control</th>
<th>Storage Condition</th>
<th>Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened</td>
<td>Frozen</td>
<td>≤20 °C (≤4 °F)</td>
</tr>
<tr>
<td>Opened</td>
<td>Refrigerated</td>
<td>2–8 °C (36–46 °F)</td>
</tr>
</tbody>
</table>

- VITROS Anti-SARS-CoV-2 Total Controls are supplied frozen.
- VITROS Anti-SARS-CoV-2 Total 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 °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 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

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.

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 Anti-SARS-CoV-2 Total Control 1 should generate Non-reactive (negative) results. VITROS Anti-SARS-CoV-2 Total Control 2 should generate Reactive (positive) results.

References

Glossary of Symbols

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

- **Do Not Reuse**
- **Use by or Expiration Date (Year-Month-Day)**
- **LOT** Batch Code or Lot Number
- **SN** Serial Number
- **REP** Catalog Number or Product Code
- **Caution**
- **Keep Dry (Protect from Moisture/Humidity)**
- **Manufacturer**
- **Date of Manufacture**
- **Authorized Representative in the European Community**
- **Corrosive**
- **Flammable**
- **Health Hazards**
- **Acute Toxicity**
- **Range**
- **Range of Means**
- **Midpoint**
- **Revised**
- **Supersedes**
- **Contains Sufficient for “n” Tests**
- **In vitro Diagnostic Medical Device**
- **Der Grüne Punkt (The Green Dot). Manufacturer follows certain packaging material waste disposal management regulations**
- **Estimated within-lab SD**
- **Serious Health Hazards**
- **Environmental or Aquatic Toxicity**

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<td>4.0</td>
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