INSTRUCTIONS FOR USE

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

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators

Rx ONLY
For in vitro diagnostic use only. For emergency authorization use only.

Intended Use

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Reagent Pack when used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators is a chemiluminescent immunoassay test intended for the qualitative detection of total antibodies to SARS-CoV-2 in human serum and plasma (K2-EDTA). The VITROS Anti-SARS-CoV-2 Total N Antibody 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 Total N Antibody 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 total SARS-CoV-2 antibodies. Total 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 Total N Antibody 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 the VITROS Anti-SARS-CoV-2 Total N Antibody test may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The VITROS Anti-SARS-CoV-2 Total N Antibody 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 caused an outbreak of Coronavirus Disease 2019 (COVID-19), resulting in a world-wide pandemic. SARS-CoV-2 is mainly transmitted through droplets and contact routes. People who are infected with SARS-CoV-2 may show symptoms of acute respiratory illness, such as fever, cough, shortness of breath, but can also be asymptomatic. Symptomatic, pre-symptomatic (infected but still symptom-free) and asymptomatic SARS-CoV-2 carriers all can be potential sources for viral transmission. Real-time reverse transcription polymerase chain reaction (rRT-PCR) detecting the genetic material of SARS-CoV-2 genes is considered the gold standard for the diagnosis of COVID-19, and SARS-CoV-2 antigen assays have also been used to detect acute infection. 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. Patients with SARS-CoV-2 infection produce antibodies to multiple viral antigens including the spike protein and the nucleocapsid protein. Notably, it is not currently known if the presence of antibodies confers protection from re-infection.

Principles of the Procedure

The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody test is performed using the VITROS Anti-SARS-CoV-2 Total N Antibody Reagent Pack and the VITROS Anti-SARS-CoV-2 Total N Antibody Calibrators on VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and 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 nucleocapsid protein antigen coated on the well. Unbound sample is removed by washing. In the second stage, horseradish peroxidase (HRP)-labeled recombinant SARS-CoV-2 nucleocapsid protein antigen is added in the conjugate reagent. The conjugate binds specifically to any anti-SARS-CoV-2 antibodies captured on the well in the first stage. Unbound conjugate is removed by a subsequent wash step. The bound HRP conjugate is measured by a luminescent reaction. 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. Bound HRP conjugate is indicative of the presence of SARS-CoV-2 antibody.

<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>

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

**Reaction Scheme**

**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 accordance with procedures defined by appropriate national biohazard safety guideline or regulation (e.g. CLSI document M29).

**WARNING:** Contains EDTA, tetrasodium, dihydrate (CAS 10378-23-1) and 2-Methyl-3-isothiazolone (CAS 2662-20-4)

The VITROS Anti-SARS-CoV-2 Total N Antibody Assay Reagent contains 1.9% EDTA, tetrasodium, dihydrate and 0.0475% 2-Methyl-3-isothiazolone. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P264: Wash face, hands and any exposed skin thoroughly after handling. P272: Contaminated work clothing must not be allowed out of the workplace. P280: Wear protective gloves and eye
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Reagents

WARNING

Contains 2-Methyl-3-isothiazolone (CAS 2682-20-4) 16


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

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.
• This product has been authorized only for detecting total 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 diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Reagents

Reagent Pack Contents

1 reagent pack containing:
100 coated wells (streptavidin, bacterial; binds ≥ 3 ng biotin per well; recombinant SARS-CoV-2 nucleocapsid antigen 14 ng/well)
- 6.0 mL assay reagent (buffer with bovine protein stabilizers and antimicrobial agent)
- 16.2 mL conjugate reagent (HRP-recombinant SARS-CoV-2 nucleocapsid antigen) 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 Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody 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 Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators (anti-SARS-CoV-2 in buffer with bovine serum albumin and antimicrobial agent, 1.0 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 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

<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)</td>
</tr>
<tr>
<td>Opened</td>
<td>Refrigerated</td>
<td>2–8°C (36–46°F)</td>
</tr>
</tbody>
</table>

- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators are supplied frozen.
- The VITROS Anti-SARS-CoV-2 Total N Antibody 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 Total N Antibody 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 N Antibody Calibrators are automatically processed in duplicate.

### Specimen Collection, Preparation and Storage

**Patient Preparation**
- No special patient preparation is necessary.

**Specimens Recommended**
- Serum
- K2-EDTA Plasma
INTENDED FOR USE IN THE UNITED STATES

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CV2TN

Testing Procedure

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. Owing 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 specimen collection tube 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 N Antibody 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 5 freeze-thaw cycles.
- 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 Total N Antibody Reagent Pack
- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators

Materials Required but Not Provided

- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent
- VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Controls

Optional Materials Not Provided

- 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.

**Note:** Do not use visibly damaged product.

Default Test Name

The default test name which will appear on patient reports is SARS-CoV2 Tot N. The default short name that will appear on the test selection menus and laboratory reports is CV2TN. 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 calibrators 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 = \[a_{LOT} \times (\text{Signal of Cal 1})\]
- 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 N Antibody 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 Anti-SARS-CoV-2 Total N Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. There are 2 VITROS Anti-SARS-CoV-2 Total N Controls (anti-SARS-CoV-2 Tot N Non-reactive and anti-SARS-CoV-2 Tot N Reactive). 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 N Antibody 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.
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.  

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.

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

**Result Calculation**

\[
\text{Result} = \frac{\text{Signal for test sample}}{\text{Cutoff value}}
\]

**Interpretation of Results**

The following table summarizes the interpretation of results obtained with the VITROS Anti-SARS-CoV-2 Total N Antibody 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: an S/C result of 20 does not necessarily contain twice as much antibody as a result of 10 S/C).

<table>
<thead>
<tr>
<th>VITROS Anti-SARS-CoV-2 Total N Antibody Test Result (S/C)</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1.00</td>
<td>Specimen is non-reactive (negative) for anti-SARS-CoV-2</td>
</tr>
<tr>
<td>≥1.00</td>
<td>Specimen is reactive (positive) for anti-SARS-CoV-2</td>
</tr>
</tbody>
</table>

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

<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>

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**Limitations of the Procedure**

**Known Interferences**
The VITROS Anti-SARS-CoV-2 Total N Antibody test was evaluated for interference. Commonly encountered substances were tested on one lot of reagent. Of the compounds tested, none were 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**
- SARS-CoV-2 serology tests should not be used to diagnose acute COVID-19. An assay that directly detects the virus should be used to evaluate symptomatic individuals for acute COVID-19, particularly those who have been in contact with the virus.
- Heterophilic antibodies in serum or plasma samples may cause interference in immunoassays. These antibodies may be present in blood samples from individuals regularly exposed to animals or who have been treated with animal serum products. Results that are inconsistent with clinical observations indicate the need for additional testing.
Performance Characteristics

Clinical Performance Characteristics

Negative Percent Agreement

1048 samples collected from apparently healthy individuals prior to December 2019 were tested on the VITROS Anti-SARS-CoV-2 Total N Antibody assay. Of the 1048 samples, 553 were serum and 495 were K₂-EDTA plasma. The results are presented in the table below. Negative percent agreement (NPA) has been calculated, along with the 95% confidence interval (95% CI).
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Performance Characteristics

Sample Matrix | Subjects (n) | Reactive Results | Non-Reactive Results | NPA | 95% CI
---|---|---|---|---|---
Serum | 553 | 5 | 548 | 99.1% | 97.9–99.6%
K₂-EDTA | 495 | 4 | 491 | 99.2% | 97.9–99.7%
Combined | 1048 | 9 | 1039 | 99.1% | 98.4–99.5%

Positive Percent Agreement
176 samples were collected from subjects determined to be positive for the SARS-CoV-2 virus by an EUA RT-PCR method. The 176 samples consisted of 131 serum samples and 45 K₂-EDTA plasma samples. The results are summarized in the tables below, with samples classified based on the number of days after onset of symptoms. Positive percent agreement (PPA) has been calculated, along with the 95% confidence interval (95% CI).

<table>
<thead>
<tr>
<th>Matrix</th>
<th>Symptom Onset (days)</th>
<th>Subjects (n)</th>
<th>Reactive Results (n)</th>
<th>Non-Reactive Results (n)</th>
<th>PPA</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>0–7</td>
<td>22</td>
<td>18</td>
<td>4</td>
<td>81.8%</td>
<td>61.5–92.7%</td>
</tr>
<tr>
<td></td>
<td>8–14</td>
<td>39</td>
<td>36</td>
<td>3</td>
<td>92.3%</td>
<td>79.7–97.4%</td>
</tr>
<tr>
<td></td>
<td>≥15</td>
<td>70</td>
<td>63</td>
<td>7</td>
<td>90.0%</td>
<td>80.8–95.1%</td>
</tr>
<tr>
<td>K₂-EDTA</td>
<td>0–7</td>
<td>0</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>8–14</td>
<td>0</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>≥15</td>
<td>45</td>
<td>44</td>
<td>1</td>
<td>97.8%</td>
<td>88.4–99.6%</td>
</tr>
</tbody>
</table>

Potentially Cross-reacting Subgroups
76 samples from the following potentially cross-reacting sub-groups were tested and none were found to be reactive in the VITROS Anti-SARS-CoV-2 Total N Antibody test.

<table>
<thead>
<tr>
<th>Sample Category</th>
<th>Number Tested</th>
<th>Samples Non-reactive</th>
<th>Samples Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>anti-influenza A IgG</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>anti-influenza A IgM</td>
<td>19</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>anti-influenza B IgG</td>
<td>17</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>anti-influenza B IgM</td>
<td>15</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>anti-HCV</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>anti-HBV</td>
<td>9</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>anti-Haemophilus influenzae</td>
<td>25</td>
<td>25</td>
<td>0</td>
</tr>
<tr>
<td>anti-229E (alpha coronavirus)</td>
<td>24</td>
<td>24</td>
<td>0</td>
</tr>
<tr>
<td>anti-NL63 (alpha coronavirus)</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>anti-OC43 (beta coronavirus)</td>
<td>21</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>anti-HKU1 (beta coronavirus)</td>
<td>11</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>anti-nuclear antibodies</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>anti-respiratory syncytial virus</td>
<td>20</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>anti-HIV</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>

Specificity

Substances that do not Interfere
The VITROS Anti-SARS-CoV-2 Total N Antibody test was evaluated for interference consistent with CLSI document EP07. Of the compounds tested, none were found to interfere with the clinical interpretation of the test at the concentrations indicated at a VITROS Anti-SARS-CoV-2 Total N Antibody result of approximately 0, 1.5-3, and 10-20 S/C.
### 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="image1" alt="Symbol" /></td>
<td>Do Not Use</td>
</tr>
<tr>
<td><img src="image2" alt="Symbol" /></td>
<td>Use by or Expiration Date (Year-Month-Day)</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>Batch Code or Lot Number</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>Catalog Number or Product Code</td>
</tr>
<tr>
<td><img src="image6" alt="Symbol" /></td>
<td>Caution</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>Keep Dry (Protect from Moisture/Humidity)</td>
</tr>
<tr>
<td><img src="image8" alt="Symbol" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td><img src="image10" alt="Symbol" /></td>
<td>Authorized Representative in the European Community</td>
</tr>
<tr>
<td><img src="image11" alt="Symbol" /></td>
<td>Corrosive</td>
</tr>
<tr>
<td><img src="image12" alt="Symbol" /></td>
<td>Health Hazards</td>
</tr>
<tr>
<td><img src="image13" alt="Symbol" /></td>
<td>Upper Limit of Temperature</td>
</tr>
<tr>
<td><img src="image14" alt="Symbol" /></td>
<td>Lower Limit of Temperature</td>
</tr>
<tr>
<td><img src="image15" alt="Symbol" /></td>
<td>Temperature Limitation</td>
</tr>
<tr>
<td><img src="image16" alt="Symbol" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="image17" alt="Symbol" /></td>
<td>Attention: The Instructions for Use (IFU) has been updated</td>
</tr>
<tr>
<td><img src="image18" alt="Symbol" /></td>
<td>For use in Slide Supply 1</td>
</tr>
<tr>
<td><img src="image19" alt="Symbol" /></td>
<td>For use in Slide Supply 2</td>
</tr>
<tr>
<td><img src="image20" alt="Symbol" /></td>
<td>SI Units</td>
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<tr>
<td><img src="image21" alt="Symbol" /></td>
<td>Conventional Units</td>
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<td><img src="image22" alt="Symbol" /></td>
<td>Value</td>
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<tr>
<td><img src="image23" alt="Symbol" /></td>
<td>Range</td>
</tr>
<tr>
<td><img src="image24" alt="Symbol" /></td>
<td>Range of Means</td>
</tr>
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<td><img src="image25" alt="Symbol" /></td>
<td>Midpoint</td>
</tr>
<tr>
<td><img src="image26" alt="Symbol" /></td>
<td>Revised</td>
</tr>
<tr>
<td><img src="image27" alt="Symbol" /></td>
<td>Supersedes</td>
</tr>
<tr>
<td><img src="image28" alt="Symbol" /></td>
<td>Contains Sufficient for &quot;n&quot; Tests</td>
</tr>
<tr>
<td><img src="image29" alt="Symbol" /></td>
<td>in vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td><img src="image30" alt="Symbol" /></td>
<td>Der Grüne Punkt (the Green Dot); Manufacturer follows certain packaging material waste disposal management regulations</td>
</tr>
<tr>
<td><img src="image31" alt="Symbol" /></td>
<td>Estimated within-lab SD</td>
</tr>
<tr>
<td><img src="image32" alt="Symbol" /></td>
<td>Serious Health Hazards</td>
</tr>
<tr>
<td><img src="image33" alt="Symbol" /></td>
<td>Environmental or Aquatic Toxicity</td>
</tr>
<tr>
<td><img src="image34" alt="Symbol" /></td>
<td>Flammable</td>
</tr>
<tr>
<td><img src="image35" alt="Symbol" /></td>
<td>Acute Toxicity</td>
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## Revision History

<table>
<thead>
<tr>
<th>Date of Revision</th>
<th>Version</th>
<th>Description of Technical Changes*</th>
</tr>
</thead>
</table>
| 2023-08-01       | 2.0     | • Warnings and Precautions: Updated Hazard and Precaution statements to align with the new Safety Data Sheets  
• Materials Required but Not Provided: Updated "Anti-SARS-CoV-2 Total Controls" to "Anti-SARS-CoV-2 Total N Controls"  
• Quality Control Material Selection:  
  – Updated "Anti-SARS-CoV-2 Total Controls" to "Anti-SARS-CoV-2 Total N Controls"  
  – Updated "Anti-SARS-CoV-2 Tot Non-reactive" to "Anti-SARS-CoV-2 Tot N Non-reactive"  
  – Updated "Anti-SARS-CoV-2 Tot Reactive" to "Anti-SARS-CoV-2 Tot N Reactive"  
• Corrected the legal manufacturer from Rochester to Pencoed |

* 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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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.

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Pencoed
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United Kingdom

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OrthoCareTechnicalSolutions@
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Distributed in the US by:
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626

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INSTRUCTIONS FOR USE

VITROS Immunodiagnostic Products
Anti-SARS-CoV-2 Total N 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 Products Anti-SARS-CoV-2 Total N test when used on the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

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 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

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N 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 Immunodiagnostic Products Anti-SARS-CoV-2 Total N Control 2 in addition contains: SARS-CoV-2 antibody. Handle as if capable of transmitting infection.

WARNING: Contains 2-Methyl-3-isothiazolone (CAS 2682-20-4)²


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

• 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 detecting total 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 the declaration is terminated or authorization is revoked sooner.

Materials Provided

3 sets of VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Controls 1 and 2 (defibrinated human plasma with anti-microbial agent, 2 mL). Control 1 is non-reactive and Control 2 is reactive.

Materials Required but Not Provided

Pipette, sample containers.

Control Storage 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 Immunodiagnostic Products Anti-SARS-CoV-2 Total N Controls are supplied frozen.
• VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N 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 Immunodiagnostic Products Anti-SARS-CoV-2 Total N Control 1 should generate Non-reactive (negative) results. VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Control 2 should generate Reactive (positive) results. If a control result is out of its specified range, <1.00 S/C for the negative control and ≥1.00 S/C for the positive control,
investigate the cause before reporting patient results. When the condition is corrected, retest the controls and confirm that results are within acceptable limits. Repeat all patient specimens before reporting results for this run.

References


Glossary of Symbols

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td>Do Not Reuse</td>
</tr>
<tr>
<td><img src="image2.png" alt="Image" /></td>
<td>Use by or Expiration Date (Year-Month-Day)</td>
</tr>
<tr>
<td><img src="image3.png" alt="Image" /></td>
<td>Batch Code or Lot Number</td>
</tr>
<tr>
<td><img src="image4.png" alt="Image" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="image5.png" alt="Image" /></td>
<td>Catalog Number or Product Code</td>
</tr>
<tr>
<td><img src="image6.png" alt="Image" /></td>
<td>Caution</td>
</tr>
<tr>
<td><img src="image7.png" alt="Image" /></td>
<td>Keep Dry (Protect from Moisture/Humidity)</td>
</tr>
<tr>
<td><img src="image8.png" alt="Image" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image9.png" alt="Image" /></td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td><img src="image10.png" alt="Image" /></td>
<td>Authorized Representative in the European Community</td>
</tr>
<tr>
<td><img src="image11.png" alt="Image" /></td>
<td>Corrosive</td>
</tr>
<tr>
<td><img src="image12.png" alt="Image" /></td>
<td>Flammable</td>
</tr>
<tr>
<td><img src="image13.png" alt="Image" /></td>
<td>Health Hazards</td>
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Revision History

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<tr>
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<th>Version</th>
<th>Description of Technical Changes*</th>
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<tr>
<td>2023-09-20</td>
<td>1.0</td>
<td>Initial version of Instructions for Use</td>
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* 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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__________________________  __________________________
Signature                      Obsolete Date

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Distributed in the US by:
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626 USA

To obtain a paper copy free of charge contact:
OrthoCareTechnicalSolutions@orthoclinicaldiagnostics.com
1 800 421 3311

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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

This product has not been US FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

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Issued September 2023

Product code: 6174442
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.

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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 the declaration is terminated or authorization is revoked sooner.

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.

Product codes: 6199975, 6199976

Issued July 2021
PGSM1506EU