The Platelia SARS-CoV-2 Total Ab assay is a semi-quantitative in vitro diagnostic test, in a one-step antigen capture format, for the detection of IgM/IgA/IgG antibodies to the SARS-CoV-2 in human serum and plasma (EDTA, heparin, ACD or citrate) specimens.
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1 INTENDED USE

The Platelia SARS-CoV-2 Total Ab assay is a semi-quantitative in vitro diagnostic test, in a one-step antigen capture format, for the detection of IgM/IgA/IgG antibodies to SARS-CoV-2 in human serum and plasma (EDTA, heparin, ACD or citrate) specimens.

This assay is an aid for the diagnosis of patients with symptoms suggestive of infection caused by SARS-CoV-2. In conjunction with clinical presentation and testing with other methods (RT-PCR, CT-Scan, specific detection for anti-SARS-CoV-2 IgM/IgA/IgG antibodies), Platelia SARS-CoV-2 Total Ab can be used to help diagnose COVID-19 disease.

This assay can also be used as a screening tool for detecting the presence of anti-SARS-CoV-2 total antibodies in order to determine individuals' immune status regarding exposure to SARS-CoV-2.

Platelia SARS-CoV-2 Total Ab can be used manually or on automated systems.

2 SUMMARY AND EXPLANATION OF THE TEST

Coronavirus (CoV) is an enveloped virus that contains a single-stranded positive-sense RNA. SARS-CoV-2, formerly known as 2019-nCoV, is a newly emerging coronavirus that mainly affects the respiratory tract that can lead to Severe Acute Respiratory Syndrome (SARS). The underlying disease caused by this virus is named COVID-19. Coronaviruses have been responsible for several outbreaks in the world during the two last decades. In 2003 and 2014, coronaviruses caused outbreaks mainly in Asia (SARS-CoV) and in the Middle East (MERS-CoV), respectively. Before the new SARS-CoV-2 emergence, six coronaviruses were known to affect humans (SARS-CoV, MERS-CoV and four other coronaviruses that cause mild upper and lower respiratory syndromes).

SARS-CoV-2 was first identified in December 2019, in Wuhan City, Hubei Province, China, after several patients developed severe pneumonia similar to that caused by SARS-CoV. The virus has since rapidly spread around the globe and in March 2020, WHO officially announced COVID-19 as a pandemic. Person-to-person transmission of the virus lead to quick spreading of COVID-19 and a high number of patients requiring intensive care urged authorities around the world to set up containment measures. The incubation period ranges from 2 to 14 days.

The virus has been detected in respiratory secretions, considered as the primary means of transmission. Once viral particles enter the respiratory tract, the virus attaches to pulmonary cells via the ACE-2 receptors followed by endocytosis. SARS-CoV-2 can also be transmitted via the fecal route.

Patients positive for SARS-CoV-2 and that are symptomatic are diagnosed with COVID-19. Symptoms can vary drastically and notably include fever, dry cough, anosmia, sputum production, headaches, dyspnea, fatigue, nausea, and diarrhea. While some cases can be asymptomatic, others can lead to acute respiratory distress syndrome (ARDS) and even death.

Diagnosis mainly relies on real-time reverse transcription polymerase chain reaction (RT-PCR) testing of respiratory specimens. However, RT-PCR can lead to false negative results due to low viral loads or unsuitable collection, handling, and storage of swabs (oropharyngeal or nasopharyngeal), or failure during the reaction process. Imagery techniques such as computed tomography (CT) can also be performed and show bilateral multilobar ground-class opacities to aid in diagnosis.

Platelia SARS-CoV-2 Total Ab detects IgM, IgA, and IgG antibodies to SARS-CoV-2. In conjunction with other diagnostic tests it can be used to determine if a patient has been exposed to SARS-CoV-2.
3 PRINCIPLE OF THE PROCEDURE

Platelia SARS-CoV-2 Total Ab is a one-step antigen capture format assay for semi-quantitative detection of total anti-SARS-CoV-2 nucleocapsid antibodies (IgM / IgA / IgG) in human serum or plasma specimens.

- The assay uses a recombinant SARS nucleocapsid Protein in a one-step antigen capture format assay.
- Serum or plasma specimens and controls are pre-diluted. Conjugate (recombinant SARS nucleocapsid Protein coupled with peroxidase) is added to each specimen and then the mixture is incubated one hour at 37°C in wells coated with the recombinant SARS nucleocapsid Protein. During this incubation, if IgM and/or IgG and/or IgA antibodies are present in the specimen, they form a complex between the recombinant SARS-nucleocapsid Protein on the wells and the recombinant SARS-nucleocapsid Protein coupled with peroxidase.
- After a washing step, the presence of immune complex (SARS-nucleocapsid Protein / anti-SARS nucleocapsid antibodies / SARS-nucleocapsid Protein labeled with peroxidase) is demonstrated by distribution of a chromogenic solution initiating a color development reaction.
- After 30 minutes of incubation at room temperature, the enzymatic reaction is stopped by addition of an acid solution. The optical density reading obtained with a spectrophotometer set at 450 / 620 nm is proportional to the amount of antibodies present in the specimen. The presence of anti-SARS-CoV-2 nucleocapsid antibodies in an individual specimen is determined by comparing the optical density reading of the specimen to the optical density of the Cut-off Control.

4 REAGENTS

4.1 Description

<table>
<thead>
<tr>
<th>Identification on label</th>
<th>Description</th>
<th>Presentation/ Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 Microplate</td>
<td>Microplate - 96 wells (12 strips of 8 wells each) sensitized with recombinant nucleocapsid protein of SARS - Specific ID number = 19</td>
<td>1 plate Ready for use 5 plates Ready for use</td>
</tr>
<tr>
<td>R2 Concentrated washing solution (20X)</td>
<td>Concentrated washing solution (20X) - TRIS-NaCl buffer (pH 7.4) - Preservative: 0.04% ProClin 300</td>
<td>1 vial 70 mL To be diluted 1 vial 235 mL To be diluted</td>
</tr>
<tr>
<td>R3 Negative Control</td>
<td>Negative Control - TRIS-NaCl buffer (pH 8 ± 0.1), bovine serum albumin, glycerol - Preservative: 0.1% ProClin 300</td>
<td>1 vial 1.0 mL Ready for use 1 vial 1.0 mL Ready for use</td>
</tr>
<tr>
<td>R4 Cut-off Control</td>
<td>Cut-off Control - TRIS-NaCl buffer (pH 8 ± 0.1), bovine serum albumin, glycerol - Rabbit polyclonal antibodies anti-SARS nucleocapsid - Preservative: 0.1% ProClin 300</td>
<td>1 vial 1.0 mL Ready for use 1 vial 1.0 mL Ready for use</td>
</tr>
<tr>
<td>R5 Positive Control</td>
<td>Positive Control - TRIS-NaCl buffer (pH 8 ± 0.1), bovine serum albumin, glycerol - Rabbit polyclonal antibodies anti-SARS nucleocapsid - Preservative: 0.1% ProClin 300</td>
<td>1 vial 1.0 mL Ready for use 1 vial 1.0 mL Ready for use</td>
</tr>
</tbody>
</table>
### Components

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>R6</td>
<td>Conjugate</td>
<td>Conjugate - Recombinant SARS nucleocapsid protein coupled with horseradish peroxidase - TRIS-NaCl buffer (pH 8 ± 0.1), phenol red - Preservative: 0.5% ProClin 300</td>
</tr>
<tr>
<td>R7</td>
<td>Sample Diluent</td>
<td>Sample Diluent - TRIS-NaCl buffer (pH 8 ± 0.1), phenol red - Preservative: 0.5% ProClin 300</td>
</tr>
<tr>
<td>R8</td>
<td>Substrate buffer</td>
<td>Substrate buffer - Citric acid and sodium acetate solution pH 4.0, containing hydrogen peroxide (H₂O₂ 0.015%) and dimethyl sulfoxide (DMSO 4%)</td>
</tr>
<tr>
<td>R9</td>
<td>Chromogen: TMB solution (11X)</td>
<td>Chromogen: TMB solution - Solution containing 3.3', 5.5' tetramethylbenzidine (TMB)</td>
</tr>
<tr>
<td>R10</td>
<td>Stopping solution</td>
<td>Stopping Solution - Sulphuric acid solution (H₂SO₄ 1N)</td>
</tr>
</tbody>
</table>

### 4.2 Storage and handling requirements

This kit should be stored at +2-8°C. Open reagents must be stored according to the instructions below.

<table>
<thead>
<tr>
<th>Identification</th>
<th>Preservation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>After opening the vacuum-sealed bag, store the microwell strips at +2-8°C for up to 4 weeks, in their original bag with desiccant resealed with tape.</td>
</tr>
<tr>
<td>R2</td>
<td>The diluted washing solution can be stored at +2-30°C for 2 weeks. The concentrated washing solution (R2) can be stored at +2-30°C until the expiration date. If opened, the concentrated washing solution (R2) can be stored at +2-8°C until the expiration date, in the absence of contamination.</td>
</tr>
<tr>
<td>R3, R4, R5, R6, R7, R8, R9</td>
<td>After opening, these reagents stored at +2-8°C, are stable for 4 weeks, in the absence of contamination.</td>
</tr>
<tr>
<td>R8 + R9</td>
<td>Once diluted, the solution is stable for up to 6 hours in the dark at +18-30°C.</td>
</tr>
<tr>
<td>R10</td>
<td>After this reagent stored at +2-8°C is opened, it is stable until the validity date shown on the label if there is no contamination.</td>
</tr>
</tbody>
</table>

### 5 WARNING AND PRECAUTIONS

For in vitro diagnostic use by a professional user in a laboratory environment only.

#### 5.1 Health and safety precautions

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
No known test method can offer complete assurance that infectious agents are absent. Therefore, all human blood derivatives, reagents and human specimens should be handled as if capable of transmitting infectious disease, following recommended Universal Precautions for bloodborne pathogens as defined by local, regional and national regulations.

Biological spills: Human source material spills should be treated as potentially infectious. Spills not containing acid should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment, with an appropriate chemical disinfectant that is effective for the potential biohazards relative to the specimens involved (commonly a 1:10 dilution of household bleach, 70-80% Ethanol or Isopropanol, an iodophor such as 0.5% Wescodyne™ Plus, etc.), and wiped dry. Spills containing acid should be appropriately absorbed (wiped up) or neutralized, the area flushed with water and wiped dry; materials used to absorb the spill may require biohazardous waste disposal. Then the area should be decontaminated with one of the chemical disinfectants.

**REMARK:** Do not place solutions containing bleach into the autoclave!

Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or biohazardous wastes must be handled and discarded in accordance with all local, regional and national regulations.

For hazard and precaution recommendations related to some chemical components in this test kit, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instruction for use. The Safety Data Sheet is available on www.bio-rad.com.

5.2. **Precautions related to the procedure**

5.2.1. **Preparing**

- DO NOT USE the kit if the packaging of components is damaged.
- DO NOT USE expired reagents.
- DO NOT USE if desiccant is absent inside microplate bag.
- Before use, wait for 30 minutes for the reagents to stabilize at room temperature (18-30°C).
- Carefully reconstitute the reagents avoiding any contamination.
- The use of disposable material is preferred for preparation of reagents. If using glassware, wash thoroughly and rinse with deionized water.
- Do not mix or associate reagents from different lots within a test run.
- Do not allow the microplate to dry between the end of the washing operation and the reagent distribution.
- The name of the test, as well as a specific identification number for the test, are written on the frame of each microplate. This specific identification number is stated on each strip too.

**Platelia SARS-CoV-2 Total Ab: Specific ID number = 19**

Verify the specific identification number before use. If the identification number is missing, or different from the stated number corresponding to the assay to be tested, the strip should not be used.

- Do not mix reagents from other kits that have different lot numbers, with the exception of the Washing Solution (R2, identification*: 20x coloured green), the peroxidase Substrate Buffer (R8, identification*: TMB buf., coloured blue), the Chromogen (R9, identification*: TMB 11X coloured purple) and the Stopping Solution (R10, identification*:1N coloured red), provided that these reagents are strictly equivalent and that the same lot number is used within a given test run.

**REMARK:** The Washing Solution (R2, identified* in green as 20X) may not be mixed with the Washing Solution (R2 identified* in blue as 10X) provided in Bio-Rad reagent kits.

*on the vial label.

- Preparation of the development solution or the conjugate working solution must be made in a clean plastic tray or glass container. Single use plastic containers are recommended. When using reusable plastic container, they can be cleaned by overnight soaking with distilled water or washing solution. When using glass container, they can be washed with 1N HCl and rinsed thoroughly with distilled water and dried.
- The development solution must be stored in the dark.
- The development solution (substrate buffer + chromogen) must be coloured pink. The modification of this pink colour within a few minutes of reconstitution indicates that the reagent cannot be used and
must be replaced. Preparation of the development solution can be made in a clean disposable single use plastic tray or glass container that has first been pre-washed with 1N HCl and rinsed thoroughly with distilled water and dried. This reagent must be stored in the dark.

- The specimen distribution must begin immediately after the conjugate distribution. Waiting time between the dispensing of the conjugate and the specimens should not exceed 30 minutes.
- The enzyme reaction is very sensitive to metal ions. Consequently, do not allow any metal element to come into contact with the various conjugate or substrate solutions.
- Never use the same container to distribute conjugate and development solution.

5.2.2. Processing

- Do not change the assay procedure.
- Each run of this assay must proceed to completion without interruption after it has been started. A delay shorter than 5 min between two steps is acceptable.
- Check the pipettes and other equipment for accuracy and correct operation.
- Do not carry out the test in the presence of reactive vapours (acid, alkaline, aldehyde vapours) or dust that could alter the enzymatic activity of the conjugate.
- Use a new distribution tip for each specimen.
- Microplate washing is a critical step in this procedure: follow the recommended number of washing cycles and make sure that all wells are completely filled and then completely emptied. Incorrect washing may lead to inaccurate results.
- Carefully follow the washing procedures described to obtain maximum test performance. With some instruments, it could be necessary to optimize the washing procedure (increase of number of cycles of washing step and/or volume of wash buffer for each cycle) to obtain an acceptable level of OD background for the negative specimens.
- Contact your local commercial contact for the adaptations and special procedures.

6 SPECIMENS

1. The test is performed on serum or plasma specimens collected in EDTA, heparin, ACD or citrate anticoagulants.
2. Comply with the following guidelines for handling, processing and storing of blood specimens:
   - Collect a blood specimen according to standard laboratory procedures. For serum, allow specimens to clot completely before centrifugation.
   - Keep tubes sealed at all times.
   - After centrifugation, extract the serum or plasma and keep it in a sealed tube.
   - The specimens can be stored at +2-8°C if the test is performed within 4 days.
   - If the test cannot be completed within 4 days, freeze the specimens at -20°C (or -80°C.)
   - Serum or plasma specimens can be subjected to a maximum of 1 freezing/thawing cycle. Previously frozen specimens should be thoroughly mixed after thawing prior to testing.
3. The results are not affected by proteinemic specimens containing 90 g/l albumin, icteric specimens containing 100 mg/l bilirubin, lipemic specimen containing the equivalent of 36 g/l triolein (triglyceride), and hemolysed specimens containing up to 10 g/l of haemoglobin.
4. Do not heat the specimens.

7 PROCEDURE

7.1 Materials required but not provided

1. Sterile distilled or demineralized water to dilute the concentrated washing solution.
2. Sodium hypochlorite (household bleach) and sodium bicarbonate.
3. Absorbent paper.
5. Protective goggles.
6. Disposable tubes.
7. Automatic or semiautomatic, adjustable or preset pipettes or multipipettes to measure and dispense 10 µL to 1000 µL, 1 mL, 2 mL and 10 mL.
8. Graduated cylinders of 25 mL, 50 mL, 100 mL and 1000 mL capacity. Vortex mixer.
9. Manual microplate washing system, water-bath, or equivalent microplate incubator, thermostatically set at 37°C ± 1°C (*).
10. Microplate reader or full automated system equipped with 450 and 620 nm filters (*).
11. Container for biohazardous waste

(*) Consult us for detailed information about the equipment recommended by our technical department

7.2 Reagents preparation

7.2.1 Ready for use reagents

Reagent 1 (R1): Microplate
Each frame support containing 12 strips is wrapped in a sealed bag. Cut the bag using scissors 0.5 to 1 cm above the sealing. Open the bag and take out the frame. Put the unused strips back with desiccant into the bag. Close the bag carefully and put it back into storage at +2-8°C

These reagents are ready for use.

7.2.2 Reagents to reconstitute

Reagent 2 (R2): Concentrated washing solution (20X)
Prepare the working Washing Solution by diluting the Concentrated washing solution 1:20 in distilled water: 50 mL of R2 in 950 mL of distilled water. Use 800 mL of working Washing Solution for one complete 12 strip microplate, excluding dead volume due to the equipment used.

Reagent 8 (R8) + Reagent 9 (R9): Enzyme development solution
Dilute 1:11 the Chromogen (R9) in the Substrate Buffer (R8) (e.g. 2 mL reagent R9 + 20 mL of R8 reagent) given that 20 mL are necessary and sufficient for 12 strips. Homogenize.

7.3 Assay Procedure

i. Strictly follow the procedure and Good Laboratory Practice.

• EIA Procedure

1. Bring reagents to room temperature (+18-30°C) for at least 30 minutes before use.
2. Use the Negative and Positive Controls with each run to validate the results.
3. Carefully set up the plan for distributing and identifying the controls and the patient specimens.
4. Prepare the dilution of the Washing Solution (R2) (Refer to section 7.2)
5. In an inert pre-dilution microplate, dilute Controls R3, R4, R5 and test specimens E1, E2, in R7 to
give a 1:5 dilution:
- Distribute 60 µL of R7, then add 15 µL of specimen in each well.
- Add 75 µL of Conjugate solution (R6) to all the wells of the pre-dilution microplate
- Mix by aspirating and rejecting once, then transfer immediately 100 µL of the pre-diluted controls and specimens to the wells of the reaction microplate (R1).

6. Cover the reaction microplate with an adhesive plate sealer, pressing firmly onto the plate to ensure a tight seal. Incubate the microplate in a thermostat controlled water bath or microplate incubator for 60 minutes (+/- 5 min) at 37°C (+/- 2°C).

7. Prepare the enzyme development solution (R8+R9) (Refer to section 7.2)

8. At the end of incubation period, remove the adhesive plate sealer. Aspirate the contents of all wells into a container for biohazard waste (containing sodium hypochloride). Wash the plate 5 times with a microplate washer (using 800 µL of Working Washing Solution). Invert microplate and gently tap on absorbent paper to remove remaining liquid.

9. Quickly distribute into each well 200 µL of the development solution (R8+R9). Allow the reaction to develop in the dark for 30 minutes (+/- 4 min) at room temperature (+18-30°C). Do not use adhesive plate sealer during this incubation step.

10. Add 100 µL of Stopping Solution (R10) to each well, using in the same order and at the same rate as for the addition of the development solution. Mix thoroughly

11. Carefully wipe the plate bottom.

12. Read the optical density of each well at 450 nm (reference filter at 620 nm) within 30 minutes after addition of the Stopping Solution (the strips must always be kept away from light before reading).

13. Before reporting results, check for agreement between the reading and the distribution plan of the plates.

7.4 Quality Control
Use the controls on each microplate every time the test is performed.

7.5 Test Validation criteria
Calculate the mean value of the optical densities of the cut-off control R4: ODₘₐₓ.
If one of the cut-off control R4 individual values differs by more than 30% from the mean value, disregard the value and carry out the calculation again with the two remaining positive control values.

<table>
<thead>
<tr>
<th>Validation criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>R4</td>
</tr>
<tr>
<td>The ODₘₐₓ R4 must be: 0.5 &lt; ODₘₐₓ R4 &lt; 1.4</td>
</tr>
<tr>
<td>R₃ / R₄</td>
</tr>
<tr>
<td>The ratio (OD R₃ / ODₘₐₓ R₄) must be ≤ 0.25</td>
</tr>
<tr>
<td>R₅ / R₄</td>
</tr>
<tr>
<td>The ratio (OD R₅ / ODₘₐₓ R₄) must be ≥ 1.1</td>
</tr>
</tbody>
</table>

7.6 Calculation / Interpretation of the results
The cut-off value ODₘₐₓR₄ corresponds to the mean value of the optical densities of the cut-off control R4.
Specimen results are expressed by ratio using the following formula: Specimen ratio = Specimen OD / ODₘₐₓR₄.

Interpretation of results
- Specimen ratio less than 0.8 is considered to be «negative» for the presence of anti-SARS-CoV-2 antibodies.
- Specimen ratio equal or more than 0.8 but less than 1.0 is considered to be «equivocal» for the presence of anti-SARS-CoV-2 antibodies. Another specimen should be collected and tested few days later.
- Specimen ratio equal or more than 1.0 is considered to be «positive» for the presence of anti-SARS-CoV-2 antibodies.
8 TEST LIMITATION

1. Clinical diagnosis of COVID-19 should not be established based on a single test result. Follow-up and supplemental testing as well as other clinical and laboratory data should be considered.

2. The detection of anti-SARS-CoV-2 antibodies in serum or plasma is linked to the frequency of the tests performed on the patients. In order to increase the sensitivity and the earliness of the test positivity, a regular monitoring of patients suspected to be infected by SARS-CoV-2 should be performed.

3. The detection of anti-SARS-CoV-2 antibodies is dependent on the presence of the analyte in the specimen. 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. During the acute infection phase and/or for immunosuppressed patients, anti-SARS-CoV-2 antibodies might not be detectable while the individual is infected by SARS-CoV-2. Thus, a negative result is not an evidence for the absence of COVID-19 infection.

4. Performance characteristics of Platelia SARS-CoV-2 Total Ab have not been evaluated with specimens of serum or plasma originating from newborns or pediatric patients.

5. Platelia SARS-CoV-2 Total Ab assay can detect total antibodies specific to SARS-CoV-1 and to SARS-CoV-2 without any differentiation.

9 PERFORMANCES CHARACTERISTICS

Performances presented here below have been obtained during Platelia SARS-CoV-2 Total Ab assay evaluations. Results obtained in laboratories can be different than these.

9.1 Analytical Performance Characteristics

Analytical studies were carried out at the Bio-Rad R&D laboratory.

9.1.1 Precision measurement

Intra-assay precision (Repeatability)

3 positive specimens and 1 negative specimen were assayed 30 times in the same run. Within-run CV are below 10% for the negative specimen and below 5% for all the positive specimens.

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>N</th>
<th>Mean Ratio</th>
<th>SD</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>30</td>
<td>0.05</td>
<td>0.004</td>
<td>7,1%</td>
</tr>
<tr>
<td>Positive 1</td>
<td>30</td>
<td>1.15</td>
<td>0.038</td>
<td>3,3%</td>
</tr>
<tr>
<td>Positive 2</td>
<td>30</td>
<td>1.54</td>
<td>0.055</td>
<td>3,6%</td>
</tr>
<tr>
<td>Positive 3</td>
<td>30</td>
<td>2.36</td>
<td>0.095</td>
<td>4,0%</td>
</tr>
</tbody>
</table>
Intermediate precision (Inter-assay)

The same specimens were assayed in 10 separate runs over 6 days. Nested ANOVA was used to estimate within run, between run, between days and total precision.

Between-run CV are below 30% for the negative specimen and below 10% for all the positive specimens

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>N</th>
<th>Mean Ratio</th>
<th>Repeatability</th>
<th>Between run</th>
<th>Between day</th>
<th>Within Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>SD</td>
<td>CV%</td>
<td>SD</td>
<td>CV%</td>
</tr>
<tr>
<td>Negative</td>
<td>20</td>
<td>0.05</td>
<td>0.005</td>
<td>10.9%</td>
<td>0.009</td>
<td>20.0%</td>
</tr>
<tr>
<td>Positive 1</td>
<td>20</td>
<td>1.26</td>
<td>0.046</td>
<td>3.6%</td>
<td>0.026</td>
<td>3.2%</td>
</tr>
<tr>
<td>Positive 2</td>
<td>20</td>
<td>1.77</td>
<td>0.053</td>
<td>3.0%</td>
<td>NA</td>
<td>6.9%</td>
</tr>
<tr>
<td>Positive 3</td>
<td>20</td>
<td>2.52</td>
<td>0.065</td>
<td>2.6%</td>
<td>0*</td>
<td>3.5%</td>
</tr>
</tbody>
</table>

Note: (*) The negative variance value is estimated at 0.

9.1.2 Analytical Specificity / Cross Reactivity

Cross-reactivity has been evaluated by testing SARS-CoV-2 seronegative specimens from patients with antibodies to other coronaviruses or medical conditions. There was no cross-reactivity (false positive results) seen with the Platelia SARS-CoV-2 Total Ab assay in any of the specimens that were tested.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Number tested</th>
<th>Nonreactive</th>
<th>Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>anti-229E (alpha coronavirus)</td>
<td>6</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>anti-NL63 (alpha coronavirus)</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>anti-OC43 (beta coronavirus)</td>
<td>13</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>anti-HKU1 (beta coronavirus)</td>
<td>7</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Anti-influenza vaccine</td>
<td>15</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>anti-Mycoplasma pneumoniae</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>anti-VZV</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>anti-HSV</td>
<td>9</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>anti-EBV</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Rheumatoid factor</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Influenza A infection</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>RSV infection</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

1 One patient was co-infected with CovHKU1 + INF A and one patient was co-infected with CoVHKU1 + RSV

9.1.3 Hook Effect

A positive specimen with high titer of anti-coronavirus Ab was serially diluted and was tested neat and diluted with the Platelia SARS-CoV-2 Total Ab assay. No negative results were observed on the neat specimen. A decrease of signal with the test of diluted specimens was observed.
No hook effect is observed on the Platelia SARS-COV-2 Total Ab assay with the test of a high positive specimen.

9.2 Clinical Performance Characteristics

The clinical performance of the Platelia SARS-CoV-2 Total Ab was assessed during a multi evaluation on specimens obtained from a general asymptomatic population of pre-epidemic individuals (blood donors, hospitalized patients) and on patients with clinical symptoms of coronavirus COVID-19 tested positive with RT-PCR assay. Both prospective and retrospective studies on asymptomatic populations and on selected infected patients were conducted.

9.2.1 Diagnostic Specificity

A total of 687 specimens (620 from blood donors and 67 from hospitalized asymptomatic patients) collected prior to the outbreak of the COVID-19 pandemic, were tested. The specificity was 99.56% (684/687) (95% confidence interval of 98.72-99.85%).

9.2.2 Diagnostic Sensitivity

A longitudinal study was performed on 51 patients (133 specimens) in the intensive care unit at 3 hospitals with clinical symptoms of COVID-19 and with a PCR positive result.

Between 2 and 5 specimens per patient were collected from 2 to 42 days post onset of clinical symptoms. When specimens were collected at >8 days after the onset of symptoms, 39 patients in the longitudinal study demonstrated a positive result with the Platelia SARS-CoV-2 assay for one or more specimens that were tested. For each patient that had a positive result, the table below summarizes when the first positive result was observed.

<table>
<thead>
<tr>
<th>Days between onset of symptoms and sample collection</th>
<th>First Reactive draw for Patient</th>
<th>Nonreactive Patient</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤8 days</td>
<td>8</td>
<td>3(^1)</td>
<td>11</td>
<td>73%</td>
</tr>
<tr>
<td>9-10 days</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>100%</td>
</tr>
<tr>
<td>11-20 days</td>
<td>30</td>
<td>1(^2)</td>
<td>31</td>
<td>97%</td>
</tr>
<tr>
<td>21-42 days</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>100%</td>
</tr>
<tr>
<td>Total</td>
<td>47</td>
<td>4</td>
<td>51</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) No additional specimens after 8 days were available to follow immune response for these patients.

\(^2\) No additional specimens after 18 days were available to follow immune response for this patient.

Seventy-three (73)% of patients were positive at less than 8 days after onset of symptoms, and 97% were positive when specimens were collected more than 8 days after onset of symptoms. The 3 patients that were negative at ≤8 days and the one patient that was negative at 18 days were not tested further to assess an immune response.

Immune response is expected to build at > 7 days (Zhao et al., 2020)\(^7\).

In this study, 39/40 patients turned positive >8 and ≤42 days post onset of symptoms. Sensitivity for PCR positive patients tested at >8 days is 97.5% (39/40) with a 95%CI [86.8%-99.9%].
(BG) опасно

(CZ) Nebezpečí

(DE) Gefahr

(DK) Fare

(EE) Ettevaatust

(EN) Danger
Causes severe skin burns and eye damage. May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. Dispose of contents/container in accordance with local/ regional/national/international regulations.

(FI) Vaara

(FR) Danger

(GR) Κίνδυνος
Προκαλεί σοβαρά δερματικά εγκαύματα και οφθαλμικές βλάβες. Μπορεί να προκαλέσει αλλεργική δερματική αντίδραση. Επιβλητές για τους υδροψίους οργανισμούς, με μακροχρόνιες επιπτώσεις. Να αποφεύγεται η ελευθέρωση στο περιβάλλον. Να φοράτε προστατευτικά γάντια/προστατευτικά ενδύματα/μέσα ατμοκηπίων/προστασίας για το μάτι/πρόσωπο. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΑ ΜΑΤΙΑ: Ξεπλύνετε προσεκτικά με νερό για αρκετά λέπτα. Εάν υπάρχουν φακοί επαφής, αφαιρέστε τους. Εφόσον είναι εύκολο, συνεχίστε να ξεπλύνετε. ΣΕ ΠΕΡΙΠΤΩΣΗ ΚΑΤΑΠΟΣΗΣ: Ξεπλύνετε το σώμα. ΜΗΝ προκαλείστε εμετό. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΟ ΔΕΡΜΑ (ή με τα μαλλιά): Αφαιρέστε αμέσως όλα τα μαλλιά ενδύματα. Ξεπλύνετε το δέρμα με νερό/στεγάζετε τους. Εάν παρατηρηθεί ερεθισμός του δέρματος ή εμφανιστεί
Pavojinga


Briesmas


Opasnost


Pericoło


(PT)
Perigo

(RO)
Pericol
Fara

(NL)
Nevarmo
Povzroča hude opekline kože in poškodbe oči. Lahko povzroči alergijski odziv kože. Škodljivo za vodne organizme, z dolgotrajnimi učinki.

(SK)
Nebezpečenstvo
Provocá arsuri grave ale prielis železara ochilor. Môže vyvoláť alergickú kožnú reakciu. Škodlivý pre vodné organizmy, s dlhodobými účinkami.