Platelia SARS-CoV-2 Total Ab

1 plate - ▽ 96 REF 72710

5 plates - ▽ 480 REF 12013798

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.

IVD CE

16008267 – 2020/06

BIO-RAD

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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

Identification on label		Description	Presentation/ Preparation	
R1	**Microplate**	**Microplate** - 96 wells (12 strips of 8 wells each) sensitized with recombinant nucleocapsid protein of SARS - Specific ID number = 19	1 plate **Ready for use**	5 plates **Ready for use**
R2	**Concentrated washing solution (20X)**	**Concentrated washing solution (20X)** - TRIS-NaCl buffer (pH 7,4) - Preservative: 0.04% ProClin 300	1 vial 70 mL **To be diluted**	1 vial 235 mL **To be diluted**
R3	**Negative Control**	**Negative Control** - TRIS-NaCl buffer (pH 8 ± 0.1), bovine serum albumin, glycerol - Preservative: 0.1% ProClin 300	1 vial 1.0 mL **Ready for use**	1 vial 1.0 mL **Ready for use**
R4	**Cut-off Control**	**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	1 vial 1.0 mL **Ready for use**	1 vial 1.0 mL **Ready for use**
R5	**Positive Control**	**Positive Control** - TRIS-NaCl buffer (pH 8 ± 0.1), bovine serum albumin, glycerol - Rabbit polyclonal antibodies anti-SARS nucleocapsid - Preservative: 0.1% ProClin 300	1 vial 1.0 mL **Ready for use**	1 vial 1.0 mL **Ready for use**

R6	**Conjugate**	**Conjugate** - Recombinant SARS nucleocapsid protein coupled with horseradish peroxidase - TRIS-NaCl buffer (pH 8 ± 0.1), phenol red - Preservative: 0.5% ProClin 300	1 vial 9 mL **Ready for use**	2 vials 23 mL **Ready for use**
R7	**Sample Diluent**	**Sample Diluent** - TRIS-NaCl buffer (pH 8 ± 0.1), phenol red - Preservative: 0.5% ProClin 300	1 vial 12 mL **Ready for use**	2 vials 23 mL **Ready for use**
R8	**Substrate buffer**	**Substrate buffer** Citric acid and sodium acetate solution pH 4.0, containing hydrogen peroxide (H_2O_2 0.015%) and dimethyl sulfoxide (DMSO 4%)	1 vial 60 mL **To be reconstituted**	2 vials 60 mL **To be reconstituted**
R9	**Chromogen: TMB solution (11X)**	**Chromogen: TMB solution** Solution containing 3.3', 5.5' tetramethylbenzidine (TMB)	1 vial 5 mL **To be reconstituted**	2 vials 5 mL **To be reconstituted**
R10	**Stopping solution**	**Stopping Solution** Sulphuric acid solution (H_2SO_4 1N)	1 vial 28 mL **Ready for use**	3 vials 28 mL **Ready for use**

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.

Identification	**Preservation**
R1	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.
R2	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.
R3, R4, R5, R6, R7, R8, R9	After opening, these reagents stored at +2-8°C, are stable for 4 weeks, in the absence of contamination.
R8 + R9	Once diluted, the solution is stable for up to 6 hours in the dark at +18-30°C.
R10	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.

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., couloured 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, lithium heparin, ACD or sodium 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 7 days.
   - If the test cannot be completed within 7 days, freeze the specimens at -20°C (or -80°C.)
   - Serum or plasma specimens can be subjected to a maximum of 5 freezing/ thawing cycles. 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.
4. Adhesive film.
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

Reagent 3 (R3): Negative Control, Reagent 4 (R4): Cut-off Control, Reagent 5 (R5): Positive Control, Reagent 6 (R6): Conjugate, Reagent 7 (R7): Sample Diluent
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

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.

	1	2	3	4	5	6	7	8	9	10	11	12
A	**R3**	**E4**										
B	**R4**	**E5**										
C	**R4**	**E6**										
D	**R4**	**E7**										
E	**R5**	**E8**										
F	**E1**	**E9**										
G	**E2**	**E10**										
H	**E3**	**E11**										

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).

   Depending on the used system, it's possible to modify the position of controls or the order of distribution, provided the modification has been first validated.
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: OD_M.

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 cut-off control values.

	Validation criteria
R4	The OD_M **R4** must be: 0.5 < OD_M **R4** < 1.4
R3 / R4	The **ratio (OD R3 /** OD_M **R4)** must be ≤ 0.25
R5 / R4	The **ratio (OD R5 /** OD_M **R4)** must be ≥ 1.1

7.6 Calculation / Interpretation of the results

The cut-off value $OD_M R4$ 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 / $OD_M R4$.

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**.

Specimen Ratio	Result
R < 0.8	Negative
0.8 ≤ R < 1.0	Equivocal
R ≥ 1.0	Positive

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

Intermediate precision

3 positive specimens and 1 negative specimen were assayed in duplicates by 2 different operators per day during 5 days. Nested ANOVA was used to estimate within run, between run, between days and total precision.

The CVs obtained on the positive specimens are less than or equal to 10% for repeatability and less than or equal to 15% for intermediate precision.

Specimen ID	N	Mean Ratio	Repeatability		Between run		Between day		Within Laboratory	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Negative	20	0,08	0,002	2,3%	0,021	25,9%	0,006	6,9%	0,021	26,9%
Positive 1	20	1,33	0,074	5,5%	0,020	1,5%	0,019	1,4%	0,079	5,9%
Positive 2	20	2,59	0,050	1,9%	0,089	3,4%	0,068	2,6%	0,122	4,7%
Positive 3	20	3,34	0,065	2,0%	0,108	3,2%	0*	NA	0,127	3,8%

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

9.1.2 Analytical Specificity / Cross Reactivity

Cross-reactivity has been evaluated by testing 168 SARS-CoV-2 seronegative specimens from patients positive for 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.

Analyte	Number tested	Non Reactive	Reactive
CoV 229E (alpha-coronavirus)	6	6	0
CoV NL63 (alpha-coronavirus)	5	5	0
CoV HKU1 (beta-coronavirus)	5	5	0
CoV OC43 (beta-coronavirus)	13	13	0
Adenovirus	2	2	0
INF A H1 N1	1[1]	1[1]	0
INF A H3N2	2	2	0
Influenza	10	10	0
Flu Vaccine	15	15	0
Metapneumovirus	3	3	0
Metapneumovirus Ab	5	5	0
ParaInfluenza 1	2	2	0
ParaInfluenza 2	1	1	0
ParaInfluenza 3	2	2	0
ParaInfluenza 4	1	1	0
Parainfluenza Virus Ab	5	5	0
Rhinovirus/Enterovirus	2	2	0
RSV (Respiratory syncytial virus)	3[1]	3[1]	0
RSV Ab	5	5	0
HIV Ab	5	5	0
HCV Ab	5	5	0
HBV	5	5	0
CMV IgG	5	5	0
CMV IgM	5	5	0
EBV IgG	5	5	0
EBV IgM	5	5	0
Malaria IgG	5	5	0
Dengue Ab	5	5	0
Rheumatoid Factor	5	5	0

HAMA	5	5	0
ANA	5	5	0
Pregnant Women	5	5	0
Anti-*E. Coli*	5	5	0
Mycoplasma pneumoniae IgG	5	5	0
Candida albicans IgG	5	5	0

[1] One patient was co-infected with CovHKU1 + INF A and one patient was co-infected with CoVHKU1 + RSV
The specificity on this target population is 100% (168/168) with a 95% Confidence Interval of [97.8%-100%].

9.1.3 Hook Effect

Three (3) high positive specimens were serially diluted and were tested neat and diluted with the Platelia SARS-CoV-2 Total Ab assay.
Whatever the specimens, no negative result was observed on non-diluted specimens and no hook effect was observed during the dilution of the 3 specimens.

No hook effect is observed on the Platelia SARS-COV-2 Total Ab assay with the test of 3 high positive specimens.

9.2 Clinical Performance Characteristics

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

9.2.1 Diagnostic Specificity

A total of 600 specimens (500 from blood donors and 100 from hospitalized asymptomatic patients) collected prior to the outbreak of the COVID-19 pandemic, were tested. The specificity was **99.3% (596/600) with a 95% Confidence Interval at [98.3% – 99.8%].**

9.2.2 Diagnostic Sensitivity

A longitudinal study was performed on 50 patients (127 specimens) hospitalized in intensive care units in 3 French hospitals with clinical symptoms of COVID-19 and with a PCR positive result.

One to five consecutive specimens were collected per patient from 2 to 92 days post onset of clinical symptoms. Results were analyzed for each patient to determine the first sample that was SARS-CoV-2 total antibody positive.

The table below summarizes when the first positive result was observed for each patient relative to day between onset of symptoms and specimen collection

Day range between onset of symptoms and specimen collection	First positive draw for Patient	Negative Patient	Total	%
2-8 days	11	1[1]	12	92%
9-15 days	30	0	30	100%
16-22 days[2]	8	0	8	100%

[1] No additional specimens after 8 days were available to follow immune response for these patients.

[2:] All patients turned positive within 22 days and their positive status was confirmed when the subsequent specimens were drawn beyond 22 days.

Ninety two, 92% (11/12) of patients turn positive between 2 to 8 days after onset of symptoms, **and 100% (38/38) were positive when specimens were collected more than 8 days after onset of symptoms**. The patient who was negative at ≤8 days was also negative with another serological predicate assay and was not tested further to assess an immune response.

According to current publications, immune response is expected to build at > 7 days (Zhao et al., 2020)[7].

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(BG) • Този продукт съдържа човешки или животински компоненти. Бъдете внимателни при работа с него.

(CZ) • Tento výrobek obsahuje lidské nebo zvířecí komponenty. Zacházejte s ním opatrně.

(DE) • Dieses Produkt enthält Bestandteile menschlichen oder tierischen Ursprungs. Vorsichtig handhaben.

(DK) • Dette produkt indeholder humane og animalske komponenter. Skal behandles med forsigtighed.

(EE) • Käesolev toode sisaldab inim-või loomseid komponente. Käsitseda ettevaatlikult.

(EN) • This product contains human or animal components. Handle with care.

(ES) • Este producto contiene componentes humanos o animales. Manejar con cuidado.

(FI) • Tässä tuotteessa on ihmisestä tai eläimistä peräisin olevia osia. Käsittele varovasti.

(FR) • Ce produit contient des composants d'origine humaine ou animale. Manipuler avec précaution.

(GR) • Αυτό το προϊόν περιέχει ανθρώπινα ή ζωικά στοιχεία. Χειριστείτε το με προσοχή.

(HR) • Ovaj proizvod sadrži ljudske ili životinjske sastojke. Pažljivo rukovati.

(HU) • A készítmény emberi vagy állati eredetű összetevőket tartalmaz. Óvatosan kezelendő.

(IT) • Questo prodotto contiene componenti umane o animali. Maneggiare con cura.

(LT) • Šiame produkte yra žmogiškosios arba gyvūninės kilmės sudėtinių dalių. Elgtis atsargiai.

(LV) • Šis produkts satur cilvēkiem vai dzīvniekiem paredzētas sastāvdaļas. Apieties uzmanīgi.

(NL) • Dit product bevat menselijke of dierlijke bestanddelen. Breekbaar.

(NO) • Dette produktet inneholder humane eller animalske komponenter. Håndteres med forsiktighet.

(PL) • Niniejszy produkt zawiera składniki pochodzenia ludzkiego lub zwierzęcego. Należy obchodzić się z nim ostrożnie.

(PT) • Este medicamento contém componentes de origem humana ou animal. Manuseie com cuidado.

(RO) • Acest produs conține materiale de origine umană sau animală. Manevrați-l cu grijă.

(SE) • Denna produkt innehåller beståndsdelar från människa eller djur. Hantera produkten varsamt.

(SL) • Izdelek vsebuje človeške ali živalske sestavine. Rokujte previdno.

(SK) • Tento výrobok obsahuje ľudské alebo zvieracie zložky. Narábajte s ním opatrne.

H314 - H317 - H412

P273 - P280
P305+P351+P338
P301+P330+P331
P303+P361+P353
P333+P313 - P501

(BG)
опасно
Причинява тежки изгаряния на кожата и сериозно увреждане на очите. Може да причини алергична кожна реакция. Вреден за водните организми, с дълготраен ефект. Да се избягва изпускане в околната среда. Използвайте предпазни ръкавици/предпазно облекло/предпазни очила/предпазна маска за лице. ПРИ КОНТАКТ С ОЧИТЕ: Промивайте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако има такива и доколкото това е възможно. Продължавайте да промивате. ПРИ ПОГЛЪЩАНЕ: изплакнете устата. НЕ предизвиквайте повръщане. ПРИ КОНТАКТ С КОЖАТА (или косата): Незабавно свалете цялото замърсено облекло. Облейте кожата с вода/вземете душ При поява на кожно дразнене или обрив на кожата: Потърсете медицински съвет/помощ. Изхвърлете съдържанието/контейнера в съответствие с местните/регионалните/националните/международните разпоредби.

(CZ)
Nebezpečí
Způsobuje těžké poleptání kůže a poškození očí. Může vyvolat alergickou kožní reakci. Škodlivý pro vodní organismy, s dlouhodobými účinky.
Zabraňte uvolnění do životního prostředí. Používejte ochranné rukavice/ochranný oděv/ochranné brýle/obličejový štít. PŘI ZASAŽENÍ OČÍ: Několik minut opatrně vyplachujte vodou. Vyjměte kontaktní čočky, jsou-li nasazeny a pokud je lze vyjmout snadno. Pokračujte ve vyplachování. PŘI POŽITÍ: Vypláchněte ústa. NEVYVOLÁVEJTE zvracení. PŘI STYKU S KŮŽÍ (nebo s vlasy): Veškeré kontaminované části oděvu okamžitě svlékněte. Opláchněte kůži vodou/osprchujte. Při podráždění kůže nebo vyrážce: Vyhledejte lékařskou pomoc/ošetření. Obsah/nádobu likvidujte v souladu s místními/regionálními/národními/mezinárodními předpisy.

(DE)
Gefahr
Verursacht schwere Verätzungen der Haut und schwere Augenschäden. Kann allergische Hautreaktionen verursachen. Schädlich für Wasserorganismen, mit langfristiger Wirkung.
Freisetzung in die Umwelt vermeiden. Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen. BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. BEI VERSCHLUCKEN: Mund ausspülen. KEIN Erbrechen herbeiführen. BEI KONTAKT MIT DER HAUT (oder dem Haar): Alle beschmutzten, getränkten Kleidungsstücke sofort ausziehen. Haut mit Wasser abwaschen/duschen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. Entsorgung des Inhalts / des Behälters gemäß den örtlichen / regionalen / nationalen/ internationalen Vorschriften.

(DK)
Fare
Forårsager svære forbrændinger af huden og øjenskader. Kan forårsage allergisk hudreaktion. Skadelig for vandlevende organismer, med langvarige virkninger.
Undgå udledning til miljøet. Bær beskyttelseshandsker/beskyttelsestøj/øjenbeskyttelse/ansigtsbeskyttelse VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning. I TILFÆLDE AF INDTAGELSE: Skyl munden. Fremkald IKKE opkastning. VED KONTAKT MED HUDEN (eller håret): Tilsmudset tøj tages straks af/fjernes. Skyl/brus huden med vand. Ved hudirritation eller udslet: Søg lægehjælp. Bortskaffelse af indholdet/beholderen i henhold til de lokale/regionale/nationale/internationale forskrifter.

(EE)
Ettevaatust
Põhjustab rasket nahasöövitust ja silmakahjustusi. Võib põhjustada allergilist nahareaktsiooni. Ohtlik veeorganismidele, pikaajaline toime.
Vältida sattumist keskkonda. Kanda kaitsekindaid/kaitserõivastust/kaitseprille/kaitsemaski. SILMA SATTUMISE KORRAL: loputada mitme minuti jooksul ettevaatlikult veega. Eemaldada kontaktläätsed, kui neid kasutatakse ja kui neid on kerge eemaldada. Loputada veel kord. ALLANEELAMISE KORRAL: loputada suud. MITTE kutsuda esile oksendamist. NAHALE (või juustele) SATTUMISE KORRAL: võtta viivitamata kõik saastunud rõivad seljast. Loputada nahka

veega/loputada duši all. Nahaärrituse või _obe korral: pöörduda arsti poole. Sisu/konteineri käitlus vastavuses kohalike/regionaalsete/ rahvuslike/rahvusvaheliste nõuetega.

(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.

(ES)
Peligro
Provoca quemaduras graves en la piel y lesiones oculares graves. Puede provocar una reacción alérgica en la piel. Nocivo para los organismos acuáticos, con efectos nocivos duraderos.
Evitar su liberación al medio ambiente. Llevar guantes que aíslen del frío/gafas/máscara. EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. EN CASO DE INGESTIÓN: Enjuagarse la boca. NO provocar el vómito. EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitarse inmediatamente las prendas contaminadas. Aclararse la piel con agua o ducharse. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido o el recipiente conforme a la reglamentación local/regional/nacional/ internacional.

(FI)
Vaara
Voimakkaasti ihoa syövyttävää ja silmiä vaurioittavaa. Voi aiheuttaa allergisen ihoreaktion. Haitallista vesieliöille, pitkäaikaisia haittavaikutuksia.
Vältettävä päästämistä ympäristöön. Käytä suojakäsineitä/suojavaatetusta/silmiensuojainta/ kasvonsuojainta. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Poista piilolinssit, _edical voi tehdä helposti. Jatka huuhtomista. JOS KEMIKAALIA ON NIELTY: Huuhdo suu. EI saa oksennuttaa. JOS KEMIKAALIA JOUTUU IHOLLE (tai hiuksiin): Riisu saastunut vaatetus välittömästi. Huuhdo/ suihkuta iho vedellä. Jos ilmenee ihoärsytystä tai ihottumaa: Hakeudu lääkäriin. Säilytä säiliö(t) noudattaen paikallisia/alueellisia/kansallisia/ kansainvälisiä määräyksiä.

(FR)
Danger
Provoque des brûlures de la peau et des lésions oculaires graves. Peut provoquer une allergie cutanée. Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.
Éviter le rejet dans l'environnement. Porter des gants de protection/des vêtements de protection/ un équipement de protection des yeux/du visage. EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. EN CAS D'INGESTION: rincer la bouche. NE PAS faire vomir. EN CAS DE CONTACT AVEC LA PEAU (ou les cheveux): enlever immédiatement les vêtements contaminés. Rincer la peau à l'eau/se doucher. En cas d'irritation ou d'éruption cutanée: consulter un médecin. Éliminer le contenu/ récipient conformément à la réglementation locale/régionale/nationale/internationale.

(GR)
Κίνδυνος
Προκαλεί σοβαρά δερματικά εγκαύματα και οφθαλμικές βλάβες. Μπορεί να προκαλέσει αλλεργική δερματική αντίδραση. Επιβλαβές για τους υδρόβιους οργανισμούς, με μακροχρόνιες επιπτώσεις.
Να αποφεύγεται η ελευθέρωση στο περιβάλλον. Να φοράτε προστατευτικά γάντια/προστατευτικά ενδύματα/μέσα ατομικής προστασίας για ταμάτια/ πρόσωπο. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΑ ΜΑΤΙΑ: Ξεπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχουν φακοί επαφής, αφαιρέστε τους, εφόσον είναι εύκολο. Συνεχίστε να ξεπλένετε. ΣΕ ΠΕΡΙΠΤΩΣΗ ΚΑΤΑΠΟΣΗΣ: Ξεπλύνετε το στόμα. ΜΗΝ προκαλέσετε εμετό. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΟ ΔΕΡΜΑ (ή με τα μαλλιά): Αφαιρέστε αμέσως όλα τα μολυσμένα ενδύματα. Ξεπλύνετε το δέρμα με νερό/στο ντους. Εάν παρατηρηθεί ερεθισμός του δέρματος ή εμφανιστεί

εξάνθημα: Συμβουλευθείτε/Επισκεφθείτεγιατρό. Απορρίψτε τα περιεχόμενα/δοχείο σύμφωνα με τους τοπικούς/εθνικούς/διεθνείς κανονισμούς.

(HR)
Opasnost
Uzrokuje teške opekline kože i ozljede oka. Može izazvati alergijsku reakciju na koži. Štetno za vodeni okoliš s dugotrajnim učincima.
Izbjegavati ispuštanje u okoliš. Nositi zaštitne rukavice/zaštitnu odijelo/zaštitu za oči/zaštitu za lice. U SLUČAJU DODIRA S OČIMA: oprezno ispirati vodom nekoliko minuta. Ukloniti kontaktne leće ukoliko ih nosite i ako se one lako uklanjaju. Nastaviti ispiranje. AKO SE PROGUTA: isprati usta. NE izazivati povraćanje. U SLUČAJU DODIRA S KOŽOM (ili kosom): odmah ukloniti/ skinuti svu zaganenu odjeću. Isprati kožu vodom/ tuširanjem. U slučaju nadražaja ili osipa na koži: zatražiti savjet/pomoć liječnika. Odložite sadržaje /spremnike u skladu s lokalnim/regionalnim/ nacionalni/međunarodnim odredbama.

(HU)
Veszély
Smarkiai nudegina odą ir pažeidžia akis. Allergiás bőrreakciót válthat ki. Ártalmas a vízi élővilágra, hosszan tartó károsodást okoz.
Kerülni kell az anyagnak a környezetbe való kijutását. Védőkesztyű/védőruha/szemvédő/ arcvédő használata kötelező. SZEMBE KERÜLÉS esetén: Több percig tartó óvatos öblítés vízzel. Adott esetben a kontaktlencsék eltávolítása, ha könnyen megoldható. Az öblítés folytatása. LENYELÉS ESETÉN: a szájat ki kell öblíteni. TILOS hánytatni. HA BŐRRE (vagy hajra) KERÜL: Az összes szennyezett ruhadarabot azonnal el kell távolítani/le kell vetni. A bőrt le kell öblíteni vízzel/zuhanyozás. Bőrirritáció vagy kiütések megjelenése esetén: orvosi ellátást kell kérni. Az edény tartalmát / a tartályt a helyi/ regionális/nemzeti/nemzetközi szabályozásoknak megfelelően kell hulladékként elhelyezni.

(IT)
Pericolo
Provoca gravi ustioni cutanee e gravi lesioni oculari. Può provocare una reazione allergica cutanea. Nocivo per gli organismi acquatici con effetti di lunga durata.
Non disperdere nell'ambiente. Indossare guanti/ indumenti protettivi/Proteggere gli occhi/il viso. IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. IN CASO DI INGESTIONE: sciacquare la bocca. NON provocare il vomito. IN CASO DI CONTATTO CON LA PELLE (o con i capelli): togliersi di dosso immediatamente tutti gli indumenti contaminati. Sciacquare la pelle/fare una doccia. In caso di irritazione o eruzione della pelle: consultare un medico. Smaltire il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

(LT)
Pavojinga
Smarkiai nudegina odą ir pažeidžia akis. Gali sukelti alerginę odos reakciją. Kenksminga vandens organizmams, sukelia ilgalaikius pakitimus.
Saugoti, kad nepatektų į aplinką. Mūvėti apsaugines pirštines/dėvėti apsauginius drabužius/naudoti akių (veido) apsaugos priemones. PATEKUS Į AKIS: Kelias minutes atsargiai plauti vandeniu. Išimti kontaktinius lęšius, jeigu jie yra ir jeigu lengvai galima tai padaryti. Toliau plauti akis. PRARIJUS: išskalauti burną. NESKATINTI vėmimo. PATEKUS ANT ODOS (arba plaukų): Nedelsiant nuvilkti/pašalinti visus užterštus drabužius. Odą nuplauti vandeniu/ čiurkšle. Jeigu sudirginama oda arba ją išberia: kreiptis į gydytoją. Turinį/talpą išpilti (išmesti) - šalinti pagal vietines / regionines / nacionalines / tarptautines taisykles.

(LV)
Briesmas
Smarkiai nudegina odą ir pažeidžia akis. Gali sukelti alerginę odos reakciją. Kenksminga vandens organizmams, sukelia ilgalaikius pakitimus.
Saugoti, kad nepatektų į aplinką. Mūvėti apsaugines pirštines/dėvėti apsauginius drabužius/naudoti akių (veido) apsaugos priemones. PATEKUS Į AKIS: Kelias minutes atsargiai plauti vandeniu. Išimti kontaktinius lęšius, jeigu jie yra ir jeigu lengvai galima tai padaryti. Toliau plauti akis. PRARIJUS: išskalauti burną. NESKATINTI vėmimo. PATEKUS ANT ODOS (arba plaukų): Nedelsiant nuvilkti/pašalinti visus užterštus drabužius. Odą nuplauti vandeniu/ čiurkšle. Jeigu sudirginama oda arba ją išberia: kreiptis į gydytoją. Turinį/talpą išpilti (išmesti) - šalinti pagal vietines / regionines / nacionalines / tarptautines taisykles.

(NL)
Gevaar
Veroorzaakt ernstige brandwonden en oogletsel. Kan een allergische huidreactie veroorzaken. Schadelijk voor in het water levende organismen, met langdurige gevolgen.
Voorkom lozing in het milieu. Beschermende handschoenen/beschermende kleding/ oogbescherming/gelaatsbescherming dragen. BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen. NA INSLIKKEN: de mond spoelen — GEEN braken opwekken. BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken — huid met water afspoelen/afdouchen. Bij huidirritatie of uitslag: een arts raadplegen. De inhoud en de verpakking verwerken volgens de plaatselijke/regionale/ nationale/internationale voorschriften.

(NO)
Fare
Forårsaker alvorlige hudforbrenninger og øyeskader. Kan forårsake allergiske hudreaksjoner. Skadelig for vannlevende organismer, langtidsvirkning.
Unngå utslipp til miljøet. Bruk vernehansker/ verneklær/vernebriller/ansiktsskjerm. VED KONTAKT MED ØYNENE: Skyll forsiktig med vann i opptil flere minutter. Fjern evt. kontaktlinser såfremt dette er lett mulig. Fortsett skyllingen. VED SVELGING: Skyll munnen. IKKE fremkall brekninger. VED HUDKONTAKT (eller kontakt med hår): Alle tilsølte klær må fjernes straks. Vask/dusj huden med vann. Ved hudirritasjon eller -utslett: Kontakt / tilkall lege. Innholdet / emballasjen skal avhendes i henhold til de lokale / regionale / nasjonale / internasjonale forskrifter.

(PL)
Niebezpieczeństwo
Powoduje poważne oparzenia skóry oraz uszkodzenia oczu . Może powodować reakcję alergiczną skóry. Działa szkodliwie na organizmy wodne, powodując długotrwałe skutki.
Unikać uwolnienia do środowiska. Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W PRZYPADKU POŁKNIĘCIA: wypłukać usta. NIE wywoływać wymiotów. W PRZYPADKU KONTATKU ZE SKÓRĄ (lub z włosami): Natychmiast usunąć/zdjąć całą zanieczyszczoną odzież. Spłukać skórę pod strumieniem wody/prysznicem. W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza. Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi.

(PT)
Perigo
Provoca queimaduras na pele e lesões oculares graves. Pode provocar uma reacção alérgica cutânea. Nocivo para os organismos aquáticos com efeitos duradouros.
Evitar a libertação para o ambiente. Usar luvas de protecção/vestuário de protecção/ protecção ocular/protecção facial. SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continuar a enxaguar. EM CASO DE INGESTÃO: enxaguar a boca. NÃO provocar o vómito. SE ENTRAR EM CONTACTO COM A PELE (ou o cabelo): despir/ retirar imediatamente toda a roupa contaminada. Enxaguar a pele com água/tomar um duche. Em caso de irritação ou erupção cutânea: consulte um médico. Eliminar o conteúdo/recipiente de acordo com a legislação local/regional/nacional/ internacional.

(RO)
Pericol
Provoacă arsuri grave ale pielii şi lezarea ochilor. Poate provoca o reacţie alergică a pielii. Nociv pentru mediul acvatic cu efecte pe termen lung.
Evitaţi dispersarea în mediu. Purtaţi mănuşi de protecţie/îmbrăcăminte de protecţie/echipament de protecţie a ochilor/ chipament de protecţie a feţei. ÎN CAZ DE CONTACT CU OCHII: clătiţi cu atenţie cu apă timp de mai multe minute. Scoateţi lentilele de contact, dacă este cazul şi dacă acest lucru se poate face cu uşurinţă. Continuaţi să clătiţi. ÎN CAZ DE ÎNGHIŢIRE: clătiţi gura. NU provocaţi voma. ÎN CAZ DE CONTACT CU PIELEA (sau părul): scoateţi imediat toată îmbrăcămintea contaminată. Clătiţi pielea cu apă/ faceţi duş. În caz de iritare a pielii sau de erupţie cutanată: consultaţi medicul. Aruncaţi conţinutul/ containerul în acord cu regulamentele locale/ regionale/naţionale/internaţionale.

(SE)
Fara
Orsakar allvarliga frätskador på hud och ögon. Kan orsaka allergisk hudreaktion. Skadliga långtidseffekter för vattenlevande organismer.
Undvik utsläpp till miljön. Använd skyddshandskar/ skyddskläder/ögonskydd/ansiktsskydd. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja. VID FÖRTÄRING: Skölj munnen. Framkalla INTE kräkning. VID HUDKONTAKT (även håret): Ta omedelbart av alla nedstänkta kläder. Skölj huden med vatten/duscha. Vid hudirritation eller utslag: Sök läkarhjälp. Innehållet / behållaren avfallshanteras enligt lokala / regionala / nationella / internationella föreskrifter.

(SL)
Nevarno
Povzroča hude opekline kože in poškodbe oči. Lahko povzroči alergijski odziv kože. Škodljivo za vodne organizme, z dolgotrajnimi učinki.
Preprečiti sproščanje v okolje. Nositi zaščitne rokavice/zaščitno obleko/zaščito za oči/zaščito za obraz. PRI STIKU Z OČMI: previdno izpirajte z vodo nekaj minut. Odstranite kontaktne leče, če jih imate in če to lahko storite brez težav. Nadaljujte z izpiranjem. PRI ZAUŽITJU: izprati usta. NE izzvati bruhanja. PRI STIKU S KOŽO (ali lasmi): takoj odstraniti/sleči vsa kontaminirana oblačila. Izprati kožo z vodo/prho. Če nastopi draženje kože ali se pojavi izpuščaj: poiščite zdravniško pomoč/ oskrbo. Vsebino/vsebnik odstranite v skladu z lokalnimi/regionalnimi/narodnimi/mednarodnimi predpisi.

(SK)
Nebezpečenstvo
Provoacă arsuri grave ale pielii şi lezarea ochilor. Môže vyvolať alergickú kožnú reakciu. Škodlivý pre vodné organizmy, s dlhodobými účinkami.
Zabráňte uvoľneniu do životného prostredia. Noste ochranné rukavice/ochranný odev/ ochranné okuliare/ochranu tváre. PO ZASIAHNUTÍ OČÍ: Niekoľko minút ich opatrne vyplachujte vodou. Ak používate kontaktné šošovky a ak je to možné, odstráňte ich. Pokračujte vo vyplachovaní. PO POŽITÍ: vypláchnite ústa. Nevyvolávajte zvracanie. PRI KONTAKTE S POKOŽKOU (alebo vlasmi): Odstráňte/vyzlečte všetky kontaminované časti odevu. Pokožku ihneď opláchnite vodou/ sprchou. Ak sa prejaví podráždenie pokožky alebo sa vytvoria vyrážky: vyhľadajte lekársku pomoc/starostlivosť. Zneškodnenie obsahu/obalu v súlade s miestnymi/oblastnými/národnými/ medzinárodnými nariadeniami.

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2020/06