Infection AFIAS COVID-19 Ab

INTENDED USE

AFIAS COVID-19 Ab in conjunction with AFIAS-1 analyzer is an *in vitro* diagnostic fluorescence Immunoassay intended for qualitative detection and differentiation of IgG/IgM antibodies to the novel coronavirus SARS-CoV-2 in human venous whole blood, serum or plasma samples.

The test may also be performed on fingerstick capillary whole blood samples directly collected in the specially designed 'AFIAS C-tips (30 µL)'.

AFIAS COVID-19 Ab is indicated as an aid in the screening of asymptomatic individuals and patients with early, mild or acute symptoms suspected of COVID-19 disease at point-of-care sites and clinical laboratories.

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease was first identified in 2019 in Wuhan, the capital of Hubei Province, China, and has since spread globally, resulting in the 2019–20 coronavirus pandemic.

The SARS-CoV-2 (2019-nCOV) is a member of the Betacoronavirus genus, that also includes Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) and Middle East Respiratory Syndrome coronavirus (MERS-CoV).

As the disease could progress to life-threatening pneumonia and multi-organ failure, prevention and control of the infection has become very essential. Since the symptoms become rapidly severe after onset of illness in absence of specific treatment, early diagnosis of SARS-CoV-2 infection is quite crucial.

AFIAS COVID-19 Ab test system is a rapid *in vitro* diagnostic test that qualitatively detects anti-SARS-CoV-2 IgG/IgM antibodies in whole blood, serum or plasma samples with high sensitivity.

PRINCIPLE

AFIAS™ COVID-19 Ab for use in conjunction with AFIAS-1 Analyzer, is an *in vitro* diagnostic test system based on lateral flow sandwich detection immunofluorescence technology.

Upon initiating the test run, clinical sample from the 'sample well' or from the 'capillary blood-filled AFIAS C-tip' (loaded into the 'tip slot' of the inserted test cartridge), is first automatically transferred to the 'Dilution buffer chamber' of the test cartridge.

Diluted clinical sample is then automatically transferred to the 'detection buffer chamber' of the test cartridge resulting in binding of the fluorochrome-antigen conjugates from the lyophilized detection buffer to the anti-SARS-CoV-2 IgG/IgM antibodies present in the clinical sample

As the clinical sample-detection buffer test mixture is further automatically delivered into the 'test mixture well' of the test cartridge, the test mixture migrates through the test strip of inserted test cartridge.

Complexes of fluorochrome-antigen conjugates with anti-SARS-CoV-2 IgG/IgM antibodies from the test mixture are further captured by the anti-human IgG and anti-human IgM antibodies immobilized respectively at the 'IgG test line' and the 'IgM test line' of the test cartridge.

AFIAS-1 automatically scans/reads the inserted test cartridge after 10 minutes after initiation of the test run. The laser light source illuminates the cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes accumulated at the test lines and the control line.

While computing the test result, AFIAS-1 takes into account ratio of fluorescence generated at the respective test line to that at the control line.

Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence generated at the respective test line and hence to the concentration of respective anti-SARS-CoV-2 antibodies in the test sample.

AFIAS-1 computes respective anti-SARS-CoV-2 antibodies concentration and ultimately displays the AFIAS COVID-19 Ab test result qualitatively as 'Negative' or 'Indeterminate' or 'Positive' based on pre-programed analytical equivocal zone and cut-offs.

TEST COMPONENTS

For performing COVID-19 Ab test on a clinical sample, following test components are required:

- AFIAS COVID-19 Ab Test Cartridge
- AFIAS COVID-19 Ab Test ID Chip
- Ordinary pipette tip
  (for testing venous whole blood, serum or plasma)
- AFIAS C-tip (30 µL)
  (only for testing fingerstick capillary whole blood)
- AFIAS-1 Analyzer

MATERIALS SUPPLIED

Each box of AFIAS COVID-19 Ab test cartridges contains following items:

- 24 sealed AFIAS COVID-19 Ab Test Cartridges
  (12 pouches; each containing two test cartridges)
- 1 AFIAS COVID-19 Ab Test ID Chip
- 1 Zipper bag containing 24 ordinary pipette tips
- 1 Zipper bag containing 24 AFIAS C-tips (30 µL)
- 1 Package Insert of AFIAS COVID-19 Ab Test
- 1 Spare cartridge zipper bag (containing a desiccant sachet)

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from AFIAS COVID-19 Ab Test Cartridge Box.

Please contact the manufacturer or its authorized distributor for more information.

- **AFIAS-1 Analyzer REF** FPRR019
- **AFIAS COVID-19 Ab Controls**

STABILITY, STORAGE AND HANDLING OF TEST ITEMS

- AFIAS COVID-19 test cartridges (sealed in aluminum foil pouches) have shelf-life of 20 months if stored at 4-30 °C.
- After opening a test cartridge pouch, if only one AFIAS COVID-19 Ab test cartridge is going to be used immediately, put the unused unsealed test cartridge immediately in the 'spare cartridge zipper bag' included in the test cartridge box.

  Store the duly locked 'spare cartridge zipper bag' at 4-30 °C. and use the unsealed test cartridge for performing the test within 30 days after resealing in the zipper bag.
- Expiration date is printed on the label of the test cartridge box as well as on each test cartridge pouch and on the face of the unsealed test cartridge
- AFIAS-1 does not allow any test run on an expired or previously used test cartridge.
- Never freeze any of the test items.
- If stored in cold conditions, allow the sealed test cartridges, controls, ordinary pipette tips and AFIAS C-tips to attain room temperature (15-30°C) for 15-30 minutes prior to using for the test.
- Do not remove the test cartridge from its aluminum foil pouch or from the spare cartridge zipper bag until just prior to its actual use for performing the test.

INSTRUCTIONS, PRECAUTIONS AND WARNINGS

- This test has not been reviewed by the FDA.
- For in vitro diagnostic use only.
- For prescription use only
- Carefully follow the instructions, precautions, warnings and procedures described in this package insert.
- Please refer to the operation manual of AFIAS-1 Analyzer for operating instructions and complete information.
- Only the test cartridges, pipette tips and AFIAS C-tips (30 µL) included in the AFIAS COVID-19 Ab test cartridge box should be used for performing AFIAS COVID-19 Ab test.
- For performing AFIAS COVID-19 Ab test using test cartridge of given lot number, AFIAS COVID-19 Ab ID chip of matching lot number must be currently or previously inserted into the ID Chip port of AFIAS-1 analyzer.
- Never use the test cartridge or any reagent of any other marketed COVID-19/SARS-CoV-2/2019-nCoV test product/kit for performing AFIAS COVID-19 Ab test. Otherwise, test results may be erroneous or misleading.
- Do not use the AFIAS COVID-19 Ab test cartridge if it is found damaged or already removed from its original pouch or from the spare cartridge zipper bag.
- Never try to use any test cartridge past the expiration date printed on the label of test cartridge box and cartridge pouch.
- Never reuse any test cartridge or pipette tip or AFIAS C-tip. Discard these test components after single use.
- AFIAS COVID-19 Ab Controls which are supplied on demand separately from the test cartridge box, must be tested as recommended in this package insert.
- Wear protective clothing such as laboratory coats, masks, disposable gloves and eye protection when specimens are collected, processed and tested.
- Never test hemolyzed, lipemic or icteric clinical samples.
- If required to be shipped, clinical samples must be packed in accordance with relevant regulations.
- Used test cartridges, pipette tips, AFIAS C-tips etc. should be handled carefully and must be disposed in accordance with relevant local regulations.

SAMPLE COLLECTION, PROCESSING AND HANDLING

- AFIAS COVID-19 Ab test should be performed only on following sample types:

Sample type	Recommended anticoagulant
Venous whole blood and plasma	Na-Heparin Li-Heparin, K_2 EDTA
Serum	*Not applicable*
Fingerstick capillary whole blood collected in AFIAS C-tips (30µL)	*Not applicable*

- Serum or plasma should be obtained within 3 hours after the collection of venous whole blood.
- It is recommended to test venous whole blood, serum and plasma sample within 24 hours after collection/ processing.
- Anti-coagulated venous whole blood samples should be tested within 4 hours after collection from patients if stored at room temperature (~25°C) and within 24 hours if stored at 2~8°C in a refrigerator. However, the whole blood sample should not be frozen in any case.
- Serum/plasma samples should be tested within 4 hours after collection from patients if stored at room temperature (~25°C) and within 48 hours if stored at 2~8°C in a refrigerator. For longer storage, serum or plasma samples should be immediately frozen at <-20 °C.
- Once frozen, serum/plasma samples should be thawed one time only for performing the test, because repeated freezing and thawing may result in erroneous/ misleading test results.
- **Following precautions must be observed for collecting, handling and testing fingerstick capillary whole blood samples using AFIAS C-tips (30µL):**

- Use only the AFIAS C-tips (30µL) provided in the AFIAS COVID-19 Ab test cartridge box for collecting and testing fingerstick capillary whole blood samples.
- Never collect fingerstick capillary whole blood sample into AFIAS C-tip (30 µL) until entire test setup is ready.
- Never collect/draw the fingerstick capillary whole blood sample into the AFIAS C-tip (30 µL) if AFIAS-1 analyzer is displaying the error message alert '*Please wait until appropriate internal temperature is reached*'. Wait until the message disappears.
- AFIAS COVID-19 Ab test cartridge must be inserted in the cartridge holder of AFIAS-1 analyzer prior to colleting patient's fingerstick capillary whole blood sample in AFIAS C-tips (30µL).
- Fingerstick capillary whole blood sample should be collected in AFIAS C-tips (30µL) directly from the patient following a standard fingerstick procedure and must be tested immediately within two minutes after collection in the C-tip.
- Ensure that capillary potion of the AFIAS C-tip (30 µL) has been filled with capillary blood sample completely up to the 'fill line' of the C-tip without entrapment of any bubble.
- AFIAS-1 does not allow the test run to be initiated if AFIAS C-tip (placed in the 'tip slot' of the AFIAS COVID-19 Ab test cartridge inserted in the cartridge holder of AFIAS-1) has not been with filled with blood sample completely up to the 'fill' line of the C-tip and/or if any air bubble is entrapped in its capillary portion.
- If the AFIAS C-tip (30 µL) has been under-filled with capillary blood sample or if any air bubble seems entrapped in the capillary blood sample collected in the C-tip, discard the blood-filled C-tip and use a new C-tip to collect a capillary blood sample from the same patient again to run the test.
- Never hold the blood-filled C-tip with its pointed end facing upwards or never hold it horizontally.
- Similarly, never place the blood-filled C-tip on any surface and never wipe off the exterior of the blood-filled C-tip using cloth or tissue paper.
- Always hold the blood-filled AFIAS C-tip (30 µL) straight up with its pointed end facing downwards, put it immediately in the 'tip slot' of the AFIAS COVID-19 Ab test cartridge already inserted in the 'cartridge holder' of AFIAS-1 and initiate the test run immediately within two minutes after collecting the sample into the C-tip.
- If the test run could not be initiated within two minutes (after collecting the blood sample into the C-tip) due to any reason, discard the blood-filled C-tip and use a new C-tip to collect the blood sample from the same patient again to run the test.

- **For collecting patient's fingerstick capillary blood sample in an AFIAS C-tip (30 µL):**

(1) Place all collection materials (powder-free gloves, zipper pouch containing AFIAS C-tips (30 µL), proper-size sterile lancet, alcohol swabs, gauze pad, bandage etc.) on a disposable pad placed on the working table.
(2) Put on the powder-free gloves.
(3) Take out one AFIAS C-tip from the C-tip zipper pouch.
(4) Gently massage patient's middle or ring finger of the non-dominant hand from finger's base to the tip several times.
(5) Scrub the finger's tip with an alcohol swab and dry thoroughly with a gauze pad.
(6) Hold the finger in a horizontal position facing the palm upwards.
(7) Choose a pricking spot that is on the side of the finger's tip
(8) Firmly prick with a sterile lancet.
(9) Squeeze the finger gently to obtain a large drop of blood but wipe off the first drop of blood using a gauze pad.
(10) Squeeze the finger gently again to obtain another large drop of blood but avoid excessive squeezing
(11) Hold the AFIAS C-tip (30 µL) horizontally and touch its pointed end to the drop of blood without touching the skin. Blood starts ascending into the C-tip by capillary action.
(12) For collecting the capillary blood sample up to the 'fill line' of the C-tip, touch the pointed end of the C-tip few times to the drop of blood.

Note: 'Fill line' of the AFIAS (30 µL) is the clearly visible boundary between the capillary portion and the middle non-capillary portion of the C-tip.

TEST SETUP

- Arrange the following test items:
  - **1 sealed AFIAS COVID-19 Ab Test Cartridge**
  - **1 AFIAS COVID-19 Ab ID Chip** of lot number matching with that of the test cartridge
  - **1 Ordinary pipette tip**
    (for testing venous whole blood, serum or plasma sample)
    Or
  - **1 AFIAS C-tip (30 µL)**
    (for testing fingerstick capillary whole blood sample)
  - **AFIAS-1 Analyzer**
- If stored in cold conditions, allow the sealed test cartridge, control, pipette tip or AFIAS C-tip to attain room temperature (15-30°C) for 15-30 minutes prior to using for the test.
- Switch on the AFIAS-1 Analyzer at least 15 minutes before running AFIAS COVID-19 Ab test on any clinical sample

  (Please refer to the operation manual of AFIAS-1 Analyzer for operating instructions and complete information.)
- Log-in by selecting the registered username (from the dropdown list which can be populated against the username field) and password when prompted by AFIAS-1.
- Perform 'system check' of AFIAS-1 using AFIAS System check Cartridge and System Check ID Chip after being prompted by AFIAS-1 analyzer.

  (**Note:** If prompted for by AFIAS-1, system check needs to be performed before testing controls or any clinical sample.

  Refer to the operation manual of AFIAS-1 for system check procedure.)
- Remove the AFIAS COVID-19 Ab test cartridge from its aluminum foil pouch or spare cartridge zipper bag and place it on a clean, dust-free, dry and flat surface.
- Within the designated area on the face of the test cartridge, write the patient's short name (preferably the initials) or any 3-4-digit patient-specific identification number.
- Input the patient ID in the designated field on AFIAS-1 screen. You may also gender and age of the patient.
- Insert the AFIAS COVID-19 Ab Test ID Chip having exactly same lot number as that of the AFIAS COVID-19 Ab Test Cartridge if

information of the same ID chip is not currently stored in the memory of AFIAS-1 analyzer.

TEST PROCEDURE

For testing whole blood/serum/plasma sample:

1) Select 'General Mode' of AFIAS-1 operation.
2) Using a micropipette, transfer 150 µL of the whole blood/serum/plasma sample into the 'sample well' of the test cartridge.

   (**Caution:** Do not add the sample into the 'test mixture well' or 'scanning window' of the test cartridge.)
3) Insert the sample-loaded test cartridge into the cartridge holder of AFIAS-1 analyzer
4) Insert an ordinary pipette tip in to the 'tip slot' of the inserted test cartridge.
5) Immediately press the 'start' button on AFIAS-1 display screen and press the 'confirm' button on the 'test run information' pop-up window if you have already inputted the patient information correctly.
6) After the 'Confirm' button is pressed, the 'test run information' window disappears.
7) AFIAS-1 performs pre-programed validation checks and mixing/pipetting steps on the inserted sample-loaded AFIAS COVID-19 Ab Test Cartridge before starting to display the remaining incubation time of the test run.
8) AFIAS-1 automatically scans/reads the inserted test cartridge and displays the test result after 10 minutes after initiation of the test run.

For testing fingerstick capillary whole sample:

1) Select 'C-tip Mode' of AFIAS-1 operation.
2) Insert an empty AFIAS COVID-19 Ab test cartridge into the cartridge holder of AFIAS-1 analyzer.
3) Draw/collect patient's fingerstick capillary whole blood sample directly into an AFIAS C-tip (30 µL).

   Caution: If the AFIAS C-tip (30 µL) has been under-filled with capillary blood sample, discard the blood-filled C-tip and use a new C-tip to collect a capillary blood sample from the same patient again to run the test.
4) Hold the capillary blood-filled C-tip straight up with its pointed end facing downwards.
5) Place the blood-filled C-tip into the 'tip slot' of the AFIAS COVID-19 Ab test cartridge (already inserted in the cartridge holder of AFIAS-1) immediately within two minutes after collecting the blood sample.
6) Immediately press the 'start' button on AFIAS-1 display screen and press the 'confirm' button on the 'test run information' pop-up window if you have already inputted the patient information correctly.
7) After the 'Confirm' button is pressed, the 'test run information' window disappears.
8) AFIAS-1 performs pre-programed validation checks and mixing/pipetting steps on the inserted sample-loaded AFIAS COVID-19 Ab Test Cartridge before starting to display the remaining incubation time of the test run.
9) AFIAS-1 automatically scans/reads the inserted test cartridge and displays the test result after 10 minutes after initiation of the test run.

   Caution: If the test run could not be initiated within two minutes (after collecting the blood sample into the C-tip) due to any reason, discard the blood-filled C-tip and use a new C-tip to collect the blood sample from the same patient again to run the test.

DISPLAY AND INTERPRETATION OF TEST RESULT

- AFIAS-1 displays the AFIAS COVID-19 Ab test result qualitatively as 'Negative' or 'Indeterminate' or 'Positive' while also displaying test result numerically in terms of cut-off index (COI) value as follows:

AFIAS COVID-19 Ab test result displayed by AFIAS-1
COVID-19 Ab IgM *COI Negative or Indeterminate or Positive
COVID-19 Ab IgG *COI Negative or Indeterminate or Positive

*Test result is negative if COI is < 0.9, indeterminate if COI is 0.9-1.1 and positive if COI is >1.1-200.

- If AFIAS COVID-19 Ab test result is 'Negative' for IgG as well as for IgM, the patient may not be infected with anti-SARS-CoV-2 but follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals.
- If the test result is 'Indeterminate' for IgG and/or for IgM, the patient may be infected with anti-SARS-CoV-2 and hence there is need to retest another sample from the patient.
- If the test result is 'Positive' for IgG and/or for IgM, the patient is most likely to be infected with anti-SARS-CoV-2.
- If the test result is 'Invalid', there must have been some procedural error or malfunction of test cartridge and/or AFIAS-1 analyzer.

  Retest another sample from the patient and if the test result continues to be displayed as 'Invalid', contact the manufacturer or its authorized service provider.

TESTING EXTERNAL CONTROLS

- Following external controls are provided on demand separately from with the AFIAS COVID-19 test cartridge box:

AFIAS COVID-19 Ab Control	**Expected/valid/acceptable control result**
AFIAS COVID-19 Ab Negative Control	COVID-19 Ab IgM *COI Negative COVID-19 Ab IgG *COI Negative
AFIAS COVID-19 Ab Positive Control 1	COVID-19 Ab IgM *COI Positive COVID-19 Ab IgG *COI Negative
AFIAS COVID-19 Ab Positive Control 2	COVID-19 Ab IgM *COI Negative COVID-19 Ab IgG *COI Positive

*Control result is negative if COI is < 0.9, indeterminate if COI is 0.9-1.1 and positive if COI is >1.1.

*If any control result is 'Indeterminate', it should be considered invalid/unacceptable and the same control should be retested.

- **The user laboratory must test each of the three AFIAS COVID-19 Ab Controls whenever any of the following situations is encountered:**

- Before testing clinical samples with any new lot of AFIAS COVID-19 Ab test cartridges
- Before testing clinical samples with any new shipment of AFIAS COVID-19 Ab test cartridges even if it belongs to a previously tested lot
- When AFIAS-1 displays the QC status as 'Required' (based on the 'QC cycle' set by the laboratory director or system administrator) for the given AFIAS COVID-19 Ab test cartridge lot number being tested
- If a newly registered operator is operating the AFIAS COVID-19 Ab test system for the first time
- If the operator is already registered but he/she has not performed any testing within last two weeks
- If there is any question concerning validity/accuracy of AFIAS COVID-19 Ab test results of clinical samples
- If there is any concern regarding physical and/or functional integrity of AFIAS-1 analyzer
- Immediately after the 'Director' or 'System administrator' has changed the date/time setting of AFIAS-1 analyzer
- After AFIAS-1 software/firmware upgrade by any authorized person
- After any servicing of AFIAS-1 analyzer by the manufacturer' technical services or its authorized service provider
- As per requirements of local, state and/or federal regulations, accrediting organizations, or laboratory operating procedures

- AFIAS COVID-19 Ab test results of clinical samples tested using a given lot of AFIAS COVID-19 Ab test cartridges should not be considered valid and reliable/acceptable unless corroborated with expected/valid/acceptable result of each of the three AFIAS COVID-19 Ab Controls tested using the same test system.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive results due to cross-reactions and/or non-specific adhesion of certain components of the clinical samples to the capture/detector antibodies of the test cartridge.
- Positive results may also be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- The test may yield false negative results. Non-responsiveness of the antigen to the antibodies is common when the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies.

  Also, instability or degradation of the antigen with time and/or temperature may cause false negative result as it makes the antigen unrecognizable by the antibodies.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals.
- Other factors such as technical/procedural errors, degradation of the test components/reagents, presence of interfering substances in the specimens, etc. may cause erroneous or misleading results.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

SUMMARY OF PERFORMANCE CHARACTERISTICS

(Note: Some of the following performance characteristics will be revised / updated as more clinical samples are tested in coming days.)

■ Analytical sensitivity

- AFIAS-1 computes respective anti-SARS-CoV-2 antibodies concentration and ultimately displays the AFIAS COVID-19 Ab test result qualitatively as 'Negative' or 'Indeterminate' or 'Positive' based on pre-programed analytical equivocal zone and cut-offs while also displaying test result numerically in terms of cut-off index (COI) value
- Test result is negative if cut-of-index (COI) is < 0.9, indeterminate if COI is 0.9-1.1 and positive if COI is >1.1-200.
- Cut-off index of AFIAS COVID-19 Ab has been determined and validated using 50 samples confirmed as negative by a molecular test.

■ Analytical specificity

- Cross-reactivity

AFIAS COVID-19 Ab test has not shown any cross-reactivity when clinical samples obtained from patients with following infections and physiological conditions were tested:

Name	Sample type
Cytomegalovirus(CMV)	Positive serum
Epstein-Barr virus(EBV)	Positive serum
Hepatitis A virus(HAV)	Positive serum
Hepatitis C virus(HCV)	Positive serum
Hepatitis B virus(HBV)	Positive serum
Herpes simplex virus(HSV)	Positive serum
Rubella virus	Positive serum
Varicella-zoster virus(VZV)	Positive serum
Treponema pallidum	Positive serum
Anti Nuclear Antibody(ANA)	Positive serum
Rheumatoid factor(RF)	Positive serum
Early stage of pregnancy	Pregnant women sample
Middle stage of pregnancy	Pregnant women sample
Hepatitis B antibody(anti-HBs)	Hepatitis B (HBsAg) Ab positive sample
Influenza A	Positive serum
Influenza B	Positive serum
RSV	Positive serum
Mycoplasma pneumoniae	Positive serum

- Interference

AFIAS COVID-19 Ab test did not show significant interference when test samples spiked with following endogenous substances and chemicals at a concentration much higher than their normal physiological level in human blood, were tested.

Material	Concentration
Li-Heparin	100,000 U/L
Na-Heparin	100,000 U/L
Na-EDTA	1.6 mg/mL (4 µM)
K2-EDTA	1.6 mg/mL (4 µM)
Sodium citrate	25 mg/mL (0.085 µM)
Hemoglobin	2 mg/ml
BSA	60 mg/ml
Bilirubin	0.24 mg/mL (400 µM)
Triglycerides	1.5 mg/ml
Cholesterol	7.7 mg/mL (20 mM)

■ Clinical performance evaluation

AFIAS COVID-19 Ab has demonstrated following clinical performance results when clinical samples collected from various asymptomatic individuals and patients suspected of COVID-19 disease were tested with AFIAS COVID-19 Ab test with AFIAS-1 analyzer and confirmed by testing with Allplex™ 2019-nCoV Assay (Seegene Inc., South Korea)

		2019-nCOV RT-PCR assay		
		Positive	Negative	Total
AFIAS COVID-19 Ab	Positive	46	0	46
	Negative	0	145	145
	Indeterminate	2	5	7
	Total	48	150	198

- Positive Percent Agreement: 95.8%
- Negative Percent Agreement: 96.7%

Note: Please refer to the table below to know the meaning of various symbols which may be printed on the labels of various components of AFIAS COVID-19 test system

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

For technical assistance; please contact:
Boditech Med Inc.'s Technical Services
Tel: +82 33 243-1400
E-mail: sales@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398
Republic of Korea
Tel: +(82) -33-243-1400
Fax: +(82) -33-243-9373
www.boditech.co.kr

EC REP **Obelis s.a**
Bd. Général Wahis 53,
1030 Brussels, BELGIUM
Tel: +(32) -2-732-59-54
Fax: +(32) -2-732-60-03
E-Mail: mail@obelis.net

CE IVD