Infection

AFIAS COVID-19 Ag

INTENDED USE

AFIAS COVID-19 Ag is a fluorescence Immunoassay (FIA) for the qualitative detection of novel corona virus (eg, SARS-CoV-2, 2019-nCoV) in human nasopharyngeal swab. It is useful as an aid in management and monitoring of SARS-CoV-2 infection (COVID-19).

For *in vitro* diagnostic use only.

INTRODUCTION

The third zoonotic human coronavirus (CoV) of the century emerged in December 2019, with a cluster of patients connected to Wuhan, Hubei Province, China. This virus, the newly identified coronavirus 2019 nCOV, could cause risky pneumonia so that prevention and control of the infection has become highly required. The 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). Since it is identified that symptoms become rapidly severe without a proper treatment after onset of illness, early diagnosis of the virus infection is quite crucial. Currently, the spread of the viral transmission become fast so that the prevention of local transmission requires a point-of care test (POCT), which shows quick outcome within 20 minutes.

AFIAS COVID-19 Ag is an in vitro diagnostic medical device that helps you to diagnose novel coronavirus infections by detecting the specific antigen of SARS-CoV-2.

PRINCIPLE

This test uses a sandwich immunodetection method; the detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized antibodies on test strip.

More antigens in the sample will form the more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for AFIAS tests to show concentration of SARS-CoV-2 antigens in sample respectively. This signal then is interpreted by the reader to display the 'Positive'/ 'Negative' in the sample.

COMPONENTS

AFIAS COVID-19 Ag consists of 'Cartridges', 'Tips', 'Extraction sets', 'spare cartridge zipperbag' and 'Instruction for use'.
Each cartridge packaged in an aluminum pouch has two components, a detector part and cartridge part.

- Cartridge part contains the membrane called a test strip which has mouse monoclonal anti-nCoV antibody at the test line and chicken IgY at the control line.
- Detector part contains the mouse monoclonal anti-nCoV antibody-fluorescence conjugate, anti-chicken IgY-fluorescence conjugate as a lyophilized granule type, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative.
- The extraction tube contains sodium chloride, sodium azide as a preservative in Tris-HCl buffer.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow instructions and procedures described in this 'Instruction for use'.
- Do not reuse cartridge and extraction set.
- Lot numbers of all the test components (Cartridge, ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect test result(s).
- The cartridge should remain sealed in its aluminum pouch until just before use. Do not use the cartridge if pouch is damaged or has already been opened.
- Allow the cartridge and sample to be at room temperature for approximately 30 minutes.
- The instrument for AFIAS tests may generate slight vibration during use.
- Used cartridges, extraction tubes, nozzles, pipette tips and swabs should be handled carefully and disposed by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.

WARNINGS AND PRECAUTIONS FOR SAMPLE

- Use the fresh samples.
- It is recommended to test the sample immediately after sample collection.
- Refrain from smoking or eating, while sample is collected.
- Do not collect samples outside of the nasopharynx. In any cases, pre-education for user is required for the proper sample collection.
- Please use fresh swab to avoid the cross-reactivity between samples. Never reuse the sterile swab.
- The improper samples such as those from an individual who has recently taken any interfering medicine or samples mistakenly mixed up with different patients shall cause inaccurate test results.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result(s) due to the non-responsiveness of the antigen to the antibodies which is most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- 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.
- The test results of the products cannot be used for diagnosis of SARS-CoV-2 virus infection.
- If the product has positive results, 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.
- In case of antigen concentration is low, the test may yield false negative results. Therefore, the negative results cannot exclude the possibility of infection completely.
- This product is only to detect the presence of a SARS-CoV-2 antigen.

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	4 - 30 °C	20 months	Unopened
		1 month	Resealed
Extraction buffer	4 - 30 °C	20 months	Disposable

- Return an unused cartridge to the spare cartridge zipper bag containing the desiccant pack. Reseal along entire edge of zip-seal.

MATERIALS SUPPLIED

REF SMFP-71
Components of **AFIAS COVID-19 Ag**

- Cartridge Box Contains
  - Cartridge 24
  - Pipette tip (Zipper bag) 24
  - Extraction set
    - Extraction buffer 24
    - Nozzle 24
  - Spare Cartridge Zipperbag 1
  - ID chip 1
  - Instruction for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS COVID-19 Ag**.
Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech COVID-19 Ag control** REF CFPO-293

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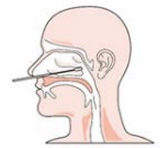
Date: 2020.11.25 19:00:40 EET
Reason: MoldSign Signature
Location: Moldova

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS COVID-19 Ag** human nasopharyngeal swab.

- **Collection method for sample**
  To collect samples, insert a sterile swab in the nasal cavity and spin it smoothly in the nasopharynx.



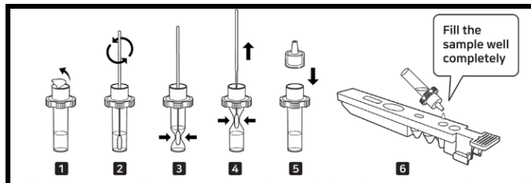
< Nasopharyngeal swab>

- It is recommended to test the sample immediately after collection. If do not use sample immediately, should store at 2-8 °C.
- Samples stored at 2-8 °C for 3 days showed no performance difference.

TEST SETUP

- Check the components of the **AFIAS COVID-19 Ag** as described below: Cartridge, Extraction tube set, ID chip, Spare cartridge zipper bag and instruction for use
- If the sealed cartridge and extraction buffer have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Empty the tip box.
- Insert the ID chip into the "ID chip port".
  (Please refer to the instrument for AFIAS tests 'operation manual' for complete information and operating instructions.)

TEST PROCEDURE



1) Open the lid of the aluminum foil of the extraction buffer tube.
2) Collect samples with a sterile swab and then put it into the extraction buffer tube. Spin the sterile swab 5 times and squeeze the sterile swab to extract the sample into the buffer.
3) Pull the sterile swab out of the extraction buffer tube.
4) Continue squeezing and pushing the swab to the top of extraction buffer tube to pull it out of tube.
5) Assemble a nozzle to the top of extraction tube.
6) Squeeze the extraction buffer tube gently to completely fill the sample well.
7) Select 'General Mode' in the instrument for AFIAS tests
8) Insert the cartridge into the cartridge holder.
9) Insert a tip into the tip hole of the cartridge.
10) Tap the 'START' icon on the screen.
11) The test results will be displayed on the screen after 12 minutes.

※ Note: Refer to the instrument for AFIAS tests Operation Manual to select sample type.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculates the test result automatically and displays **'Positive'/ 'Negative'.**
- If test result is Invalid, you need to perform a new test on a new test cartridge with a new test sample.

QUALITY CONTROL

- The Quality control tests should be used to confirm the reliability and the validity of **AFIAS COVID-19 Ag**.
- The positive/negative controls are provided with the product for quality control.
- Quality control tests should be performed both to verify proper operation of instrument and to exclude any possible performance change in storage.
- For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.

PERFORMANCE CHARACTERISTICS

▪ Analytical sensitivity

- **Cut-off**
  The cut-off value is 1 as COI (Cut off index) that is obtained from algorithm of the instrument.

<COVID-19 Ag judgment standard (positive/negative)>

COI (Cut-off index)	Judgment
< 1	Negative (-)
≥ 1	Positive (+)

▪ Analytical specificity

- **Cross-reactivity**
  There was no significant cross-reactivity on 30 various other viruses and 36 various bacteria with the AFIAS COVID-19 Ag test.

	Virus		
1	Corona virus - FCV(3A2)	16	Echovirus 25
2	Corona virus - FIP(2A4)	17	Echovirus 3
3	Influenza A virus H3N2 Hongkong	18	Echovirus 6
4	Influenza B virus B/Lee/40	19	Echovirus 9
5	Respiratory Syncytial virus A	20	Enterovirus 71
6	Adenovirus type1	21	HCMV-AD-169
7	Adenovirus type2	22	HSV-1 - F(3A20)
8	Adenovirus type3	23	HSV-2 - MS(4A6)
9	Adenovirus type4	24	Meales virus
10	Adenovirus type6	25	Mumps virus
11	Adenovirus type7	26	Polio virus - sabin(3A4)
12	Coxaievirus A2	27	Rhinovirus - RV21
13	Coxaievirus A4	28	Rhinovirus -RV14
14	Coxakie virus B1 - conn5	29	Rhinovirus -RV71
15	Coxakie virus B3 – nancy (5A1)	30	Rubella virus

	Bacteria
1	*Candida albicans*
2	*Candida glabrata*
3	*Candida tropicalis*
4	*Citrobacter freundii*
5	*Corynebacterium sp.*
6	*Corynebacterium diphtheriae*
7	*Enterococcus faecalis*
8	*Enterococcus gallinarum*
9	*Escherichia coli*
10	*Hemophilus influenzae*
11	*Hemophilus parainfluenzae*
12	*Klebsiella oxytoca*
13	*Klebsiella pneumoniae*
14	*Lactobacillus sp.*
15	*Legionella spp.*
16	*Listeria monocytogenes*
17	*Moraxella catarrhalis*
18	*Mycobacterium tuberculosis*
19	*Neisseria gonorrhoeae*
20	*Neisseria meningitidis*
21	*Neisseiria sicca*
22	*Proteus mirabilis*
23	*Proteus vulgaris*
24	*Pseudomonas aeruginosa*
25	*Serratia marcescens*
26	*Staphylococcus aureus*
27	*Staphylococcus epidermidis*
28	*Stenotrophomonas maltophilia*
29	*Streptococcus sp. (Grourp D)*
30	*Streptococcus agalactiae (Group B)*
31	*Streptococcus anginosus (Group F)*
32	*Streptococcus dysgalactiae (Group C)*
33	*Streptococcus dysgalactiae (Group G)*
34	*Streptococcus mutans*
35	*Streptococcus pneumoniae*
36	*Streptococcus pyogenes*

- **Interference**
  There was no significant interference effect on from these substances.

	Interference materials	Conc.
1	Nasal sprays drop	20%
2	Nasal corticosteroids	20%
3	Homeopathic allergy relief medicine	20%
4	Mouth wash (Listerin)	5 mg/mL
5	Throat lozenges, oral anesthetic & analgesic	5 mg/mL
6	Antiviral drugs (Tamiflu; Oseltamivir)	5 mg/mL
7	Antibiotic nasal ointment (Bactroban; mupirocin)	5 mg/mL
8	Whole blood	1%
9	Analgesic (Acetaminophen)	10 mg/mL
10	Analgesic (Ibuprofen)	10 mg/mL
11	Povidone-iodine	1%
12	Acetylsalicylic acid (Aspirin)	20 mg/mL
13	Antibacterial (cefadroxil)	5 mg/mL
14	Mucin (Porcine stomach)	0.50%
15	Throat lozenge (VICKS; cetylpyridinium chloride)	20 mg/mL
16	Throat lozenge (dipotassium glycyrrhizinate)	20 mg/mL
17	Throat lozenge (Nandina extraction)	20 mg/mL

▪ Precision

- Between lots
  One person tested three different lots of **AFIAS COVID-19 Ag**, ten times at each concentration of the control standard.
- Between persons
  Three different persons tested one lot of **AFIAS COVID-19 Ag**, ten times at each concentration of the control standard.
- Between days
  One person tested one lot of **AFIAS COVID-19 Ag** during three days, ten times at each concentration of the control standard.
- Between sites
  One person tested **AFIAS COVID-19 Ag** at three different site, ten times at each concentration of the control standard.

Cal.	Between lot		Between person	
	Positive/No.	Positive rate	Positive/No.	Positive rate
Cal 1	0/30	0%	0/30	0%
Cal 2	30/30	100%	30/30	100%
Cal 3	30/30	100%	30/30	100%
Cal.	Between day		Between site	
	Positive/No.	Positive rate	Positive/No.	Positive rate
Cal 1	0/30	0%	0/30	0%
Cal 2	30/30	100%	30/30	100%
Cal 3	30/30	100%	30/30	100%

▪ Clinical performance evaluation
AFIAS COVID-19 Ag has demonstrated the following clinical performance results.

		RT-PCR		
		Pos.	Neg.	Total
AFIAS COVID-19 Ag	Positive	21	2	23
	Negative	3	55	58
	Total	24	57	81

- Clinical sensitivity: 87.5%
- Clinical specificity: 96.5%

REFERENCES

1. Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases Interim guidance (2020) 17 Jan, WHO.
2. Wölfel et al. Virological assessment of hospitalized cases of coronavirus disease 2019 (2020) Nature. [Epub ahead of print]
3. Trivedi SU et al. Development and Evaluation of a Multiplexed Immunoassay for Simultaneous Detection of Serum IgG Antibodies to Six Human Coronaviruses (2019) Sci Rep. 9: 1390
4. Yongchen et al. Different longitudinal patterns of nucleic acid and serology testing results based on disease severity of COVID-19 patients (2020) Emerg Microbes Infect 20: 1

Note: Please refer to the table below to identify various symbols.

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:
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