RAPID POINT OF CARE

COVID-19 Ab Test

Introduction to AFIAS COVID-19 Ab

Coronavirus disease (COVID-19) is an infectious disease caused by acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease was first identified in 2019 in Wuhan, 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 essential. Since the symptoms become rapidly severe after onset of illness in absence of specific treatment, early diagnosis os SARS-CoV-2 infection is quite crucial.

- ✔ Fast & precise results within 10 minutes
- ✔ High sensitivity with TRF immunoassay
- ✔ Finger-prick blood available (30 µL)
- ✔ Room temperature storage

AFIAS COVID-19 Ab Test System is a rapid *in vitro* diagnostic fluorescence immunoassay test intended for qualitative detection and differentiation of IgG/IgM antibodies to the novel coronavirus SARS-CoV-2 utilizing whole blood, serum or plasma samples.

Immunostics, Inc. is a subsidiary of Boditech Med Inc. a leading developer of products for in-vitro diagnostics and diagnostic reagents in South Korea with over 20 years of proven history. With about 25,000 installations worldwide, Boditech is leading the way in on-site point of care diagnostics utilizing its automated highly sensitive fluorescence immunodiagnostic devices and reagents.

AFIAS COVID-19 Ab, *Continued*

Sample Type

Whole blood/Serum/Plasma (100 µL)
Fingertip blood with C-tip (30 µL)

Sample Type	Recommended anticoagulant
Venous whole blood and plasma (100 µL)	Na-Heparin Li-Heparin, K2 EDTA, Sodium Citrate
Serum (100 µL)	Not applicable
Fingerstick capillary whole blood collected in AFIAS C-tips (30 µL)	Not applicable

Reaction Time

10 minutes

Interpretation of Result

AFIAS COVID-19 Ab Test Result
COVID-19 Ab IgM *COI **Negative** or **Intermediate** or **Positive** COVID-19 Ab IgG *COI **Negative** or **Intermediate** or **Positive**
*Test result is negative if COI is <0.9, intermediate if COI is 0.9-1.1 and positive if COI is >1.1-200

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-19 Ab test and confirmed by testing with Allplex™ 2019-nCOV Assay (Seegene Inc., South Korea).

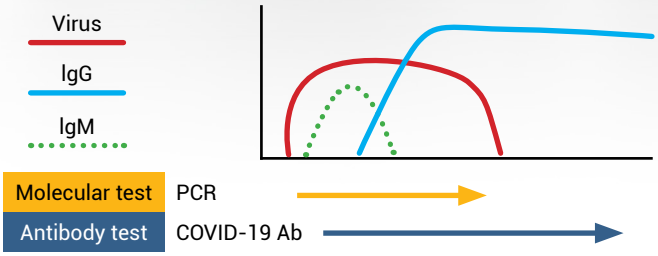
		2019-nCOV RT-PCR assay		
		Positive	Negative	Total
AFIAS COVID-19 Ab	Positive	46	0	46
	Negative	0	145	145
	Intermediate	2	5	7
	Total	48	150	198

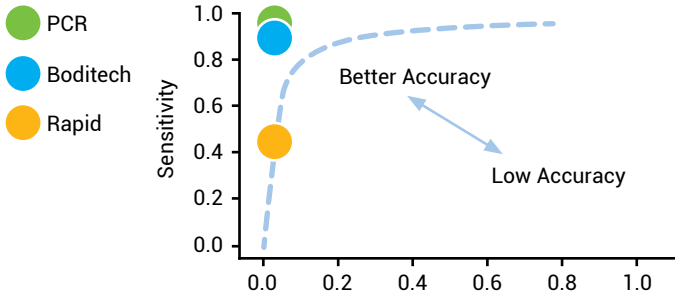
Positive Percent Agreement: 95.8%

Negative Percent Agreement: 96.7%

- **Inspire Health Alliance is partnered with Boditech to provide COVID-19 antibody testing.**
- **Boditech's test, which utilizes its AFIAS Analyzer, is the most accurate on-site point of care antibody test available in the marketplace.**
- **The test is designed to be used on-site at the point of care.**
- **Results are obtained within 10 minutes.**
- **Inspire expects that the Boditech COVID-19 test will receive FDA approval under the Emergency Use Authorization during April 2020.**

High Sensitivity (Time resolved fluorescence immunoassay)





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.

This test is under review by the FDA under Emergency Use Authorization

Immunostics, inc.
Subsidiary of Boditech Med, Inc.

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