CE

INNOVITA® 2019-nCoV Ab Test (Colloidal Gold)
(IgM/IgG Serum/Plasma/Venous whole blood Combo)

REF **YF319C**

For Emergency Authorization Use (EUA) only

For in vitro diagnostic use only

For prescription use only

Instruction for Use

1. Introduction

1.1 Intended Use

The Innovita 2019-nCoV Ab Test (Colloidal Gold) is a rapid lateral flow chromatographic immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma (sodium citrate, lithium heparin, and dipotassium EDTA) and venous whole blood (sodium citrate, lithium heparin, and dipotassium EDTA). The Innovita 2019-nCoV Ab Test (Colloidal Gold) is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The Innovita 2019-nCoV Ab Test (Colloidal Gold) should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of Innovita 2019-nCoV Ab Test (Colloidal Gold) early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for Innovita 2019-nCoV Ab Test (Colloidal Gold) may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

The Innovita 2019-nCoV Ab Test (Colloidal Gold) is only for use under the Food and Drug Administration's Emergency Use Authorization.

1.2 Summary

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus SARS-CoV-2 are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

2. About the kit

2.1 Test Principle

Innovita 2019-nCoV Ab Test (Colloidal Gold) is a rapid lateral flow chromatographic immunoassay for the detection of SARS-CoV-2 IgM and IgG antibodies in human serum, plasma (sodium citrate, lithium heparin, and dipotassium EDTA) and venous whole blood (sodium citrate, lithium heparin, and dipotassium EDTA).

The cassette contains two test panels with separate specimen wells and results windows for IgM and for IgG. Specifically, each test panel contains (1) recombinant SARS-CoV-2 antigen (S1 and NP proteins) and mouse IgG antibodies labeled with colloidal gold as a tracer, (2) one detection line (T) in each result window, and (3) one quality control line (C) in each result window. The nitrocellulose membrane is coated with mouse anti-human monoclonal IgM (μ chain) antibodies (T line in the IgM result window), mouse anti-human monoclonal IgG (γ chain) antibodies (T line in the IgG result window), and goat-anti- mouse IgG antibodies (control lines C in both IgM and IgG result windows).

When the test specimen and diluent are loaded on the INNOVITA® 2019-nCoV Ab Test (Colloidal Gold), it will flow along the nitrocellulose membrane. If the specimen contains specific IgM or IgG antibodies against SARS-CoV-2, they will bind the colloidal gold-labeled SARS-CoV-2 antigens to form a complex that will be captured in the respective IgM or IgG result window to form a purple-red line (T). If the antibodies are not present above the detection limit of the test, no purple-red line (T) will form in the respective IgM or IgG result windows. The control lines (C) are used as a procedural control. The control lines should always appear in both result windows if the test procedure is performed properly and the reagents are working as intended.

2.2 Materials provided in kits

1. Sealed foil pouches each containing:
    a. One cassette device:
    b. One desiccant
2. Specimen diluent: 6 mL per vial (1 vial for 20 tests, 2 vials for 40 tests)
    a. Contains 20mM PBS, Sodium Casein and PC300
3. Instructions for use

2.3 Materials required but not provided

1. Specimen collection tubes;
2. Centrifuge (for serum/plasma only);
3. Micropipette, 5-50uL (to add specimens)；50-200uL (to add diluent)
4. Timer
5. External positive and negative controls (available for purchase separately from Innovita)
    - Innovita 2019-nCoV IgM/IgG Antibody Quality Controls (cat # YF 1301QC)
        i. 2019-nCoV IgM Positive Control: Lyophilized humanized anti-SARS-CoV-2 IgM antibody in negative control serum matrix containing inactivated human serum, phosphate buffered saline, sucrose, and ProClin 300.
        ii. 2019-nCoV IgG Positive Control: Lyophilized humanized anti-SARS-CoV-2 IgG antibody in negative control serum matrix containing inactivated human serum, phosphate buffered saline, sucrose, and ProClin 300.
        iii. 2019-nCoV IgM/IgG Negative Control: Lyophilized negative control matrix containing inactivated human serum, phosphate buffered saline, sucrose, and ProClin 300.

2.4 Storage and Stability

1. The kit can be stored at 4 – 30℃ for up to 8 months. DO NOT FREEZE.
2. Use the test within 1 hour after opening the pouch under 60% humidity.
3. See production date and expiration date on label. Do not use beyond the expiration date.

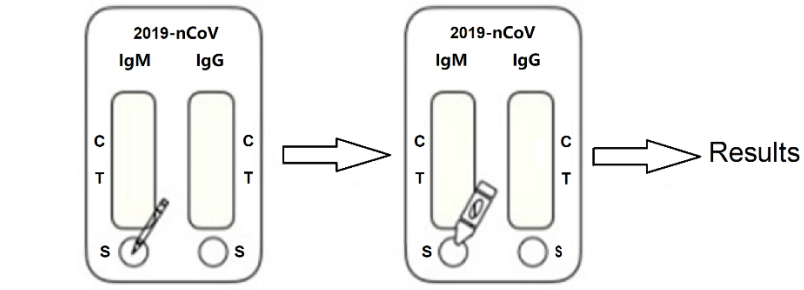
2.5 Specimen Collection and Handling

Consider any materials of human origin as infectious and handle using standard biosafety procedures.

1. Serum/plasma/venous whole blood specimens should be collected using standard phlebotomy protocols.
2. The venous whole blood specimens (sodium citrate, lithium heparin, and dipotassium EDTA) can be stored at 2℃ - 8℃ for up to 48 hours, and should not be frozen.
3. Serum and plasma (sodium citrate, lithium heparin, and dipotassium EDTA) specimens can be stored at 20℃-25℃ up to 8 hours, 2℃-8℃ up to 48 hours, and frozen at -20℃ or below for longer storage. Samples should not be repeatedly frozen and thawed (and recommended not to be thawed more than once).
4. It is recommended to test the sample immediately after collection.
5. Attention should be paid to aseptic operation during the collection and storage of samples.

2.6 Test Procedure

1. Allow test device, specimen and buffer to equilibrate to room temperature (15-30°C) prior to opening the pouch. Remove the test device from the sealed aluminum foil pouch.
2. Add 20μL venous whole blood or 10μL serum/plasma specimens into each specimen well, and then add 80μL or 2 drops of specimen diluent into each specimen well.
3. Wait for the colored lines to appear at room temperature.
4. Read results between 10-15 minutes. Do not read the result after 15 minutes.



Add 20 μL venous whole blood or 10 μL serum/plasma

Add 80 μL (or 2 drops) of specimen diluent

3. Warnings and Precautions

⚠ **CAUTION:** The samples of this assay contains human sourced and/or potentially infectious components. As no known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. These human specimens should be handled as if infectious using laboratory safety procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories,[1] OSHA Standards on Bloodborne Pathogens,[2] CLSI Document M29-A4,[3] and other appropriate biosafety practices.[4] Therefore all human sourced materials should be considered infectious. These precautions include, but are not limited to, the following:

- Wear gloves when handling specimens or reagents.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect spills of specimens by including the use of a tuberculocidal disinfectant such as 1.0% sodium hypochlorite or other suitable disinfectants.[1]
- Decontaminate and dispose of all potentially infectious materials in accordance with local, state, and federal regulations.[4]
- The Innovita 2019-nCoV Ab Test (Colloidal Gold) specimen diluent buffer contains the following components:
    - Sodium Chloride (EC no. 231-598-3)
    - Disodium hydrogen phosphate (EC no. 231-448-7)
    - Casein (EC no. 232-555-1)

The following warnings apply:

Warnings

H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H315	Causes skin irritation
H402	Harmful to aquatic life*
H412	Harmful to aquatic life with long lasting effects
P261	Avoid breathing mist/vapors/spray
P264	Wash hands thoroughly after handling
P280	Wear protective gloves/protective clothing/eye protection
P273	Avoid release to the environment
P302 + P352	IF ON SKIN: wash with plenty of water
P333 + P313	If skin irritation or rash occurs: get medical advice/attention

P362 + P364	Take off contaminated clothing and wash before reuses
P305 + P351 + P338	IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: get medical advice/attention.
P501	Dispose of contents/container in accordance with local regulations.

**** Not applicable where regulation EC 1272/2008 (CLP) has been implemented.**

Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet. It is available from your local distributor.

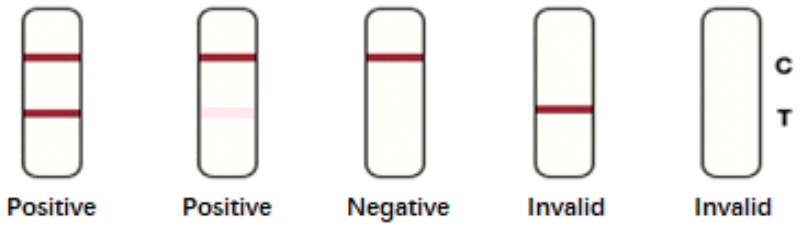
1. As with any test procedure, good laboratory practice is essential to the proper performance of this test. The INNOVITA ® Kit should be performed by qualified and trained staff to avoid the risk of erroneous results.
2. For prescription use only. For in vitro diagnostic use only. For Emergency Use Authorization Only. Do not use after expiration date.
3. This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
4. This test has been authorized only for the detection of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
5. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
6. All patient samples should be handled as if infectious, using good laboratory procedures as outlined in Biosafety in Microbiological and Biomedical Laboratories1 and in the CLSI Document M29-A4.3 Only personnel proficient in handling infectious materials and the use of the Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit should perform this procedure.
7. Closely follow procedures and guidelines provided to ensure that the test is performed correctly. Any deviation from the procedures and guidelines may affect optimal test performance.
8. False positive results may occur if carryover of samples is not adequately controlled during sample handling and processing.
9. The INNOVITA Kit is only for use with serum, plasma, and venous whole blood that have been handled and stored as described in the Section 2.4 and 2.5 of this package insert.
10. Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality.
11. During preparation of samples, compliance with good laboratory practices is essential to minimize the risk of cross-contamination between samples.
12. Excessive or inadequate samples may yield false or invalid results.
13. Components contained in the INNOVITA Kit are intended to be used together. Do not mix components from different kit lots. For example, do not use the device from lot X with the specimen diluent from lot Y.
14. Do not use kits or reagents after the expiration dates shown on the labels.
15. Work area must be considered potential sources of contamination. Change gloves after contact with potential contaminants (specimens) before handling unopened reagents, or specimens.
16. The test kit is sealed in a protective foil pouch. Do not use if pouch is damaged or open. Remove test kit from pouch just prior to use. Do not touch the reaction area of test kit.
17. Do not use damaged test kit. Do not reuse the test kit.
18. Decontaminate and dispose of all potentially biohazardous materials in accordance with local, state, and federal regulations.[4] All materials should be handled in a manner that minimizes the chance of potential contamination of the work area.
19. Human serum, plasma or venous whole blood samples should be considered as potentially infectious. Operators should wear protective clothing, masks, gloves and take other appropriate safety precautions to

avoid or reduce the risk of infection.

20. This test should be performed at room temperature (15 to 30℃). If stored refrigerated, ensure that the pouch and buffer are brought to room temperature before performing testing.
21. Humidity and temperature can adversely affect results. Testing must be performed within one hour after opening the pouch under 60% humidity.
22. The test device cannot be reused.

3.1 Results Interpretation

1. **IgM Positive**: The presence of two purple-red lines (T and C) within the IgM result window indicates positive for SARS-CoV-2 IgM antibody.
2. **IgG Positive**: The presence of two purple-red lines (T and C) within the IgG result window indicates positive for SARS-CoV-2 IgG antibody.
3. Negative: Only one purple-red line appearing at the control line (C) in each window indicates negative result.
4. **Invalid**: If control lines (C) fail to appear in one or both result windows, no matter whether the T line is visible or not, the test is invalid. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, you should immediately stop using the kit with the same LOT No. and contact your local distributor.



* A line with any intensity of color should be considered as a positive result. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.

3.2 Quality Control

An internal procedural control is included in the test. A colored line appearing in the control line region (C) in each result window is an internal valid procedural control, confirming sufficient specimen volume and correct procedural technique. If the control lines (C) fail to appear in one or both IgG and IgM result windows, no matter whether the T line is visible or not, the test in invalid.

External controls are not supplied with this kit; however, external positive and negative controls are available for purchase separately from Innovita (Innovita 2019-nCoV IgM/IgG Antibody Quality Controls; cat # YF 1301QC). It is recommended that positive and negative controls are tested each time when a new lot is used, when a new operator performs the test, or when the test is run in a new room/laboratory, etc. as a good laboratory practice to confirm the test procedure and to verify proper test performance

4. Limitations

For use under an Emergency Use Authorization only.

1. This test is only to be used in CLIA certified laboratories that meet requirements to perform moderate or high complexity testing and not in point-of-care or at-home testing settings.
2. This test can only be used for the analysis of serum, plasma (sodium citrate, lithium heparin, and dipotassium EDTA), and venous whole blood (sodium citrate, lithium heparin, and dipotassium EDTA) samples. Do not use with fingerstick (capillary) whole blood samples.
3. The test is limited to the qualitative detection of IgM and IgG antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
4. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status.
5. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

6. False negative results may occur for immune-compromised individuals or individuals who receive immunosuppressive therapy.
7. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgG or IgM antibodies may not be detected in the first few days of infection; the sensitivity of the INNOVITA 2019-nCoV Ab Test (Colloidal Gold) early after infection is unknown. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
8. A negative 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, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test.
9. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second, different serology test to confirm an adaptive immune response.
10. False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible cause. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
11. Reading test results earlier than 10 minutes or later than 15 minutes after the addition of specimen diluent may yield erroneous results.
12. The test may have lower sensitivity for IgG detection in symptomatic individuals less than 15 days since symptom onset.
13. Not to be used for the screening of donated blood.
14. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

5. Conditions of Authorization for the Laboratory

The INNOVITA 2019-nCoV Ab Test(Colloidal Gold) Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

Authorized laboratories using the INNOVITA 2019-nCoV Ab Test(Colloidal Gold) ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media
2. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Innovita (Tangshan) Biological Technology Co., Ltd (info@innovita.com.cn) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must

also be trained in and be familiar with the interpretation of results of the product.

7. Innovita (Thanshan) Biological Technology Co., Ltd., authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

***The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests" as "authorized laboratories."**

6. Performance Characteristics

6.1 Cross reactivity:

Cross-reactivity of INNOVITA 2019-nCoV Ab Test (Colloidal Gold) was evaluated using samples which contain antibodies to the pathogens and conditions listed below, and also samples from HIV positive individuals. No false positive INNOVITA 2019-nCoV Ab Test (Colloidal Gold) results were found with the following:

IgM results for all samples

Types of specimens	Number of Samples	Innovita 2019-nCoV Ab Test (Colloidal Gold) –IgM Test Results		
		Pos	Neg	% Cross-reactivity
H1N1 (new type influenza A virus H1N1 2009) IgM	2	0	2	0%
H1N1 (seasonal influenza virus H1N1) IgM	2	0	2	0%
H3N2 IgM	2	0	2	0%
H5N1 IgM	2	0	2	0%
H7N9 IgM	2	0	2	0%
Influenza B virus (Flu B) IgM	5	0	5	0%
Haemophilus Influenzae (HI) IgM	5	0	5	0%
Parainfluenza virus (PIV) IgM	5	0	5	0%
Respiratory Syncytial Virus (RSV) IgM	5	0	5	0%
Chlamydia pneumoniae (CP) IgM	5	0	5	0%
Mycoplasma pneumoniae (MP) IgM	5	0	5	0%
Adenovirus (ADV) IgM	5	0	5	0%
Enterovirus A IgM	5	0	5	0%
Measles virus (MV) IgM	5	0	5	0%
Rotavirus (RV) IgM	5	0	5	0%
Varicella-zoster virus (VZV) IgM	5	0	5	0%
Coxsackievirus group B (CoX B) IgM	5	0	5	0%
Rhinovirus (RhV) IgM	5	0	5	0%
EB virus IgM	5	0	5	0%
Cytomegalovirus (CMV) IgM	5	0	5	0%
Mumps Virus (MUV) IgM	5	0	5	0%
HIV	5	0	5	0%
HCV IgM	5	0	5	0%
HBcAb IgM	5	0	5	0%
Systemic lupus erythematosus	5	0	5	0%
Coronavirus HKU1IgM	3	0	3	0%
Coronavirus OC43 IgM	3	0	3	0%
Coronavirus NL63 IgM	3	0	3	0%
Coronavirus 229E IgM	3	0	3	0%
Rheumatoid factor (RF)	4	0	4	0%
Anti-nuclear antibody (ANA)	4	0	4	0%
Anti-mitochondrial Antibody (AMA)	4	0	4	0%
Human anti-mouse antibody (HAMA)	4	0	4	0%

IgG results for all samples

Types of specimens	Number of Samples	Innovita® 2019-nCoV Ab Test (Colloidal Gold) –IgG Test Results		
		Pos.	Neg.	% Cross-reactivity

H1N1 (new type influenza A virus H1N1 2009) IgG	2	0	2	0%
H1N1 (seasonal influenza virus H1N1) IgG	2	0	2	0%
H3N2 IgG	2	0	2	0%
H5N1 IgG	2	0	2	0%
H7N9 IgG	2	0	2	0%
Influenza B virus (Flu B) IgG	5	0	5	0%
Haemophilus Influenzae (HI) IgG	5	0	5	0%
Parainfluenza virus (PIV) IgG	5	0	5	0%
Respiratory Syncytial Virus (RSV) IgG	5	0	5	0%
Chlamydia pneumoniae (CP) IgG	5	0	5	0%
Mycoplasma pneumoniae (MP) IgG	5	0	5	0%
Adenovirus (ADV) IgG	5	0	5	0%
Enterovirus A IgG	5	0	5	0%
Measles virus (MV) IgG	5	0	5	0%
Rotavirus (RV) IgG	5	0	5	0%
Varicella-zoster virus (VZV) IgG	5	0	5	0%
Coxsackievirus group B (CoX B) IgG	5	0	5	0%
Rhinovirus (RhV) IgG	5	0	5	0%
EB virus IgG	5	0	5	0%
Cytomegalovirus (CMV) IgG	5	0	5	0%
Mumps Virus (MUV) IgG	5	0	5	0%
HIV	5	0	5	0%
HCV IgG	5	0	5	0%
HBcAb IgG	5	0	5	0%
Systemic lupus erythematosus	5	0	5	0%
Coronavirus HKU1IgG	3	0	3	0%
Coronavirus OC43 IgG	3	0	3	0%
Coronavirus NL63 IgG	3	0	3	0%
Coronavirus 229E IgG	3	0	3	0%
Rheumatoid factor (RF)	4	0	4	0%
Anti-nuclear antibody (ANA)	4	0	4	0%
Anti-mitochondrial Antibody (AMA)	4	0	4	0%
Human anti-mouse antibody (HAMA)	4	0	4	0%

6.2 Endogenous/Exogenous Potentially Interfering Substances

Low titer SARS-CoV-2 antibody positive serum samples and SARS-CoV-2 antibody negative serum samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positive or false negative INNOVITA 2019-nCoV Ab Test (Colloidal Gold) results were found with the following:

Name of Substance	Concentration	Name of Substance	Concentration
Triglyceride	25mg/ml	Interferon	200mg/L
Bilirubin	0.2mg/mL	Oseltamivir	30mg/L
Hemoglobin	5.0mg/mL	Abidol	40mg/L
Human IgM	0.8mg/mL	Levofloxacin	200mg/L
Human IgG	4mg/mL	Azithromycin	100mg/L
Epinastine hydrochloride	4mg/L	Ceftriaxone	400mg/L
Ribavirin	40mg/L	Meropenem	200mg/L

6.3 Class Specificity

Class specificity was evaluated in three studies. Two studies evaluated the assay's capability of detecting IgG or IgM in the presence of different dilutions of IgM or IgG respectively. Results indicate that the presence of high titer IgG antibodies do not interfere with detection of low levels of IgM and the presence of high titer IgM antibodies do not interfere with detection of low levels of IgG using the Innovita 2019-CoV Ab Test (Colloidal Gold). The third study evaluated the assay's specificity in detecting IgM when a reducing agent, β-mercaptoethanol was added to the sample. The results demonstrated a loss of IgM positivity after reducing agent treatment. All three studies demonstrate that the assay specifically detects IgM and IgG.

6.4 Matrix Equivalency

A matrix equivalency study was conducted to evaluate the performance of the assay when the claimed specimen types are used (serum, plasma (lithium heparin, sodium citrate and dipotassium EDTA, and venous whole blood (lithium heparin sodium citrate and dipotassium EDTA). Each specimen type performed equivalently. Lithium heparin, sodium citrate and dipotassium EDTA were not shown to interfere with the detection of antibodies in plasma or venous whole blood samples using this kit.

6.5 Clinical performance

A) Innovita multisite study (Study 1):

The clinical performance of the INNOVITA 2019-nCoV Ab Test (Colloidal Gold) was evaluated in China with a total of 468 clinical specimens collected during the COVID-19 pandemic. Of these, 163 were from individuals with previously confirmed positive RT-PCR test results for SARS-CoV-2 RNA with documented RT-PCR test dates, and 305 were from individuals with negative RT-PCR test results for SARS-CoV-2 RNA. Of the 468 samples, 65 samples were serum and 403 were plasma. Symptom onset data was not available for the study subjects. Positive serology results with the INNOVITA 2019-nCov Ab Test (Colloidal Gold) were stratified by days post-PCR results at the time of blood collection for 163 of the study subjects. Positive percent agreement (PPA) and negative percent agreement (NPA) to PCR was evaluated. The results are shown below.

Overall Clinical Study Results (IgM/IgG) By Days Post PCR for 163 Samples

Days post- PCR	Number of PCR-Positive samples	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgM/IgG Results		
		Positive	PPA	95%CI
≤ 7	107	94	87.85%	80.32% -92.76%
8-14	29	28	96.55%	82.83% -99.39%
≥ 15	27	27	100%	87.55% -100%

IgM Results Stratified by Days Post PCR

Days post- PCR	Number of PCR-Positive samples	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgM Results		
		Positive	PPA	95%CI
≤ 7	107	84	78.50%	69.81% -85.23%
8-14	29	22	75.86%	57.89% -87.78% %
≥ 15*	27	13	48.15%	30.74%-66.02%

**NOTE: Symptom onset data was not available for this study. Results were analyzed by days post-PCR test date. Acceptable IgM PPA performance was demonstrated for samples tested ≥ 15 days post-symptom onset in additional studies (described below) where symptom onset information was documented.*

IgG Results Stratified by Days Post PCR

Days post- PCR	Number of PCR-Positive samples	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgG Results		
		Positive	PPA	95%CI
≤ 7	107	88	82.24%	73.7% -88.2%
8-14	29	27	92.31%	78.04% -98.09%
≥ 15	27	27	100%	87.55% -100%

The overall NPA was 98.03% (299/305; 95% CI: 95.78% - 99.10%)

B) Innovita US study (Study 2):

An additional clinical study was performed to further evaluate the performance of INNOVITA ® 2019-nCoV Ab Test (Colloidal Gold) with a total of 66 clinical specimens (serum/plasma) collected in the USA from individuals with documented dates of symptom onset. Of these, 36 samples were from individuals with previously confirmed positive RT-PCR test results for SARS-CoV-2 RNA from 8 to 40 days after known symptom onset, and 30 known negative samples were collected prior to the onset of the pandemic. The results are as follows:

Overall Clinical Study Results (IgM/IgG) By Stratified by Days Post Symptom Onset

Days post-symptom onset	Number of samples tested	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgM/IgG Results		
		IgM + IgG	PPA	95% CI
≤7	0	N/A	N/A	N/A
8-14	6	6	100.00%	54.07% - 100%
≥ 15	30	27	90.00%	73.47% - 97.89%

IgM Results Stratified by Days Post Symptom Onset

Days post-symptom onset	Number of samples tested	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgM Results		
		IgM	PPA	95% CI
≤7	0	N/A	N/A	N/A
8-14	6	6	100.00%	54.07% - 100%
≥ 15	30	26	86.67%	69.27% - 96.24%

IgG Results Stratified by Days Post Symptom Onset

Days post-symptom onset	Number of samples tested	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgG Results		
		IgG	PPA	95% CI
≤7	0	N/A	N/A	N/A
8-14	6	5	83.33%	35.88% -99.58%
≥ 15	30	27	90.00%	73.47% - 97.89%

The overall NPA was 100% (30/30; 95% CI: 88.43% - 100%)

C) *Innovita Longitudinal Study (Study 3):*

A longitudinal study was conducted to evaluate the performance of the test in samples collected overtime during the course of infection with SARS-CoV2. In this study, 164 dipotassium EDTA plasma samples from 49 patients were collected at different time points from the onset of symptoms. All individuals enrolled in this study were found to be positive for SARS-CoV-2 infection via a PCR test. Data summarizing the first result per subject per time bin below (n = 101 samples evaluated):

Overall Study Results (IgM/IgG) Stratified By Days Post Symptoms Onset

Days post-symptom onset	Number of samples tested	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgM/IgG Results		
		Positive	PPA	95% CI
≤ 7	15	9	60.00%	35.75% - 80.18%
8-14	41	37	90.24%	77.45% - 96.14%
≥ 15	45	44	97.78%	88.43% - 99.61%

IgM Results Stratified by Days Post Symptoms Onset

Days post-symptom onset	Number of samples tested	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgM Results		
		Positive	PPA	95% CI
≤ 7	15	9	60.00%	35.75% - 80.18%
8-14	41	37	90.24%	77.45% - 96.14%
≥15	43*	42	97.67%	87.94% - 99.59%

* IgM results were unavailable for 2 samples, resulting in 99 samples for evaluation.

IgG Results Stratified by Days Post Symptoms Onset

Days post-symptom onset	Number of samples tested	Innovita 2019-nCoV Ab Test (Colloidal Gold) IgG Results		
		Positive	PPA	95% CI
≤ 7	15	7	46.67%	24.81% - 69.88%
8-14	41	36	87.80%	74.46% - 94.68%
≥15	45	44	97.78%	88.43% - 99.61%

D) Independent Clinical Agreement Validation Study at NCI:

The INNOVITA 2019-nCov Ab Test (Colloidal gold) was tested on May 28, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the INNOVITA 2019-nCov Ab Test (Colloidal gold). The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include i) Seventy (70) samples selected without regard to clinical status, “Negatives” and ii) Ten (10) samples selected from banked serum from HIV+ patients, “HIV+”. Testing was performed by one operator using 1 lot of INNOVITA 2019-nCov Ab Test (Colloidal gold). Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For the evaluation of cross-reactivity with HIV+, it was determined whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the Tables below.

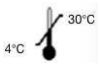
Summary Results

	Comparator Method			**Collected pre-2020**		**Total**
	Antibody Positive			**Antibody Negative**		
INNOVITA ® 2019-nCoV Ab Test (Colloidal Gold).	**IgM+ IgG+**	**IgM+ IgG-**	**IgM- IgG+**	**Negative**	**HIV+**	
IgM+, IgG+	26	-	-	-	-	26
IgM+, IgG-	2	-	-	1	-	3
IgM-, IgG+	2	-	-	1	-	3
IgM-, IgG-	-	-	-	68	10	78
Total	30	-	-	70	10	110

Summary Statistics

Measure	**Estimate**	**Confidence Interval**
IgM Sensitivity	93.3% (28/30)	(78.7%, 98.2%)
IgM Specificity	98.8% (79/80)	(93.3%, 99.8%)
IgG Sensitivity	93.3% (28/30)	(78.7%, 98.2%)
IgG Specificity	98.8% (79/80)	(93.3%, 99.8%)
Combined Sensitivity	100% (30/30)	(88.7%, 100%)
Combined Specificity	97.5% (78/80)	(91.3%, 99.3%)
Combined PPV for prevalence =5.0%	67.8%	(35 %, 88.4%)
Combined NPV for prevalence =5.0%	100%	(99.4%, 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

Index of Symbols

	For Prescription Use Only		For in vitro diagnostic use only
	Consult instruction for use		Contains sufficient for <n> tests
	Manufacturer		Catalogue Number
	Stored between 4-30℃		Lot number
	Caution		Use by
	Keep away from sunlight		Keep dry

	Do not reuse		Do not use if package is damaged
	Warning		
EC REP	Authorized Representative in the European Community		
CE	CE Mark		

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