EN Quality approved by SD BIOSENSOR / For *in vitro* diagnostics use only

REF Q-NCOV-01C

STANDARD Q

COVID-19 IgM/IgG Combo

STANDARD™ Q COVID-19 IgM/IgG Combo Test

PLEASE READ CAREFULLY BEFORE YOU PERFORM THE TEST

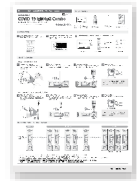
SD BIOSENSOR

KIT CONTENTS

Test device (individually in a foil pouch with desiccant)

Buffer bottle

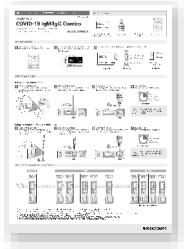
Capillary tube (20μl)



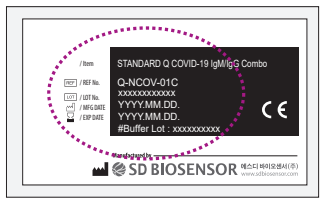
Instructions for use

PREPARATION

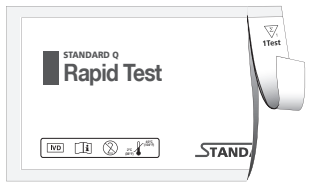
1 Carefully read instructions for using STANDARD Q COVID-19 IgM/IgG Combo Test.



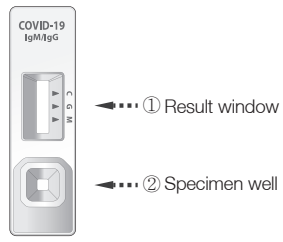
2 Check the expiry date at the back of the foil pouch. Do not use the test device, if expiry date has passed.



3 Check both the test device and the desiccant in the foil pouch.



<Foil pouch>



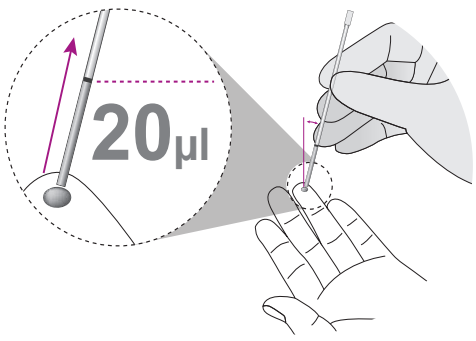
<Test device>

<Desiccant>

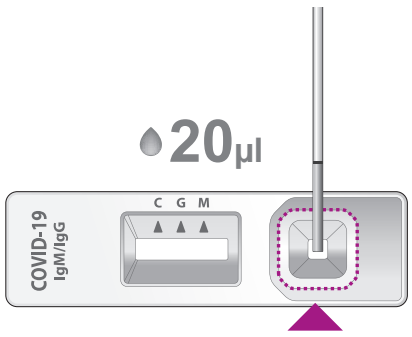
TEST PROCEDURE

Using Capillary whole blood

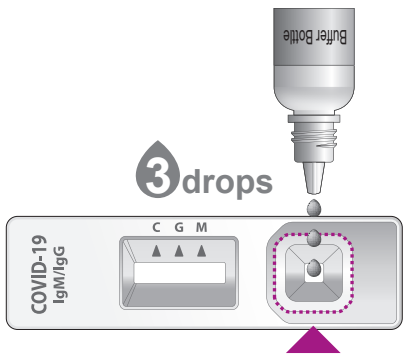
1 Collecting of Specimen
Using a capillary tube, collect the 20μl of capillary whole blood to the black line of the capillary tube.



2 Adding of Specimen
Add the collected capillary whole blood to the specimen well of the test device.



3 Dropping of buffer
Add 3 drops (90μl) of buffer vertically into the specimen well of the test device.

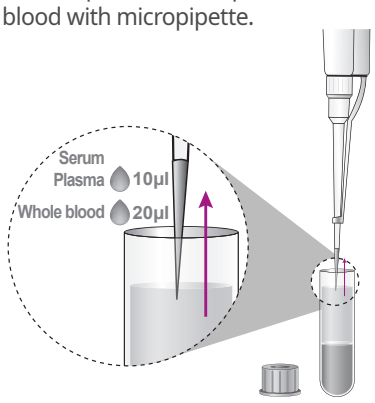


4 Reading Time
Read the test result at 10~15 minutes.

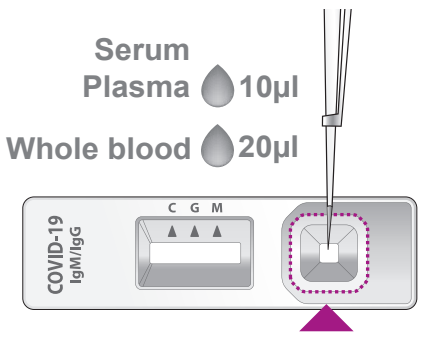
CAUTION
- Do not read test results after 15 minutes. It may give false results.

Using serum/plasma/venous whole blood

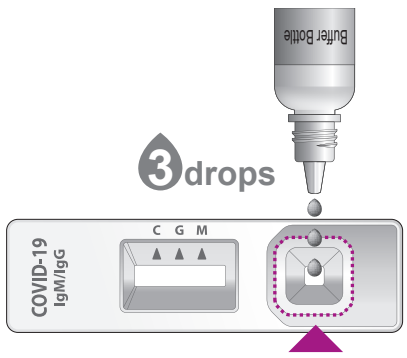
1 Collecting of Specimen
Using a micropipette, collect the 10μl of serum, plasma or 20μl of venous whole blood with micropipette.



2 Adding of Specimen
Add the collected serum, plasma or venous whole blood to the specimen well of the test device.



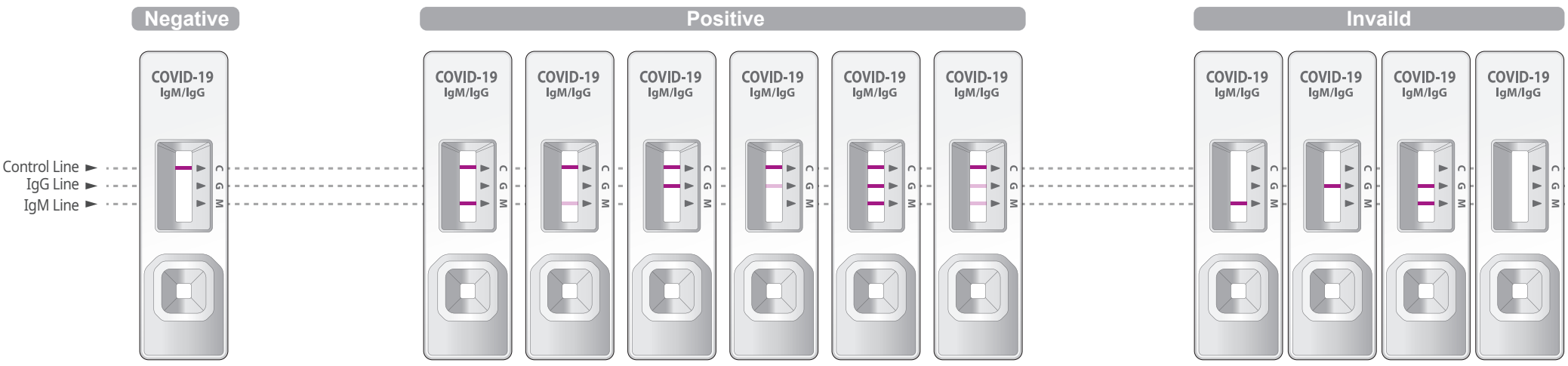
3 Dropping of buffer
Add 3 drops (90μl) of buffer vertically into the specimen well of the test device.



4 Reading Time
Read the test result at 10~15 minutes.

CAUTION
- Do not read test results after 15 minutes. It may give false results.

INTERPRETATION OF TEST RESULT



Re-test with a new test device.

1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
2. A colored bands will appear in the lower section of the result window. These bands are each test line of IgM/IgG (M, G).
3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

*** STANDARD Q COVID-19 IgM/IgG Combo Test may cross-react with antibody against SARS-CoV-1.**
*** 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.**
*** Positive results should be considered in conjunction with the clinical history, RT-PCR results and other data available.**

STANDARD™ Q COVID-19 IgM/IgG Combo Test

SD BIOSENSOR

EXPLANATION AND SUMMARY

[Introduction]

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "COVID-19", was discovered due to Wuhan Viral Pneumonia cases in 2019 and was named by the World Health Organization on January 12, 2020. WHO confirmed that COVID-19 can cause colds, the Middle East Respiratory Syndrome (MERS) and more serious diseases such as severe acute respiratory syndrome (SARS). This kit is helpful for the auxiliary diagnosis of coronavirus infection. The test results are for clinical reference only and cannot be used as a basis for confirming or excluding cases alone.

[Intended use]

STANDARD Q COVID-19 IgM/IgG Combo Test is a rapid chromatographic immunoassay for the qualitative detection of specific antibodies to SARS-CoV-2 present in human serum, plasma or whole blood. This test is for in vitro professional diagnostic use and intended as an aid to diagnosis of SARS-CoV-2 infection in convalescent phase of patient with clinical symptoms with SARS-CoV-2 infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection.

[Test principle]

STANDARD Q COVID-19 IgM/IgG Combo Test has three pre-coated lines, "C" Control line, "G" and "M" Test line for the device on the surface of the nitrocellulose membrane. The control line and two test lines in the result window are not visible before applying any specimens. Monoclonal anti-nucleocapsid antibody is coated on the control line region and monoclonal anti-human IgG antibody and Monoclonal anti-human IgM antibody is coated on the "G" and "M" test line region. Recombinant COVID-19 nucleocapsid protein conjugated with colloidal gold particles are used as detectors for "M" and "G" test line. During the test, SARS-CoV-2 antibodies in the specimen interact with recombinant COVID-19 nucleocapsid protein conjugated with colloidal gold particles making antibody-antigen gold particle complex. This complex migrates on the membrane via capillary action until the "M" and "G" test line, where it will be captured by the Monoclonal anti-human IgG antibody or Monoclonal anti-human IgM antibody. A violet test line would be visible in the result window if SARS-CoV-2 antibodies are present in the specimen. The intensity of violet test line will vary depending upon the amount SARS-CoV-2 antibodies present in the specimen. If SARS-CoV-2 antibodies are not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

[Kit contents]

① Test device (individually in a foil pouch with desiccant) ② Buffer bottle
③ Capillary tube (20μl) ④ Instructions for use

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use the buffer of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.
11. Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as Heparin, EDTA, Sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
3. They should be brought to room temperature prior to use.

[Plasma]

1. Collect the venous blood into the commercially available anti-coagulant tube such as Heparin, EDTA, Sodium citrate by venipuncture and centrifuge blood to get plasma specimen.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
3. They should be brought to room temperature prior to use.

[Whole blood]

• Capillary whole blood

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Using a capillary tube, collect the 20μl of capillary whole blood to the black line of the capillary tube.
5. The capillary whole blood must be tested immediately after collection.

• Venous whole blood

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as Heparin, EDTA , Sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1-2 days after collection.
3. Do not use hemolyzed blood Specimens.

CAUTION

- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

PERFORMANCE CHARACTERISTICS

[Clinical evaluation]

Performance characteristic for the STANDARD Q COVID-19 IgM/IgG Combo Test for rapid detection of anti-SARS-CoV-2 antibodies was established in retrospective, single institute, randomized, single-blinded study conducted at a trial site in KOREA during the 2020 SARS-CoV-2 pandemic situation. A total of 336 retrospective specimens were tested using the STANDARD Q COVID-19 IgM/IgG Combo Test. These specimens consisted of serum from PCR positive or negative confirmed patients. The performance of the STANDARD Q COVID-19 IgM/IgG Combo Test were compared to a commercialized molecular assay. Although the STANDARD Q COVID-19 IgM/IgG Combo Test allows to test for IgM and IgG separately, due to the differing inter-patient time response to the virus, any individual with positive result for the IgM or the IgG test should be read as a positive for anti-SARS-CoV-2 antibodies. The combined test result (positive for IgM and/or IgG or negative for IgM and/or IgG) was used to calculate the total test sensitivity and specificity.

• Test sensitivity

The seroconversion time of IgM and IgG antibodies varies from person to person, but it was estimated to be around 7 days after onset of symptom[4,5]. The STANDARD Q COVID-19 IgM/IgG Combo Test showed **96.50% of sensitivity** using specimens from patients 7 days after symptom onset (combined IgM+IgG).

Table 1. Summary of the sensitivity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR using specimens **7 days after symptom onset**

≥ 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	138	0	138
	Negative	5	0	5
	Total	143	0	143
Sensitivity		**96.50% (138/143, 95% CI, 92.03% - 98.86%)**		

Table 2. Summary of the sensitivity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR using specimens **within less than 7 days after symptom onset**

< 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	26	0	26
	Negative	7	0	7
	Total	33	0	33
Sensitivity		78.79% (26/33, 95% CI, 61.09% - 91.02%)		

Table 3. Summary of the sensitivity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR using specimens in **the period of 7 days to 14 days after symptom onset**

7-14 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	52	0	52
	Negative	4	0	4
	Total	56	0	56
Sensitivity		92.86% (52/56, 95% CI, 82.71% - 98.02%)		

Table 4. Summary of the sensitivity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR using specimens **14 days after symptom onset**

> 14 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	86	0	86
	Negative	1	0	1
	Total	87	0	87
Sensitivity		98.85% (86/87, 95% CI, 93.76% - 99.97%)		

• Test specificity

The STANDARD Q COVID-19 IgM/IgG Combo Test showed **95% of specificity** (combined IgM+IgG).

Table 5. Summary of the specificity of the STANDARD Q COVID-19 IgM/IgG Combo Test compared to PCR

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 IgM/IgG Combo Test	Positive	0	8	8
	Negative	0	152	152
	Total	0	160	160
Specificity		**95.00% (152/160, 95% CI, 90.39% - 97.82%)**		

ANALYTICAL PERFORMANCE

1. Limit of Detection: IgM-9.37 ug/ml, IgG-3.75 ug/ml
2. Cross-Reactivity: No cross-reactivity for the specimen of HIV Seroconversion panel, Japanese Encephalitis positive, Zika virus positive, Chikungunya positive, Dengue IgM positive, Salmonella typhi IgM positive, Rubella IgM, CMV IgG/IgM, Tick borne encephalitis IgM positive, West Nile Virus positive, Treponema palladium, HAV IgM positive, HAV IgG positive, HBV Ab positive, HCV Ab positive, Influenza vaccine positive, Leishmania positive, Brucella IgM positive, Chagas positive, Toxoplasma positive, Filariasis positive, Mycoplasma pneumonia IgM positive, Mycoplasma pneumonia IgG positive, Mycoplasma pneumonia IgM positive, Influenza A IgM positive, Influenza B IgM positive, Influenza A and B IgG+IgM positive and Tuberculosis positive.
3. Interference study: For Exogenous substances, there was no interference with medicines such as Zanamivir (for Influenza), Oseltamivir (for Influenza), Artemether-lumefantrine (for Malaria), Doxycycline hyclate (for Malaria), Quinine (for Malaria), Lamivudine (Retroviral medication), Ribavirin (for HCV), Daclatasvir (for HCV). Also there was no interference with Anti-inflammatory medication (Acetaminophen, Acetylsalicylic acid, Ibuprofen), Antibiotic (Erythromycin, Ciprofloxacin), Dietary substances (Caffeine, Ethanol, Biotin), Triglycerides, Cholesterol, Bilirubin(Unconjugate), Hemoglobin and Anticoagulants (EDTA, Heparin, Sodium citrate). For Edogenous substances, there was no interference with human anti-mouse antibody, whole blood of pregnant women and whole blood having elevated levels of hemoglobin, elevated levels of C-reactive protein and Elevated IgG or IgM samples.
4. Matrix Equivalency: The matrix and anticoagulant does not affect the detection of COVID-19 IgG and IgM in 25 contrived specimen between serum, plasma(Heparin, EDTA, Sodium citrate), venous whole blood(Heparin, EDTA, Sodium citrate), and capillary whole blood(collected in EDTA-treated tubes).

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of SARS-CoV-2 IgM/IgG in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate anti- SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
7. A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or an molecular assay or ELISA.
8. Positive test results do not rule out co-infections with other pathogens.
9. Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV-1.
10. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

EXTERNAL QUALITY CONTROL

1. Positive and negative controls are optional contents (STANDARD COVID-19 IgM/IgG Control(Cat No. 10COVC20)) and these controls can be provided as a means on additional quality control to demonstrate a positive or negative reaction.
2. Quality controls should be treated and tested the same as patient specimens.
3. It is recommended that positive and negative controls be run:
   - once for each new lot.
   - once for each untrained operator.
   - as required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements.

NOTIFICATION FOR COVID-19 ANTIBODY TESTS

1. This test has not been reviewed by the FDA.
2. 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 should be considered to rule out infection in these individuals.
3. 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.
4. 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 or past or present infection with SARS virus (no. 6).
5. Not for the screening of donated blood.
6. The test procedure should be conducted in ambient temperature and pressure.
7. Results of these tests should be appropriately recorded in a test report.

BIBLIOGRAPHY

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2. Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.2020
3. Diagnosis and treatment of pneumonia caused by new coronavirus (trial version 4) National Health Commission. 2020
4. Guo L et al. Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19). Clinical Infectious Disease. 2020
5. Zhao J et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Clinical Infectious Disease. 2020

CE IVD

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REF Reference number | IVD *In vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | To indicate the temperature limitations in which the transport package has to be kept and handled. | Note | Do not re-use. | Use by | LOT Batch code | Manufacturer | Date of manufacture | Indicate that you should keep the product dry | Keep away from sunlight | Do not use if packaging is damaged