Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit

Instruction For Use

For prescription use only. For in vitro diagnostic use only.
For Emergency Use Authorization (EUA) only.
Store at 2℃-30℃

(Colloidal Gold Method)

CONTENT

1. INTENDED USE

The Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit is a single-use rapid immunochromatographic test for the qualitative detection and differentiation of Immunoglobulin M(IgM) and Immunoglobulin G(IgG) antibodies to SARS-CoV-2 in human serum, plasma (heparin, dipotassium EDTA, and sodium citrate), and venous whole blood (heparin, dipotassium EDTA, and sodium citrate). The Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit 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 Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited 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.

Results are for the detection of SARS-CoV-2 antibodies. IgM and IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time that 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 Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit early after infection is unknown. Negative results do not preclude SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit 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 a second, different IgG or IgM assay.

The Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. TEST PRINCIPLE

The Biohit SARS-CoV-2 IgM/IgG Antibody Test is based on the immunochromatographic method. The SARS-CoV-2 IgM/IgG is detected by SARS-CoV-2 recombinant N-protein antigen and mouse anti human IgM/IgG antibody. SARS-CoV-2 IgM/IgG in the sample reacts with SARS-CoV-2 recombinant N-protein antigen bound to gold particles. This complex migrates along the membrane and reaches the IgM/IgG test line (T) which contains mouse anti human IgM/IgG antibody against SARS-CoV-2 IgM/IgG complex. The sample diluent is supplied for the lateral chromatography process, to provide a suitable environment for the reaction of antigen and antibody.

When the result is positive, the gold-labelled SARS-CoV-2 recombinant antigen-antibody complex binds to the IgM/IgG test line (T) and a purplish red color develops. When the result is negative, the sample does not contain any SARS-CoV-2 recombinant N-protein antigen-antibody complex that can bind to the IgM/IgG test line (T) so no color becomes visible. Development of a purplish red control line (C) helps ensure the addition of sufficient specimen volume and adequate migration have occurred and that the test was properly performed.

3. KIT COMPONENTS

No.	Content	Quantity
1	Instruction for use	1 piece
2	Test Card	25 cassettes
3	Sample Diluent (Phosphate buffer containing casein)	1 vial
4	Dropper	25 droppers

4. WARNINGS AND PRECAUTIONS

4.1. For prescription use only. For in vitro diagnostic use only. Do not use after expiration date.

4.2. 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.

4.3. This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

4.4. 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

4.5. Samples for human serum, plasma or whole blood 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.

4.6. This test should be performed at 18 to 30℃ (64 to 86°F). If stored refrigerated, ensure that the pouch and buffer are brought to operating temperature before performing testing.

4.7. Follow the instructions for use carefully. Reliability of assay results cannot be guaranteed if there is any deviation from the instructions in this package insert.

4.8. Professionals must handle the potentially contaminated materials safely according to local requirements.

4.9. Do not smoke, drink, eat, or use cosmetics in the working area. Wear Personal Protective Equipment (PPE) and disposable gloves when working with samples and reagents. Wash hands after operations.

4.10. Wipe and wash any splashed sample with highly effective disinfectant. Avoid splashing and the formation of aerosols.

4.11. Use a new clean disposable sample dispensing plastic dropper or tip for every sample to avoid cross contamination.

4.12. Decontaminate and dispose of all samples, reaction kits, and potentially contaminated materials as if they were infectious waste, in a biohazard waste container.

4.13. Once the Cassette is removed from the pouch, Use the Cassette as soon as possible to avoid being humidified. The Cassette is sensitive to humidity as well as to heat.

4.14. Do not use the Cassette if the pouch is damaged or the seal is broken.

4.15. The Cassette cannot be reused.

5. STORAGE CONDITIONS AND SHELF LIFE

The test card is stored at 2℃-30℃ and do not use after expiration date printed on the label. The test card sealed inside the aluminium foil bag shall be used within 1 hour after opening.

6. APPLICABLE INSTRUMENTS

None.

7. SAMPLE REQUIREMENTS

7.1. Applicable to human serum, plasma (heparin, dipotassium (K_2)-EDTA, and sodium citrate), and venous whole blood (heparin, K_2-EDTA, and sodium citrate) samples.

7.2. For whole blood, collect blood specimen into a collection tube (containing heparin, EDTA or Citrate) by venipuncture. The anticoagulative whole blood sample should not be stored for more than 6 hours at normal temperature (18-30℃). The sample should not be stored for more than 1 day at 2-8℃, do not freeze whole blood specimens.

7.3. For serum and plasma (heparin, K_2-EDTA, and sodium citrate) samples, the samples should be tested immediately after collection. Serum and plasma (heparin, K_2-EDTA, and sodium citrate) samples can be stored for 5 days at 2-8℃. If long-term storage is required, it should be stored at -20℃ (It has been confirmed that the sample can be stored for 3 months at -20℃). Serum or plasma specimens can be subjected to a maximum of 3 freezing/ thawing cycles.

7.4. Let the samples reach room temperature and mix well before testing. When there are visible particles in the sample, it should be centrifuged before the test to remove the precipitate.

7.5. If there is a lot of lipid (Triglyceride concentration over 37 mmol/L), hemolysis or turbidity in the sample, please do not use the sample to avoid affecting the result interpretation.

8. MATERIALS REQUIRED BUT NOT PROVIDED

- Sample vortex mixer
- 10-100μl pipette and tips
- Test tubes
- Sample collection tubes
- Timer
- External Positive controls for IgG and IgM antibodies and Negative control available for separate purchase:
  - Positive Control: Anti-SARS-CoV-2 antibodies (IgM and IgG) in heat inactivated serum.
  - Negative Control: Heat inactivated serum.

9. TEST PROCEDURES

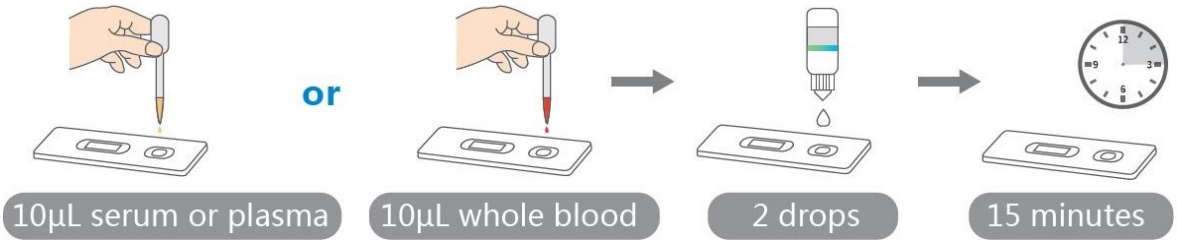
Step 1: Take out the sample to be tested and let it reach room temperature. Mix the sample well before testing.

Step 2: Tear the aluminium foil bag to open, take out the detection card and place it on the horizontal surface.

Step 3: Write the sample number on the test card.

Step 4: Take 10μL (or 1 drop from the dropper) of the sample to be tested (serum, plasma or whole blood sample) from the sample tube with the pipette and add 80μL (or 2 drops from the sample diluent vial) of sample diluent into the sample hole on the test card immediately, and ensure that there is no bubble during the operation.

Step 5: Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.

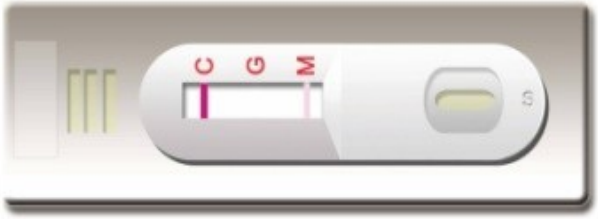


10. INTERPRETATION OF THE RESULTS

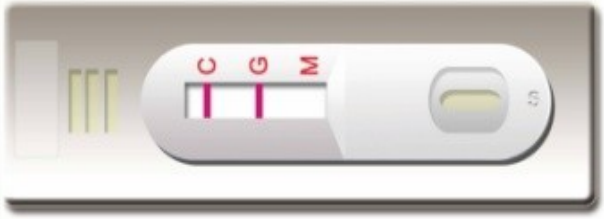
10.1. Negative: If only C-line appears, it means that SARS-CoV-2 antibody is not detected, and the result is negative:

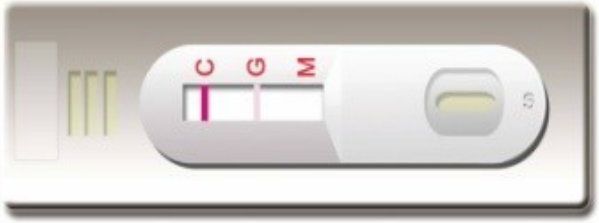
10.2. Positive:

10.2.1 If both the C-line and the M-line appear, it means that the IgM antibody against SARS-CoV-2 is detected, and the test result is IgM antibody is positive:

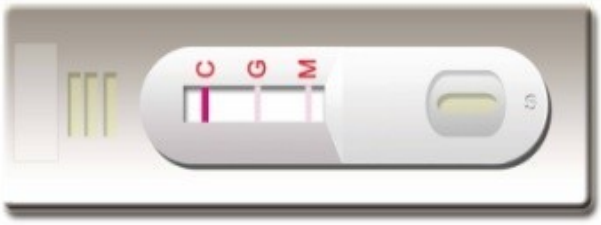


10.2.2 If both the C-line and the G-line appear, it means that the IgG antibody against SARS-CoV-2 is detected, and the test result is IgG antibody is positive：

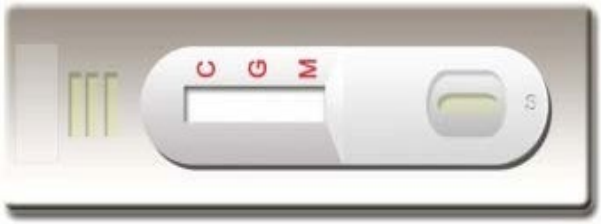


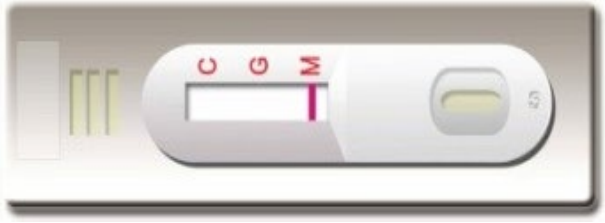


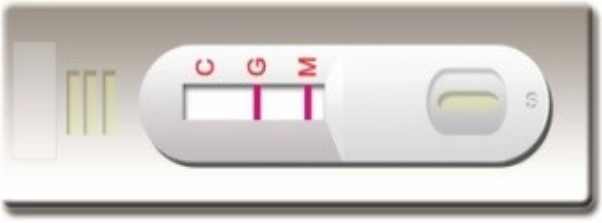
10.2.3 If the C-line, M-line and G-line are all present, it means that SARS-CoV-2 IgG and IgM antibodies are detected, and the test result is IgG and IgM antibody positive:



10.3. Invalid result: if C- line is not observed, it is invalid whether there is a detection line or not, and the sample should be re-tested using a new test card:







11. LIMITATION OF THE PROCEDURES

For use under an Emergency Use Authorization Only

11.1. This test is only to be used in CLIA certified laboratories and not in point-of-care or at-home testing settings.

11.2. This test can only be used for the analysis of serum, plasma (heparin, K_2-EDTA, and sodium citrate), and venous whole blood (heparin, K_2-EDTA, and sodium citrate) samples.

11.3. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit early after infection is unknown. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

11.4. 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.

11.5. 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 an alternative serology test to confirm an immune response. 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.

11.6. The test is limited to the qualitative detection of 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.

11.7. Do not use with blood obtained from a fingerstick procedure.

11.8. Reading test results earlier than 15 minutes or later than 20 minutes after the addition of sample diluent may yield erroneous results.

11.9. 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.

11.10. This test is not to be used for screening donated blood.

11.11. The test may have lower sensitivity for IgG detection in symptomatic individuals prior to 15 days since symptom onset.

11.12. The sensitivity of the test is impacted after being open for two hours — the density of IgG and IgM test line becomes weak. Testing must be performed within one hour after opening the pouch.

11.13. 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.

12. CONDITONS OF AUTHORIZATION FOR THE LABORATORY

The Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labelling 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 Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit (“your product” in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

12.1. Authorized laboratories* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating Fact Sheets may be used, which may include mass media.

12.2. Authorized laboratories using your product will use it 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 this product are not permitted.

12.3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

12.4. 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.

12.5. Authorized laboratories will collect information on the performance of this product and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Biohit Healthcare (Hefei) Co., Ltd. (public@chinabiohit.com or 86-551-65652770) any suspected occurrence of false reactive or false non-reactive results and significant

deviations from the established performance characteristics.

12.6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use this product in accordance with the authorized labelling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

12.7. 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 the 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 the requirements to perform moderate or high complexity tests" as "authorized laboratories."

13. PERFORMANCE CHARACTERISTICS

Cross-reactivity

Cross-reactivity of the Biohit SARS-CoV-2 IgM/IgG Antibody Test was evaluated by using clinical serum samples containing antibodies to the underlying conditions listed below. Five samples with antibodies to underlying conditions 1 to 7, and 20 samples with antibodies to conditions 8 to 12, were tested in singlicate with three separate lots of this Biohit SARS-CoV-2 IgM/IgG antibody test. None of the antibodies to the listed underlying conditions cross-reacted with this Biohit SARS-CoV-2 IgM/IgG antibody test kit to generate false positive results.

Sample number	Name of potential cross-reactants
1	Anti-influenza A (IgG and IgM)
2	Anti- influenza B (IgG and IgM)
3	Anti-HCV (IgG and IgM)
4	Anti-HBV (IgG and IgM)
5	ANA
6	Anti-respiratory syncytial virus (IgG and IgM)
7	Anti-Haemophilus influenzae (IgG and IgM)
8	Anti-229E (alpha coronavirus) IgG
9	Anti-NL63 (alpha coronavirus) IgG
10	Anti-OC43 (beta coronavirus) IgG
11	Anti-HKU1 (beta coronavirus) IgG
12	Anti-rhinovirus IgG

Endogenous/exogenous interference

One set of sample diluent, serum, plasma (heparin, K_2-EDTA, and sodium citrate), and venous whole blood (heparin, K_2-EDTA, and sodium citrate) samples positive for SARS-CoV-2 IgM/IgG antibodies, and another set of serum, plasma (heparin, K_2-EDTA, and sodium citrate), and venous whole blood (heparin, K_2-EDTA, and sodium citrate) samples negative for SARS-CoV-2 IgM/IgG antibodies were prepared. Both sets were spiked with one of the following substances at the concentrations specified below, and tested in multiple replicates. No false positive or false negative results were found with the following substances:

Purified mucin	60 g/L
Bilirubin	342 µmol/L

Triglyceride	37 mmol/L
Hemoglobin	2 g/L
Rheumatoid factor	30 IU/mL
HAMA	25 mg/mL
α – interferon	40 ng/mL
Zanamivir	10 μg/L
Ribavirin	20 mg/mL
Oseltamivir	250 μg/L
Peramivir	30 mg/L
Lopinavir	12 mg/L
Ritonavir	12.5 mg/L
Abidor	10 μg/mL
Levofloxacin	25 mg/L
Azithromycin	25 mg/mL
Ceftriaxone	10 μg/mL
Meropenem	3.3 mg/mL
Tobramycin	125 mg/L
Histamine hydrochloride	50 mg/L

Clinical Evaluation

Study 1: Biohit Clinical Agreement and Seroconversion

Methods: a retrospective study was carried out with 186 samples from a local hospital during the COVID-19 pandemic, including 78 samples of other (non SARS-CoV-2-mediated) respiratory tract infections (negative for SARS-CoV-2 infection by PCR) and 108 samples of healthy people (lacking respiratory symptoms by physical examination, and negative for SARS-CoV-2 infection by PCR). All samples were tested with Biohit SARS-CoV-2 IgM/IgG antibody test kit and negative percent agreement to PCR was evaluated.

The Negative Percent Agreement (NPA) of IgM and IgG are as follows:

	Reference method	NPA	95% Confidence Limit
SARS-CoV-2 IgM	SARS-CoV-2 PCR	99.46% (185/186)	97.04%- 99.99%
SARS-CoV-2 IgG	SARS-CoV-2 PCR	100% (186/186)	98.04%- 100%

To evaluate the performance of the Biohit SARS-CoV-2 IgM/IgG antibody test kit over time with PCR positive patients, 197 serum samples were collected serially from 40 hospitalized SARS-CoV-2 PCR positive patients at different days following the onset of symptoms between 1-7, 8-14 and at least 15 days.

The Positive Percent Agreement (PPA) According to Days From Onset of Symptoms:

		IgG			IgM		
Days from onset of symptoms	PCR positive at any time	Samples with Positive results (Serum)	PPA*	95%CI	Samples with Positive results (Serum)	PPA *	95%CI
≤7	12	0	0		4	33.33%	13.81% - 60.93%
8-14	53	30	56.6%	43.26% - 69.05%	44	83.02%	70.78% - 90.80%
≥15	132	127	96.21%	91.43% - 98.37%	129	97.73%	93.53% - 99.22%
Total	197						

*PPA= Positive Percent Agreement.

Study 2: Biohit Additional Negative Percent Agreement

Methods: a retrospective study was carried out with 791 samples from a local hospital. These samples could be classified into two groups, one group is 647 PCR confirmed negative samples, including 203 samples selected from patients with other respiratory tract infections, 416 samples selected from pregnant patients, and 28 samples selected from healthy people undergoing physical examination. All these 647 serum samples were collected in the Clinical Laboratory of the hospital from February to March 2020, and these patients were confirmed SARS-CoV-2 negative by PCR. The other group is samples taken prior to the COVID-19 outbreak. All these 144 inpatients were selected from non-respiratory departments, and their serum samples were collected in the Clinical Laboratory of the hospital from May 2019 to October 2019. Negative percent agreements were evaluated in comparison to negative PCR results or pre-outbreak presumed negative status.

IgM Test Results Statistics (PCR negative samples)

No	Samples	Sample size	IgM Positive	IgM
1	Other respiratory infection samples	203	5	198
2	Pregnancy test samples	416	2	414
3	Physical examination samples	28	0	28
4	Total	647	7	640

IgG Test Results Statistics (PCR negative samples)

No	Samples	Sample size	IgG Positive	IgG Negative
1	Other respiratory infection samples	203	0	203
2	Pregnancy test samples	416	0	416
3	Physical examination samples	28	0	28
4	Total	647	0	647

Negative Percent Agreement (NPA) statistics

IgM NPA=100%×640/647=98.92%; 95%CI: 97.78% to 99.56%

IgG NPA=100%×647/647=100%; 95%CI: 99.43% to 100%.

IgM Test Results Statistics (Samples taken prior to the COVID-19 outbreak)

No	Samples	Sample size	IgM Positive	IgM
1	Sample of inpatients in other departments	144	0	144
2	Total	144	0	144

IgG Test Results Statistics (Samples taken prior to the COVID-19 outbreak)

No	Samples	Sample size	IgG Positive	IgG Negative
1	Sample of inpatients in other departments	144	0	144
2	Total	144	0	144

Negative Percent Agreement (NPA) statistics

IgM NPA=100%×144/144=100%; 95%CI: 97.47% to 100%.
IgG NPA=100%×144/144=100%; 95%CI: 97.47% to 100%.

Study 3: Independent Clinical Agreement Validation

The Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit was tested on 2020-05-28 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 Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit. 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 Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit antibody tests. 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

Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit	Comparator Method Antibody Positive			Collected pre-2020 Antibody Negative		Total
	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	
IgM+,IgG+	29			4		33
IgM+,IgG-						
IgM-,IgG+						
IgM-,IgG-	1			66	10	77
Total	30			70	10	110

Summary Statistics

Measure	Estimate	Confidence Interval
IgM Sensitivity	96.7%(29/30)	(83.3%; 99.4%)
IgM Specificity	95.0%(76/80)	(87.8%; 98%)
IgG Sensitivity	96.7%(29/30)	(83.3%; 99.4%)
IgG Specificity	95.0%(76/80)	(87.8%; 98%)
Combined Sensitivity	96.7%(29/30)	(83.3%; 99.4%)
Combined Specificity	95.0%(76/80)	(87.8%; 98%)
Combined PPV for prevalence = 5.0%	50.4%	(26.5%; 72.7%)
Combined NPV for prevalence = 5.0%	99.8%	(99%; 100%)
Cross-reactivity with HIV+	0.0%(0/10), not detected	

Important limitations of study 3:

- Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device
- These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.
- Information about anticoagulants used is not known.
- The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations."

14. PROCEDURAL NOTES

14.1. Read this manual carefully before using this test.

14.2. This test needs to be conducted in a laboratory under proper testing conditions. All samples and materials in the testing process should be handled according to the operational

specifications of an infectious disease laboratory.

14.3. Protect the test cassette from moisture.

14.4. All reagents and samples should reach room temperature (18-30℃) before use.

14.5. Do not use lipemic samples.

14.6. Do not use hemolytic samples.

14.7. Do not use turbid or contaminated samples.

14.8. Do not dilute the sample before testing.

14.9. Do not store this kit in a frozen condition.

14.10. The interpretation of the test results must be carried out in strict accordance with this manual.

14.11. Use of this test kit is limited to qualitative detection of SARS-CoV-2 antibody in human serum, plasma (heparin, K_2-EDTA, and sodium citrate), and venous whole blood (heparin, K_2-EDTA, and sodium citrate).

14.12. False negative results will be caused when the antibody titer in the sample is lower than the minimum detection limit of the test or when the antibody does not appear at the time of sample collection.

15. DATE OF ISSUE

Biohit SARS-CoV-2 IgM/IgG antibody test kit insert.

Version 04, 16 December, 2021

16. EXPLANATION OF THE SYMBOLS USED

IVD	For in vitro diagnostic use
REF	Catalogue number
LOT	Batch code
	Manufacturer
	Date of manufacture
	Use by
	Do not use if package is damaged
	Consult instruction for use
	Temperature limit at 2°C~30°C.

	Contents sufficient for 25 tests
	Do not re-use
	Caution
	Keep dry

17. GENERAL INFORMATION

Applicant/ Manufacturer

Name: Biohit Healthcare (Hefei) Co., Ltd.

Address: Building D9, Innovation Park, No.800 West Wangjiang Road, High-Tech Zones, Hefei, Anhui Province, P.R. China

Post code: 230088

Contact telephone: +86-551-65652770

Order contact: market@chinabiohit.com

Technical: public@chinabiohit.com

US Distributor

Virality Diagnostics LLC

25 Science Park, Suite 235

150 Munson Avenue

New Haven, CT 06511

Phone: (212) 502-2000

Fax: (212) 208-4688

Website: www.viralitydiagnostics.com

Email: info@viralitydiagnostics.com

Instruction for use of Biohit SARS-CoV-2 IgM/IgG Control

1. PRODUCT NAME

Biohit SARS-CoV-2 IgM/IgG Control

2. PACKING SPECIFICATION

2 Vials (0.1mL/Vial)

3. INTENDED USE

Biohit SARS-CoV-2 IgM/IgG controls are intended for use as assayed quality controls to monitor the performance of Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit. The performance characteristics of Biohit SARS-CoV-2 IgM/IgG Control have not been established for any other assays or instrument platforms.

For Emergency Use Authorization only.

4. KIT COMPONENTS

No.	Content	Components	Specifications
1	Instruction for use	/	1 piece
2	SARS-CoV-2 IgM/IgG Positive control	Anti SARS-CoV-2 antibody (IgM), Anti SARS-CoV-2 antibody (IgG), Serum, ProClin300	0.1 mL
3	SARS-CoV-2 IgM/IgG Negative control	Serum, ProClin300	0.1 mL

5. STORAGE CONDITIONS AND VALIDITY

Store at -20℃ or below. Valid for 9 months.

6. PROCEDURE

6.1 The quality control material is taken out from the storage environment and placed at room temperature to thaw. After complete dissolution, it is placed at room temperature for 30 minutes and used immediately.
6.2 Mix gently upside down before use.
6.3 Operate according to the instruction of use of Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit.
6.4 The results of Biohit SARS-CoV-2 IgM/IgG positive control should be positive.
6.5 The results of Biohit SARS-CoV-2 IgM/IgG negative control should be negative.
6.6 Quality control is a single use product. Tighten the bottle cap after use, and treat it as potential biological hazardous material.

7. PRECAUTIONS

7.1 For Emergency Use Authorization only.
7.2 For *in vitro* diagnostic use only.
This product has not been FDA cleared or approved;
This product 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;
This product has been authorized for use with the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. The emergency use of your product as described in this letter of authorization.
7.3 The controls are intended for professional use only.
7.4 Please read this manual carefully before using this control products.
7.5 The quality controls should be used prior to the expiration date given on the labeling.
7.6 Warning: This product contains human source and or potential infectious ingredients. Please refer to the main components section of this manual. There is no known method to fully guarantee that human source materials or inactivated microorganisms are not infectious. Therefore, all human source materials should be regarded as potential infectious.
7.7 Discard contents/containers in accordance with local regulations.
7.8 The product is only suitable for the quality control of Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit .

8. EXPLANATION OF THE SYMBOLS USED

IVD	For in vitro diagnostic use
REF	Catalogue number
LOT	Batch code
	Manufacturer
	Date of manufacture
	Use by Date
	Do not use if package is damaged
	Consult instruction for use

	Temperature limit at -20°C.
	Do not re-use
	Caution
	Keep dry

9. MANUFACTURER

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