BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test

Instructions for Use

For prescription use only
For in vitro diagnostic use only
For Emergency Use Authorization only

【Intended Use】

The BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test is a lateral flow immunoassay intended for qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma (potassium EDTA), and potassium EDTA venous whole blood. The BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test is intended 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 BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test 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 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 positive results to the appropriate public health authorities.

The sensitivity of the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test 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 the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test assay 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 BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

【Summary】

SARS-CoV-2 belongs to the broad family of viruses known as coronaviruses. It is a positive-sense single-stranded RNA (+ssRNA) virus. Other coronaviruses are capable of causing illnesses ranging from the common cold to more severe diseases such as Middle East respiratory syndrome (MERS). It is the seventh known coronavirus to infect people, after 229E, NL63, OC43, HKU1, MERS-CoV, and the original SARS-CoV. Protein modeling experiments on the spike (S) protein of the virus suggest that it has sufficient affinity to the angiotensin converting enzyme 2 (ACE2) receptors of human cells to use them as a mechanism of cell entry. Studies have shown that SARS-CoV-2 has a higher affinity to human ACE2 than the original SARS virus strain.

SARS-CoV-2 infections cause COVID-19 disease. People who have confirmed COVID-19 have a range of symptoms, from little to no symptoms to severe illness and death. Symptoms can include: fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat, or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but do not develop any symptoms and do not feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. People with fever, cough and difficulty breathing should seek immediate medical attention.

Human-to-human transmission of the virus has been confirmed and occurs primarily via respiratory droplets from coughs and sneezes within a range of about 6 feet (1.8m). It is possible that the virus can be infectious even during the incubation period.

After SARS-CoV-2 infection, anti-SARS-CoV-2 antibodies will appear in the blood of human body resulting from adaptive immune response in most individuals. Usually IgM antibodies can be detected 5~10 day after symptom onset, and IgG can be detected several days later.

【Test Principle】

This test is based on colloidal gold immunochromatography assay. During the test, specimens and detection buffer are applied to the test cartridges. If there are SARS-CoV-2 IgG or IgM antibodies in the specimens, they combine with colloidal gold-labeled SARS-CoV-2 recombinant antigen forming IgM-virus antigen-colloidal gold complex (complex M) or IgG-virus antigen-colloidal gold complex (complex G).

During lateral flow, the complex M and complex G move along the nitrocellulose membrane toward

the end of the absorbent paper. When passing the line M (coated with anti-human IgM antibodies), the complex M is captured by anti-human IgM antibody resulting in coloring on line M; when passing the line G (coated with anti-human IgG antibodies), the complex G is captured by anti-human IgG antibody resulting in coloring on line G; when passing the line C, colloidal gold-labeled DNP is captured by quality-control antibody resulting in coloring on line C.

【Components】

1. Test cartridge 25/kit (enough for 25 tests)

2. Detection buffer 1 bottle/kit (enough for 25 tests)

3. Pipette 25/kit (enough for 25 tests)

4. Instructions for use 1 copy/kit

【Materials required but not provided】

1. Specimen collection tubes

2. Timer

3. External control set (including 1negative control and 1 positive control) - catalog number: BT1338

【Storage Instructions】

1. The shelf life of BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test is 5 months at room temperature or 9 months at 2~8°C.

2. The BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test can be shipped and distributed under room temperature.

3. Test cartridge should be used right after opening the pouch.

【Warnings and Precautions】

1. 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.

2. 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.

3. 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. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner

4. Wear protective clothing and disposable gloves while handling the kit reagents.

5. Do not pipette by mouth.

6. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.

7. Wash hands thoroughly after performing the test.

8. Use in ventilated area.

9. Avoid contact with eyes; use safety glasses; in case of contact, flush with water immediately and contact a doctor.

10. Dispose of all specimens and components of the kit as potentially infectious agents.

11. Do not use the kit or any kit component past the indicated expiration date.

12. Do not use any other reagents from different lots in this test.

13. Do not use any reagent in other test kits.

14. Avoid microbial contamination of reagents.

15. Bring all reagents or components to room temperature before use.

16. For manual pipetting of samples and controls, use individual pipette tips to eliminate carryover.

17. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.

18. Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate test results.

19. Professionals must handle the potentially contaminated materials safely according to local and state requirements.

20. Do not use it if the container or pouch is damaged or broken.

21. Test is for single use only. Do not re-use under any circumstances.

22. Once the cartridge is removed from the pouch, use the cartridge as soon as possible to avoid being humidified. The cartridge is sensitive to humidity as well as to heat.

23. The device contains material of human or animal origin and may transmit infectious agents and should be handled with extreme caution. No known test method can offer complete assurance that products derived from human sources will not transmit infectious agents

【Sample Collection and Preparation】

1. The specimen type should be potassium EDTA plasma, serum or potassium EDTA venous whole blood.

2. The SARS-CoV-2 IgG/IgM Rapid Qualitative Test has not been evaluated with fingerstick specimens. This test is not authorized for use with fingerstick whole blood.

3. The specimen collection container should be venous blood collection tubes for serum or EDTA anticoagulant tube for plasma and whole blood.

4. Sample collection:

a) Venipuncture for human serum or plasma collection should be performed according to currently recommended procedures, if the serum or plasma sample can't be tested in a timely manner, it should be stored in refrigerator at 2-8℃ for up to 14 days or at -20℃ for up to 3 months.

b)The venipuncture for human whole blood collection should be performed according to currently recommended procedures, if the venous whole blood sample can't be tested immediately after collection, it should be stored in refrigerator at 2-8℃ for up to 3days. Do not freeze.

5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Serum and plasma specimens cannot be frozen and thawed more than 3 times.

6. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

7. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

8. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents

【Test Procedure】

The test should be performed at room temperature（~25℃）.

Step 1: Preparation

Bring the test kit, detection buffer, and sample components to room temperature.

Tear and open the aluminum foil pouch, take the test cartridge out, and place on a level surface.

Step 2: Sampling and Loading

Use the pipette (provided within the kit) to take specimen from the original specimen container and

add 1 drop (10~15uL) specimen (plasma, serum or venous whole blood) into the “S” well of the test cartridge. Then add 3 drops of detection buffer (~100uL) using the drip bottle containing detection buffer into the “D” well of the test cartridge.

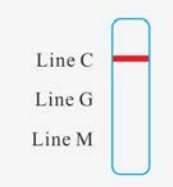
Step 3: Testing

Wait 10 min to allow the reaction to complete and read the result visually afterward. Results should be read between 10 and 20 min.

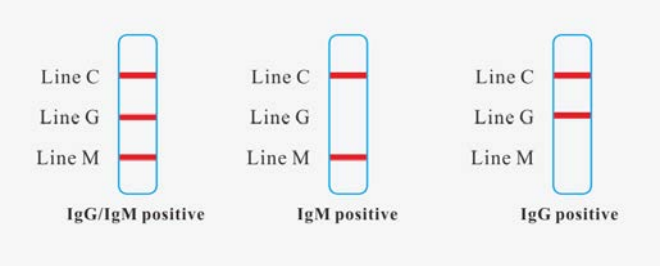
【Interpretation of results】Line C must be colored to have a valid test result.

Valid test results:

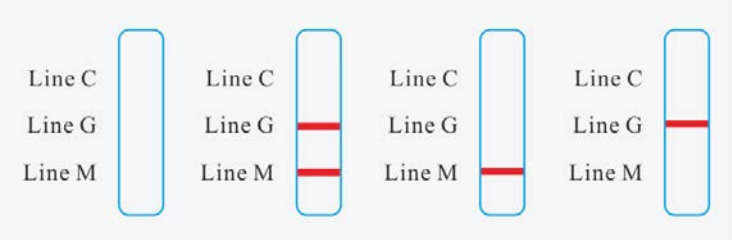
1. Negative result: there is coloration on line C only, as shown in the following picture, suggesting that SARS-CoV-2 IgG or IgM antibodies were not detected.



2. Positive result: There is coloration on line C, line G and/or line M, shown in the following pictures, suggesting that SARS-CoV-2 IgG and/or IgM antibodies were detected.



Invalid result: there is no coloration on line C, as shown in the following pictures. The test is invalid. It is possible that an error in operation occurred. Repeat the assay with a new cartridge.



【Quality Control】

A built-in procedural control (C line) on the cartridge ensures that the test has been stored and performed correctly. The C line should always appear after performing the test. If C line does not appear, discard the cartridge. The test is invalid and should be repeated with a new cartridge.

External positive and negative controls are not supplied with this kit (can be purchased separately); however, external positive and negative controls should be tested consistent with good laboratory practice to confirm the test procedure and to verify proper test performance. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations.

The SARS-CoV-2 IgG/IgM Control Set is available to purchase separately from Xiamen Biotime Biotechnology Co., Ltd as external controls. The control set (catalog number: BT1338) can be ordered through website (www.biotime.cn), telephone (+86-592-6883156) and email (baotai@biotime.cn). One negative and one positive control are included in the control set. Returning expected test results for each control in the control set indicates appropriate performance of SARS-CoV-2 IgG/IgM Rapid Qualitative Test. If any control of the control set fails to provide the expected result, patient samples should not be tested. Clinical specimens can be run in the BIOTIME SARS-CoV-2 IgG/IgM Rapid Test if the controls yield the expected results. Please refer to the *Instructions For Use* of Biotime SARS-CoV-2 IgG/IgM Control Set for expected test results as well as other information. It is recommended that the controls are tested when:

A. A new operator uses the kit;

B. A new lot of test kits is used;

C. A new shipment of kits is used;

D. The temperature used during storage of the kit falls outside of the recommended conditions;

E. The temperature of the test area falls outside of 15-30°C;

F. To verify a higher than expected frequency of positive or negative results;

G. To investigate the cause of repeated invalid results; or

H. A new test environment is used (e.g., natural light vs. artificial light).

【Limitations】

For prescription use only.

For in vitro diagnostic use only.

For Emergency Use Authorization only.

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

2. Use of SARS-CoV-2 IgG/IgM Rapid Qualitative Test is limited to laboratory personnel who have been trained. Not for home use.

3. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

4. Results should only be used in conjunction with other clinical and laboratory data.

5. The test specimens should be plasma, serum or venous whole blood. Do not use with fingerstick samples.

6. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

7. SARS-CoV-2 IgG antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days. SARS-CoV-2 IgM antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 8 days.

8. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies[1, 2].

9. Testing with a molecular diagnostic should be performed to evaluate for acute SARS-CoV-2 infection in symptomatic individuals.

10. Results from antibody testing should not be used to diagnose or exclude acute COVID-19 infection or to inform infection status.

11. The test should not be used to evaluate an immune response in people who have received vaccination or treated with antibody therapy to SARS-CoV-2 coronavirus.

12. Hemolyzed, lipemic or turbid samples should not be tested.

13. 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. This test cannot be used as a quantitative test.

14. A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. 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 SARS-CoV-2 IgG/IgM Rapid Qualitative Test 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. Positive results must be confirmed with another available method and interpreted in conjunction with the patient's clinical information. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

15. 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.

16. Not for the screening of donated blood.

【Conditions of Authorization for the Laboratory】

The SARS-CoV-2 IgG/IgM Rapid Qualitative Test 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/vitro-diagnostics-euas.

Authorized laboratories using the SARS-CoV-2 IgG/IgM Rapid Qualitative Test ("the 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 the 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 the product will use the 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 the product are not permitted.

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

4. Authorized laboratories using the 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 the product and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Xiamen Biotime Biotechnology Co., Ltd (baotai@xmbtsw.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which they become aware.

6. All laboratory personnel using the product must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the 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. Xiamen Biotime Biotechnology Co., Ltd, authorized distributors, and authorized laboratories using the 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."

【Performance Characteristics】

1. Cross reactivity

To evaluate potential cross-reactivity of the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test, a total of 48 potentially cross-reactive plasma and venous whole blood samples were tested. No cross reactivity was observed while testing 48 plasma and venous whole blood clinical specimens with common respiratory infections, including *Mycoplasma pneumonia*, *Chlamydia pneumoniae*, HIV, HBV, HCV and other Coronaviruses (HKU1，OC43 NL63 and 229E). Between 7 and 10 clinical specimens were tested for each of the above infections, as indicated below.

Virus/Bacteria/Parasite Antibody positive	**Number Tested**	**Number Reactive with BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test**	**% Cross-reactivity**
anti-HKU1 (beta coronavirus)	8	0	0.00%
anti-OC43 (beta coronavirus)	8	0	0.00%
anti-NL63 (alpha coronavirus)	7	0	0.00%
anti-229E (alpha coronavirus)	7	0	0.00%
anti-*Chlamydia pneumonia*	8	0	0.00%
anti-*Mycoplasma pneumonia*	10	0	0.00%
Total	**48**	**0**	**0.00%**

Additionally, 27 anti-HIV-positive, 52 anti-HBV-positive, and 9 anti-HCV-positive specimens were evaluated with the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test as part of the clinical performance evaluation and no false positive results were observed.

2. Clinical performance

Positive Percent Agreement (PPA):

Clinical validation study of the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test was conducted at three sites in China. Serum and plasma specimens from 380 subjects were evaluated; 120 of them were confirmed positive by an EUA authorized RT-PCR assay while 260 subjects were confirmed PCR negative by the same assay.

The performance of the test in serum samples collected from PCR-positive subjects by days from symptom onset was as follows:

Serum	Days from onset of symptoms	Total PCR Positive Samples	Biotime Positive Results	PPA	95% CI
IgG	⩽ 7	69	32	46.38%	35.11% - 58.02%
	8 - 14	34	23	67.65%	50.84% - 80.87%
	⩾ 15	17	17	100.0%	81.57% - 100.00%
	Total subjects	120			
IgM	⩽ 7	69	38	55.07%	43.38% - 66.23%
	8 - 14	34	32	94.12%	80.91% - 98.37%
	⩾ 15	17	17	100.0%	81.57%% - 100.00%
	Total subjects	120			

The performance of the test in plasma samples collected from PCR-positive subjects by days from symptom onset was as follows:

Plasma	Days from onset of symptoms	Total PCR Positive Samples	Biotime Positive Results	PPA	95% CI
IgG	⩽ 7	11	8	72.73%	43.44% - 90.25%
	8 - 14	22	16	72.73%	51.85% - 86.85%
	⩾ 15	16	16	100.00%	80.64% - 100.00%
	Total subjects	49*			
IgM	⩽ 7	11	8	72.73%	43.44% - 90.25%
	8 - 14	22	21	95.45%	78.20% - 99.19%
	⩾ 15	16	16	100.00%	80.64% - 100.00%
	Total subjects	49*			

*These 49 plasma samples are paired samples with 49 of the 120 serum samples reported in Table 6.

Longitudinal Study:

A longitudinal study to evaluate seroconversion with the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test using 236 serum samples and 50 plasma samples (the plasma samples were paired with 50 of the 236 serum samples) collected over the course of time, up to 3 times within each time range bin, from the 120 SARS-CoV-2 PCR positive subjects was conducted.

The table below represents the study design and results of serial bleeds by days from symptom onset in serum:

	Days from onset of symptoms	**1st serial measurement**		**2nd serial measurement**		**3rd serial measurement**		**Total Bleeds**
		No. tests	**No. Biotime Pos**	**No. tests**	**No. Biotime Pos**	**No. tests**	**No. Biotime Pos**	
IgG	0 - 7	69	32	59	50	44	44	
	8 - 14	34	23	12	12	1	1	
	≥15	17	17	0	0	0	0	
IgM	0 - 7	69	38	59	49	44	43	
	8 - 14	34	32	12	12	1	1	
	≥15	17	17	0	0	0	0	
	Total Subjects	120		71		45		236

The following table represents the study design and results of serial bleeds by days from symptom onset in plasma:

	Days from onset of symptoms	**1st serial measurement**		**2nd serial measurement**		**Total Bleeds**
		No. tests	**No. Biotime Pos**	**No. tests**	**No. Biotime Pos**	
IgG	**0 - 7**	11	8	1	0	
	8 - 14	22	16	0	0	
	≥15	16	16	0	0	
IgM	**0 - 7**	11	8	1	0	
	8 - 14	22	21	0	0	
	≥15	16	16	0	0	

	Total Subjects	49		1		50

Additionally, 260 serum and 55 plasma samples (the plasma samples were paired with 55 of the 260 serum samples) were collected from the 260 SARS-CoV-2 PCR negative subjects.

Negative Percent Agreement (NPA):

The NPA of the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test in serum and plasma was as follows:

Matrix	**Total PCR Negative Samples**	**IgM/IgG Biotime Negative Results**	**NPA (95% CI)**
Serum	260	256	98.46% (96.11% - 99.40%)
Plasma	55	55	100.00% (93.47% - 100.00%)

3. Independent Clinical Agreement Validation Study

The BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test was tested on May 29, 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 COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma). 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 one lot of the BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For evaluation of cross-reactivity with HIV+, it was evaluated 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). Study results and summary statistics are presented in tables below.

Summary results of the independent evaluation.

BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test		Comparator Method			Total
		Positive (IgM/IgG) +	Negative (IgM/IgG)-	Negative, HIV+	
Positive	IgM +/ IgG+	29	0	0	29
	IgM+, IgG-	1	1	0	2
	IgM-, IgG+	0	1	1	2
Negative	IgM- / IgG)-	0	68	9	77
Total		30	70	10	110

Summary statistics of the independent evaluation.

Measure	Estimate	Confidence Interval
IgM Sensitivity	100% (30/30)	(88.7% - 100%)
IgM Specificity	98.8% (79/80)	(93.3% - 99.8%)
IgG Sensitivity	96.7% (29/30)	(83.3% - 99.4%)
IgG Specificity	97.5% (78/80)	(91.3% - 99.3%)
Combined Sensitivity	100% (30/30)	(88.7% - 100%)
Combined Specificity	96.2% (77/80)	(89.5% - 98.7%)
Combined PPV for prevalence = 5.0%	58.4%	(30.9% - 80.4%)
Combined NPV for prevalence = 5.0%	100%	(99.3% - 100%)
Cross-reactivity with HIV+	10.0% (1/10), may be present	

Limitations of the study:

- 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.

【Bibliography】

1. HAMA Interference with Murine Monoclonal Antibody-Based Immunoassays. Journal of Clinical Immunoassay,1993,16:294-299.

2. The Nature of Heterophilic Antibodies and the Role in Immunoassay Interference. Journal of Clinical Immunoassay,1992,15:108-114

【Symbol】

Symbol	Description	Symbol	Description
	Catalogue number		In vitro diagnostic medical device
	Lot number		Consult instructions for use
	Date of manufacture		Keep dry
	Expiry date		Keep away from sunlight
	Manufacturer		Store at 2-30℃
	Do not re-use		European authorized representative
	Do not use if package is damaged		For Prescription Only

【In Vitro Diagnostic Medical Device Technical Assistance】

For technical assistance, call Biotime Technical Services at +86-592-688-3577, email baotai@biotime.cn, or visit Biotime website at http:// www.biotime.cn

【General Information】

Manufacturer

Name: Xiamen Biotime Biotechnology Co., Ltd.

Address: 3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 361026, P. R. China.

Contact Telephone: +86-592-688-3577

Website: www.biotime.cn

Version No: A/0

Modifying Date: July, 26th, 2020