



TBG Biotechnology Corp.

**TBG SARS-CoV-2 IgG / IgM Rapid  
Test Kit Cat. No. 20010  
Instruction for Use**

**For in vitro diagnostic use**

**For Emergency Use Authorization Only**

**For Prescription Use Only**

**The performance of this device has not been established in samples collected from individuals less than 15 days following the onset of symptoms. Samples should be collected from individuals greater than 14 days following the onset of symptoms. Samples should not be tested if collected from individuals less than 15 days post symptom onset. Samples collected from SARS-CoV-2-infected individuals that are tested greater than 30 days post symptom-onset may yield negative IgM results.**

## Intended Use

The TBG SARS-CoV-2 IgG / IgM Rapid Test Kit is a lateral flow immunoassay intended for qualitative detection and differentiation of IgG and IgM antibodies to SARS-CoV-2 in human serum and plasma [Acid Citrate Dextrose (ACD)]. The TBG SARS-CoV-2 IgG / IgM Rapid 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 TBG SARS-CoV-2 IgG/IgM Rapid 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. IgG and/or 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 positive results to the appropriate public health authorities.

The sensitivity of TBG SARS-CoV-2 IgG / IgM Rapid Test Kit 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 TBG SARS-CoV-2 IgG / IgM Rapid 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 second, different IgG or IgM assay.

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

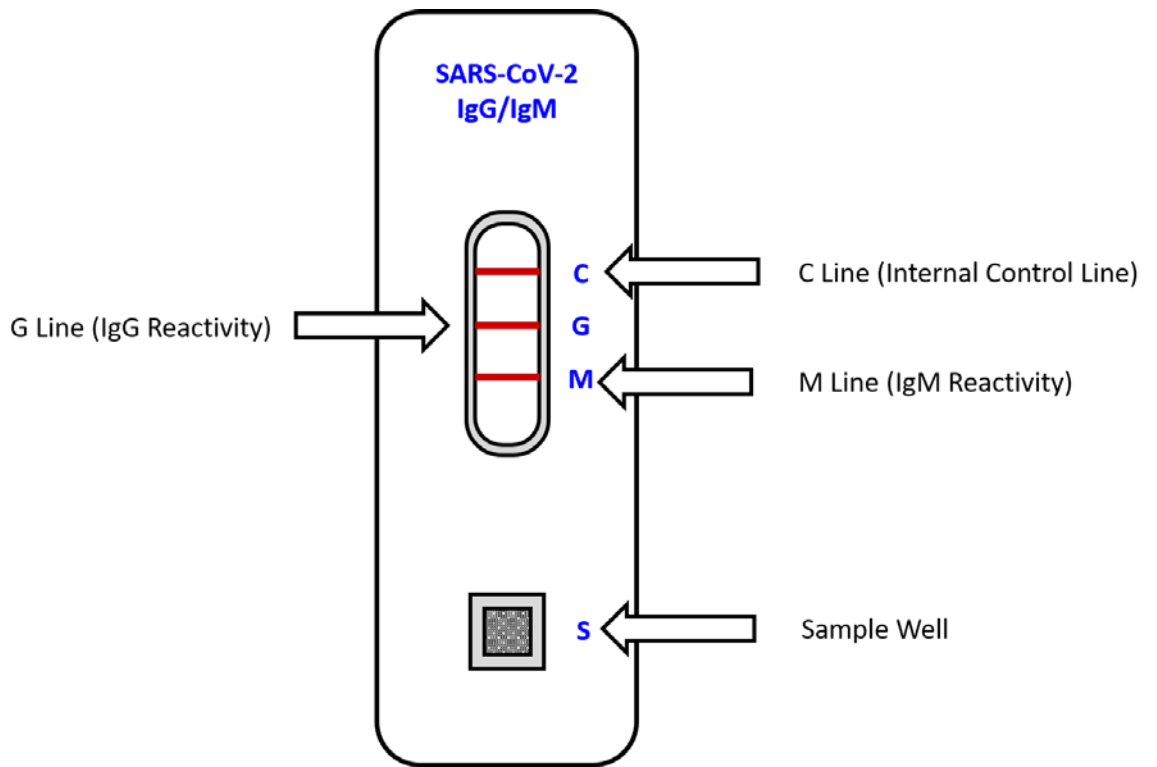
## **Principles(s)**

The TBG SARS-CoV-2 IgG/IgM Rapid Test Kit is a lateral flow chromatographic immunoassay which can detect antibodies against the SARS-CoV-2 virus. The test card consists of:

1. A conjugate pad containing SARS-CoV-2 recombinant antigens (S and N proteins) conjugated with colloidal gold (SARS-CoV-2 conjugates) and rabbit IgG-gold conjugates;
2. Nitrocellulose membrane strip containing an IgG Line (G Line), coated with mouse anti-human IgG, an IgM Line (M Line) coated with mouse anti-human IgM, and the control Line (C Line) coated with goat anti-rabbit IgG.

By adding the appropriate volume of sample specimen into the sample well of the test card, the sample will migrate by capillary action along the test card. If anti-SARS-CoV-2 virus IgG is present in the sample, it will bind to the SARS-CoV-2 recombinant protein present in the sample well to form an immunocomplex. As the immunocomplex continues to migrate, it will be captured by the anti-human IgG Line, forming a red colored G Line, indicating a SARS-CoV-2 virus IgG positive test result. If the anti-SARS-CoV-2 virus IgM is present, it will bind to the SARS-CoV-2 recombinant protein and form an immunocomplex. The same principles apply as the IgM immunocomplex is capture by the anti-human IgM line to forming a red colored M Line indicating positive SARS-CoV-2 virus IgM detection. The test also contains an internal control (C Line). As the sample migrates from the conjugate pad, it will carry the pre-coated rabbit IgG conjugate towards the C Line that contains goat anti-rabbit IgG capture antibody. The C Line will become red regardless of the development status of the G and M Lines. If no C Line is observed, the test result is invalid and the specimen must be retested.

Diagram of the TBG SARS-CoV-2 IgG / IgM Rapid Test Card



## **Reagents and Equipment**

### Reagents and Consumables Included in the Kit

- Disposable Test Card x 25 pcs
- Disposable Capillary Tube x 25 pcs
- Sample Diluent x 1 bottle
- Instruction for Use Leaflet x 1 copy

### Equipment, Reagents, Materials Required but Not Included in Test Kit

- External Positive and Negative Controls – Catalog No. 20010-C
- Serum blood collection tubes
- Plasma (Acid Citrate Dextrose) blood collection tubes
- Vortex mixer
- Sample storage tubes
- Desktop Centrifuge (for blood collection tubes and small storage tubes)
- Adjustable pipettes (200  $\mu$ L, 10  $\mu$ L)
- Sterile pipette tips with filters
- Powder free latex gloves

## **Warnings and Precautions**

For In Vitro Diagnostics; For Emergency Use Authorization, For Prescription Use

- This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by 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.
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV2, not for any other viruses or pathogens.
- 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. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- This product should only be used by trained professional.
- Hemolytic samples cannot be used for testing.
- Do not use turbid contaminated samples for testing.
- Do not dilute the sample for testing, or you may get inaccurate results.
- Wait 15 minutes after the sample and the Sample Diluent have been added to the sample well for the completion of the reaction. Results must be

read visually within 5 minutes after the completion of the reaction.

- Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the test card should be used within 1 hour.
- Do not use expired devices.
- Bring all reagents to room temperature (15-30°C) before use.
- Do not use the components of any other type of test kit as a substitute for the components in this kit.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical samples. Wash hands thoroughly after performing the test.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Prepare the negative and positive controls as instructed and treat them in the same manner as patient specimens for operator protection.
- Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

## **Storage and Handling Conditions**

- Store the TBG SARS-CoV-2 IgG / IgM Rapid Test kit at 2°C ~ 8°C in a dry place and avoid direct sunlight.
- The test card will be invalid due to moisture absorption after opening the inner package, please use it within 1 hour.
- The TBG SARS-CoV-2 IgG / IgM Rapid Test kit shelf life is 9 months from date of manufacturer when stored at 2°C - 8°C .

## **Specimen Collection and Preparations**

### **From Plasma**

- Collect blood specimen, by venipuncture, into a blood collection tube containing Acid Citrate Dextrose .
- Centrifuge the sample to separate the plasma.
- Transfer the plasma into a new pre-labeled storage tube.
- Plasma specimens should be stored at 2-8°C if not tested immediately. If the sample is not tested within 3 days, it should be stored at -20°C for longer storage. Avoid freeze-thaw cycles. Thaw and mix samples properly before testing.

### From Serum

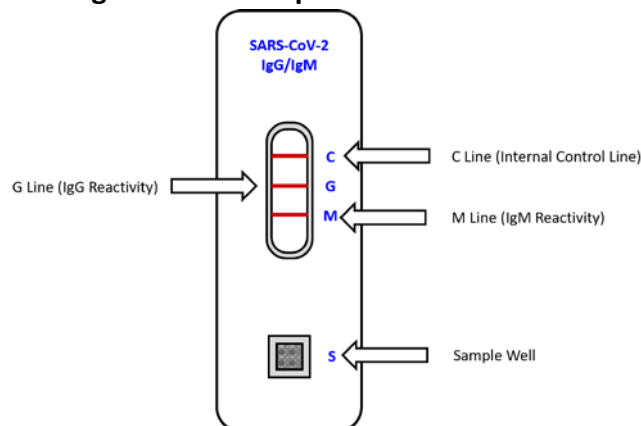
- Collect blood specimen, by venipuncture, into a collection tube that does not contain anticoagulant.
- Allow the blood to clot and separate the serum by centrifugation.
- Transfer the serum into a new pre-labeled storage tube.
- Serum specimens should be stored at 2-8°C if not tested immediately. If the sample is not tested within 3 days, it should be stored at -20°C for longer storage. Avoid freeze-thaw cycles. Thaw and mix samples properly before testing.

## Protocols

### Test Card Processing Procedure

- Bring all the samples and test components to room temperature and mix the specimen well once thawed.
- Tear open the aluminum pouch for the test card at the notch.
- Remove the test card and place it on a clean and flat surface.
- Label the test card with the specimen ID number.
- Using the disposal capillary tube draw the sample [serum or plasma (ACD)] up the 10 µL line indicated on the capillary tube.
- Avoiding air bubbles, carefully dispense the sample into the center of sample loading well. The required sample volume is 10 µL.
- Immediately following the addition of the samples, add 2 drops of Sample Diluent into the sample well.
- Wait 15 minutes for the completion of the reaction. Results must be read visually within 5 minutes after the completion of the reaction.

**Diagram of the Disposable Test Card**



## Quality Control

### Controls Materials

- The internal control is built in within each test card at the C Line position and is coated with a goat anti-rabbit IgG capture antibody. As the sample migrates from the conjugate pad, it will carry the pre-coated rabbit IgG conjugate towards the C Line that contains goat anti-rabbit IgG capture antibody. The C Line will become red regardless of the development status of the G and M Lines. If no C Line is observed, the test result is invalid and the specimen must be retested with a new test card.

**NOTE: Positive and negative controls are not included in the TBG SARS-CoV-2 IgG / IgM Rapid Test kit but are manufactured by TBG Biotechnology Corp., and can be purchased separately using the following catalog number – Catalog No. 20010-C.**

- Positive control (PC) solution includes one vial with IgG and IgM antibodies against SARS-CoV-2 diluted in pooled COVID-19 free human serum. Each vial contains a volume of 100  $\mu$ L and is sufficient for single use. The concentration of each antibody is 10ng/ $\mu$ L.
- Negative control (NC) solution includes one vial of SARS-CoV-2 negative pooled serum. The vial contains a volume of 100  $\mu$ L and is sufficient for a single use.

By adding 10 $\mu$ L of the PC solution to the sample well, the antibodies will bind to the recombinant N protein to form an antibody-antigen immunocomplex. The immunocomplex will be captured by the mouse anti-human IgG and IgM capture antibodies as they migrate through the test card. C, G and M Line are expected to appear within the 15 minutes after the addition of the Sample Diluent.

In contrast, adding 10 $\mu$ L of the NC solution will not form any SARS-CoV-2 related immunocomplex and therefore only a C Line will appear to indicate that the test is valid.

PC and NC should be tested under the following situations:

- New operator uses the test kit.
- New lot of test kits is used.



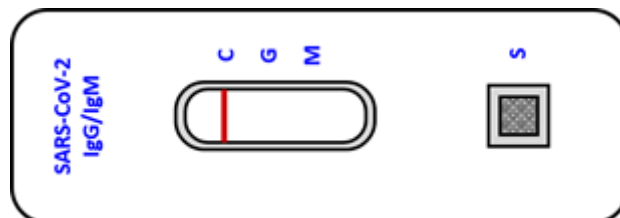
- New shipment of test kits is used.
- The temperature of the test environment falls outside of 15-30°C.
- An abnormal frequency of positive or negative sample results are reported.
- During investigation of the cause of repeated invalid results.
- During the validation of a new test environment.

## Interpretation of Results

Assessment of TBG SARS-CoV-2 IgG / IgM Rapid Test Kit results should be performed after the PC and NC have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted, should not be reported and a new test sample should be run in a new Test Card. In order to interpret the results of the test card, please use the diagram below to locate the sample well, C Line, M Line, G Line and use the following guidance for results interpretation.

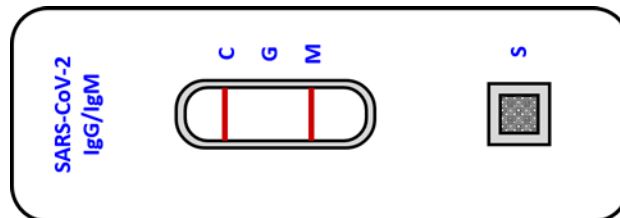
### Valid Assays:

**Non-Reactive:** If only the C Line is present, the absence of any burgundy color in both test lines (M and G) indicates that no SARS-CoV-2 antibody is detected. The result is non-reactive.

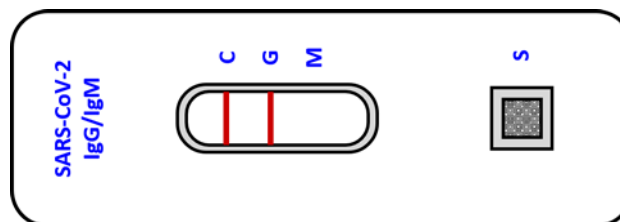


**Reactive:**

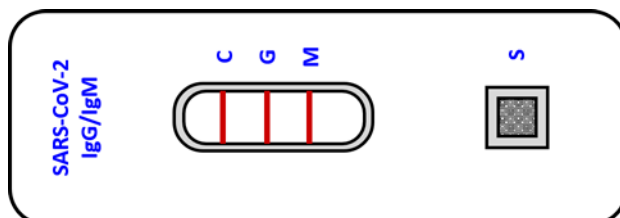
In addition to the presence of the C Line, if the M Line is developed, the test detects SARS-CoV-2 IgM antibodies. The result is IgM reactive.



In addition to the presence of the C Line, if the G Line is developed, the test detects SARS-CoV-2 IgG antibodies. The result is IgG reactive.



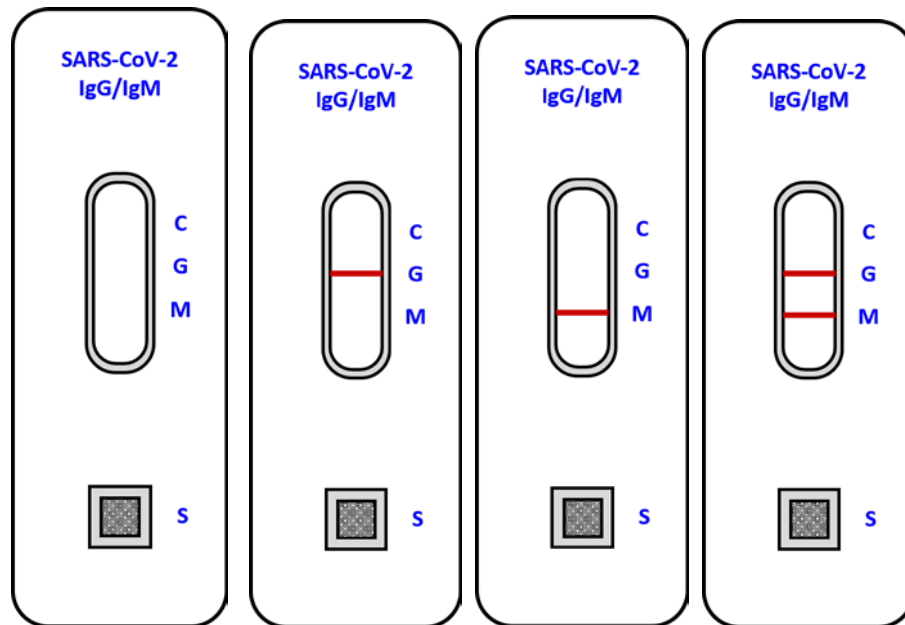
In addition to the presence of the C Line, if both the M and the G Lines are developed, the test detects SARS-CoV-2 IgG and IgM antibodies. The result is IgG and IgM reactive.



*Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings.*

**Invalid:**

If no C Line is developed, the assay is invalid regardless of any burgundy color in the test lines as indicated below. Repeat the assay with a new Test Card.



## **Limitation of Procedure**

- Use of this test is limited to laboratory personnel who have been trained in immunoassay and appropriate usage of this kit according to the product insert and its authorized label as well as being familiar with its protocol and interpretation of the results. This test is not for home use or point of care (POC) use.
- The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, or plasma (ACD) specimens from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
- The test is limited to the qualitative detection of antibodies to SARS-CoV-2 in human serum or acid citrate dextrose (ACD) plasma.
- The TBG SARS-CoV-2 IgG/IgM Rapid Test Kit 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.

- The test results must be interpreted between 15 and 20 minutes after addition of the Sample Diluent. The test results should not be interpreted after 20 minutes.
- Negative results do not preclude SARS-CoV2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first several days of infection; the sensitivity of this 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. Therefore, it is recommended that all negative test results undergo confirmatory testing using other method and/or qualified assays.
- Analytical study results revealed IgG cross-reactivity (false positive results) in 1 out of the 5 serum samples tested that contained anti-OC43 (beta coronavirus) antibodies, and 1 out of 5 samples tested that contained anti-HKU1 (beta coronavirus) antibodies.
- This test should not be used to diagnose or exclude acute SARS-CoV-2 infection.
- A negative or non-reactive 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 the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody detected by the test.
- 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 but different serology test to confirm an adaptive 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.
- Testing with a molecular diagnostic should be performed to evaluate for active infection in symptomatic individuals.
- It is not known at this time whether the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
- The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.
- This test should not be used for screening of donated blood.

## **Conditions of Authorization for Laboratory**

- The TBG Biotechnology Corp. SARS-CoV-2 IgG/IgM Rapid Test Kit Letter of Authorization\*, along with the authorized Fact Sheet for Healthcare Providers,

the authorized Fact Sheet for Patients, 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 TBG SARS-CoV-2 IgG/IgM Rapid Test Kit (“your product” in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:
  - Authorized laboratories using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
  - Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
  - Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
  - 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.
  - 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](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and TBG Biotechnology Corp ([COVID19@tbgbio.com](mailto:COVID19@tbgbio.com)) 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.
  - 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.
  - TBG Biotechnology Corp., 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 and high complexity tests” as “authorized laboratories.”

## **Product Performance Summary**

### **1) Clinical Agreement Study:**

The clinical performance of the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit was evaluated through a clinical study conducted in Wuhan Mobile Cabin Hospital, in Wuhan, China.

Retrospective serum samples were collected from 580 subjects, 97 COVID-19 positive patients confirmed by an FDA authorized SARS-CoV-2 PCR test. Negative retrospective serum samples were collected from 483 subjects in September 2019 (pre-pandemic). Testing of serum samples using the SARS-CoV-2 IgG / IgM Rapid Test Kit was conducted at the Reach Reference Laboratory in Wuhan, China.

A total of 580 serum samples were tested and included in the study analysis. A total of 97 serum samples were obtained from patients whose respiratory sample was confirmed positive for SARS-CoV-2 using EUA approved Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing). Serum samples and respiratory samples of the positive patients were not collected at the same time point. A total of 483 serum samples were obtained from COVID-19 negative subjects (pre-pandemic).

### **Clinical Sensitivity (Positive Percent Agreement – PPA)**

Table 1, and Table 2, below illustrate the clinical performance results (PPA) stratified by *Days Post Symptom Onset*, for IgG and IgM, respectively.

**Table 1. Wuhan China - Clinical Performance Results Summary  
IgG – Days Post Symptom Onset (Serum Samples)**

Days Post Symptom Onset <sup>†</sup>	# of PCR Positive	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit		
		# of Positive	PPA	95% CI
≤7 days	0	0	0	N/A
8 to 14 days	0	0	0	N/A
15 to 30 days	56	54	96.4%	87.9 – 99.0%
Unknown*	41	40	97.6%	87.4 – 99.6%

<sup>†</sup> A large percentage [42.3% (41/97)] of samples were collected >30 days post symptom onset.

\*The days post symptom onset is unknown. The line data provides a date range of symptom onset “1/20/2020 – 2/10/2020”. This date range is based on patients own recollection after having been moved from hospital to hospital without their medical records. It is estimated that the testing was done between 30 and 51 days from onset of symptoms (PCR test date is indicated as 2/13/2020).

**Table 2. Wuhan China - Clinical Performance Results Summary  
IgM – Days Post Symptom Onset (Serum Samples)**

Days Post Symptom Onset	# of PCR Positive	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit		
		# of Positive	PPA	95% CI
≤7 days	0	0	0	N/A
8 to 14 days	0	0	0	N/A
15 to 30 days	56	49	87.5%	76.4 – 93.8%
Unknown*	41	0	0	N/A

\*The days post symptom onset is unknown. The line data provides a date range of symptom onset “1/20/2020 – 2/10/2020”. This date range is based on patients own recollection after having been moved from hospital to hospital without their medical records. It is estimated that the testing was done between 30 and 51 days from onset of symptoms (PCR test date is indicated as 2/13/2020).

#### Clinical Specificity (Negative Percent Agreement – NPA)

Table 3, below illustrates the clinical performance (NPA) results using serum samples presumed to be negative since they were collected prior to December 2019.

**Table 3. Wuhan China - Clinical Performance Results Summary (NPA)  
(Serum Samples)**

Number of Negative Samples Tested	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit	
	IgM/IgG Negative Results	NPA (95% CI)
483	482	99.8% (98.8-99.96%)

Independent Clinical Agreement Evaluation:

The TBG SARS-CoV-2 IgG / IgM Rapid Test Kit was tested on June 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 TBG SARS-CoV-2 IgG / IgM Rapid 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 one lot of the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit. 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 Table 5 below.



**Table 5. FNLCR/NCI Independent Evaluation – Summary Results**

SARS-CoV-2 IgG/IgM Rapid Test Kit	Comparator Method			Collected pre-2020		Total
	Antibody Positive			Antibody Negative		
	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	
IgM+, IgG+	28			3		31
IgM+, IgG-				1		1
IgM-, IgG+						
IgM-, IgG-	2			66	10	78
Total	30			70	10	110

Table 2: Summary Statistics

Measure	Estimate	Confidence Interval
IgM Sensitivity	93.3% (28/30)	(78.7%; 98.2%)
IgM Specificity	95.0% (76/80)	(87.8%; 98%)
IgG Sensitivity	93.3% (28/30)	(78.7%; 98.2%)
IgG Specificity	96.2% (77/80)	(89.5%; 98.7%)
Combined Sensitivity	93.3% (28/30)	(78.7%; 98.2%)
Combined Specificity	95.0% (76/80)	(87.8%; 98%)
Combined PPV for prevalence = 5.0%	49.6%	(25.4%; 72.5%)
Combined NPV for prevalence = 5.0%	99.6%	(98.7%; 99.9%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

**Limitations of the FNLCR/NCI Independent Evaluation:**

- 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.
- 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.

**2) Analytical Performance Studies****a) Cross-Reactivity:**

The cross-reactivity study for the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit was designed to evaluate potential interference from antibodies against other viruses whose infection produces symptoms similar to those observed during SAR-CoV-2 virus infection. Hospital patient serum with the corresponding antibodies was collected and tested according to the test kit instructions. A total of five unique patient serum samples were tested for each potential cross reactant. As summary of the study results is illustrated in Table 6 below.

**Table 6: Cross-Reactivity Study Results Summary**

<b>Virus Antibody Tested</b>	<b>Sample Type</b>	<b>Results</b>
Anti-Flu A IgM	Serum	(5/5) 100% Negative
Anti-Flu A IgG	Serum	(5/5) 100% Negative
Anti-Flu B IgM	Serum	(5/5) 100% Negative
Anti-Flu B IgG	Serum	(5/5) 100% Negative
Anti-HCV IgM	Serum	(5/5) 100% Negative
Anti-HCV IgG	Serum	(5/5) 100% Negative
Anti-HBV IgM	Serum	(5/5) 100% Negative
Anti-HBV IgG	Serum	(5/5) 100% Negative
ANA	Serum	(5/5) 100% Negative
Anti-RSV IgM	Serum	(5/5) 100% Negative
Anti-RSV IgG	Serum	(5/5) 100% Negative
Anti-Rhinovirus IgM	Serum	(5/5) 100% Negative
Anti-Rhinovirus IgG	Serum	(5/5) 100% Negative
Anti-Haemophilus Influenza IgM	Serum	(5/5) 100% Negative
Anti-Haemophilus Influenza IgG	Serum	(5/5) 100% Negative
Anti-229E (Alpha coronavirus)	Serum	(5/5) 100% Negative
Anti-NL63 (Alpha coronavirus)	Serum	(5/5) 100% Negative
Ant-OC43 (Beta coronavirus)	Serum	(4/5) 80% Negative
Anti-HKU1 (Beta coronavirus)	Serum	(4/5) 80% Negative

The majority of the serum samples produced a negative result with no observation of cross-reactivity for either IgM or IgG. However IgG cross-reactivity was observed in 1 out of the 5 serum samples tested that

contained anti-OC43 (beta coronavirus) antibodies and 1 out of 5 serum samples tested that contained anti-HKU1 (beta coronavirus) antibodies. A statement reflecting these findings is included in the limitation section of this test package insert.

***b) Class Specificity:***

A class specificity study was conducted to demonstrate that the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit accurately distinguishes between anti-SARS-CoV-2 IgM and IgG antibodies. Contrived test panel samples were prepared by spiking humanized mAb against N protein of SARS-CoV-2 into presumed COVID-19 human serum samples (from five unique healthy donors), and into the test kit sample diluent. Test panel sample preparation is described as follows:

1. Sample Diluent Only (Negative Control)
2. Sample Diluent + 20ng IgM mAb (Positive Control)
3. Sample Diluent + 20ng IgG mAb (Positive Control)
4. Sample Diluent + 20ng IgG and IgM mAb (Positive Control)
5. COVID-19 Negative Serum
6. Neg. serum + 20ng IgM mAb
7. Neg. serum + 20ng IgG mAb
8. Neg. serum + 20ng IgG and IgM mAb

All samples were tested initially using the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit. Following initial testing, all samples were treated with dithiothreitol (DTT), and tested using the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit again. The study results are summarized in Table 7 below.

**Table 7. Class Specificity Study Result Summary –DTT Treatment**

Sample ID	Total Samples Tested	NO DTT Treatment	DTT Treatment	Expected Result After DTT Treatment (IgM/IgG)	Result Agreement
		Result (IgM/IgG)	Result (IgM/IgG)		
Diluent only	N/A	-/-	-/-	-/-	(2/2) Yes
Diluent + IgG mAb	N/A	-/+	-/+	-/+	(2/2) Yes
Diluent + IgM mAb	N/A	+/-	-/-	-/-	(2/2) Yes
Diluent + IgG + IgM mAb	N/A	+/+	-/+	-/+	(2/2) Yes
Neg. Serum only	5	-/-	-/-	-/-	(10/10) yes

Neg. Serum + IgG mAb	5	-/+	-/+	-/+	(10/10) yes
Neg. Serum + IgM mAb	5	+/-	-/-	-/-	(10/10) yes
Neg. Serum + IgG + IgM mAb	5	+/+	-/+	-/+	(10/10) yes

The results reported for the study demonstrate that the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit is antibody class specific.

## **Bibliography**

- None

## **Trademarks Used in this Document**

- TBG Biotechnology Corp.\_

## **Patents Used in this Document**

None

	For Emergency Use Authorization (EUA) Only
	TBG Biotechnology Corp., 13F-1, No.237, Sec.1, Datong Rd, Xizhi Distr., New Taipei City, Taiwan 221 Telephone: +1 877-822-2461      Website: <a href="http://www.tbgbio.com">www.tbgbio.com</a> Email:COVID19@tbgbio.com



TBG Biotechnology Corp.

**TBG SARS-CoV-2 IgG / IgM Rapid Test Control Set**  
**Catalog No. 20010-C**  
**Format: 2 vials with 0.1ml per vial.**

1. **Intended Use:** The TBG SARS-CoV-2 IgG / IgM Rapid Test Controls set are intended for use as quality controls to ensure proper performance of the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit (Cat. No. 20010, TBG Taiwan).
2. **Specifications:** This product contains 2 vials with 0.1ml of volume and for single use.
3. **Components Included:**
  - 3.1. Positive Control x 1 vial. 0.1ml per vial. This vial contains IgG and IgM antibodies against SARS-CoV-2 diluted in pooled COVID-19 free human serum. The concentration of each antibody is 10ng/ $\mu$ L.
  - 3.2. Negative Control x 1 vial. 0.1ml per vial. This vials contains COVID-19 free human serum.
  - 3.3. Instruction For Use: 1 copy of the instruction for use is included with each kit.
4. **Storage and Handling Conditions:** This product is stable for 1 month, when stored at 2-8°C.
5. **Protocols:**
  - 5.1. Remove the product from storage and allow thawing at room temperature (25  $\pm$  5°C).
  - 5.2. Once thawed, use the product within 15 minutes, according to the instructions provided in the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit (Cat. No. 20010, TBG Taiwan).
  - 5.3. These products are meant for single use and should be used within 15 minutes after thaw.
  - 5.4. The Positive Control should result in a TBG SARS-CoV-2 IgG / IgM Rapid Test positive reaction with visible IgG, IgM, and Control Lines.
  - 5.5. The Negative Control should result in a TBG SARS-CoV-2 IgG / IgM Rapid Test reaction with only a visible Control Line.
  - 5.6. After use, dispose of any remaining product as biological hazardous waste.
6. **Precaution**
  - 6.1. For Emergency Use Authorization only.
  - 6.2. 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 TBG SARS-CoV-2 IgM/IgG Rapid Test Kit for the presence of IgG and IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens; and This product 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.

- 6.3. The controls are intended for professional use only.
- 6.4. Please read this manual carefully before using this control product.
- 6.5. The quality controls should be used prior to the expiration date indicated on the label.
- 6.6. 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.
- 6.7. Discard contents/containers in accordance with local regulations.
- 6.8. The product is only suitable for the quality control of TBG SARS-CoV-2 IgG / IgM Rapid Test Kit.

- 7. **Bibliography:** None
- 8. **Trademarks Used in this Document:** TBG Biotechnology Corp.
- 9. **Patents Used in this Document:** None

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