Novel Coronavirus (SARS-CoV-2) Rapid Testing Kit

Company Profile:

TBG

MEDIGEN BIOTECHNOLOGY CORP

Manufactured:

Mase in Taiwan

Offical Website:

http://www.tbgbio.com/en

http://www.medigen.com.tw/zh/%e9%a6%96%e9%a0%81/

http://www.medigen.com.tw/en/tbg-diagnostics-limited-listed-on-australian-securities-exchange-asx-on-february-3-2016/

Certification:

CE

MOQ:

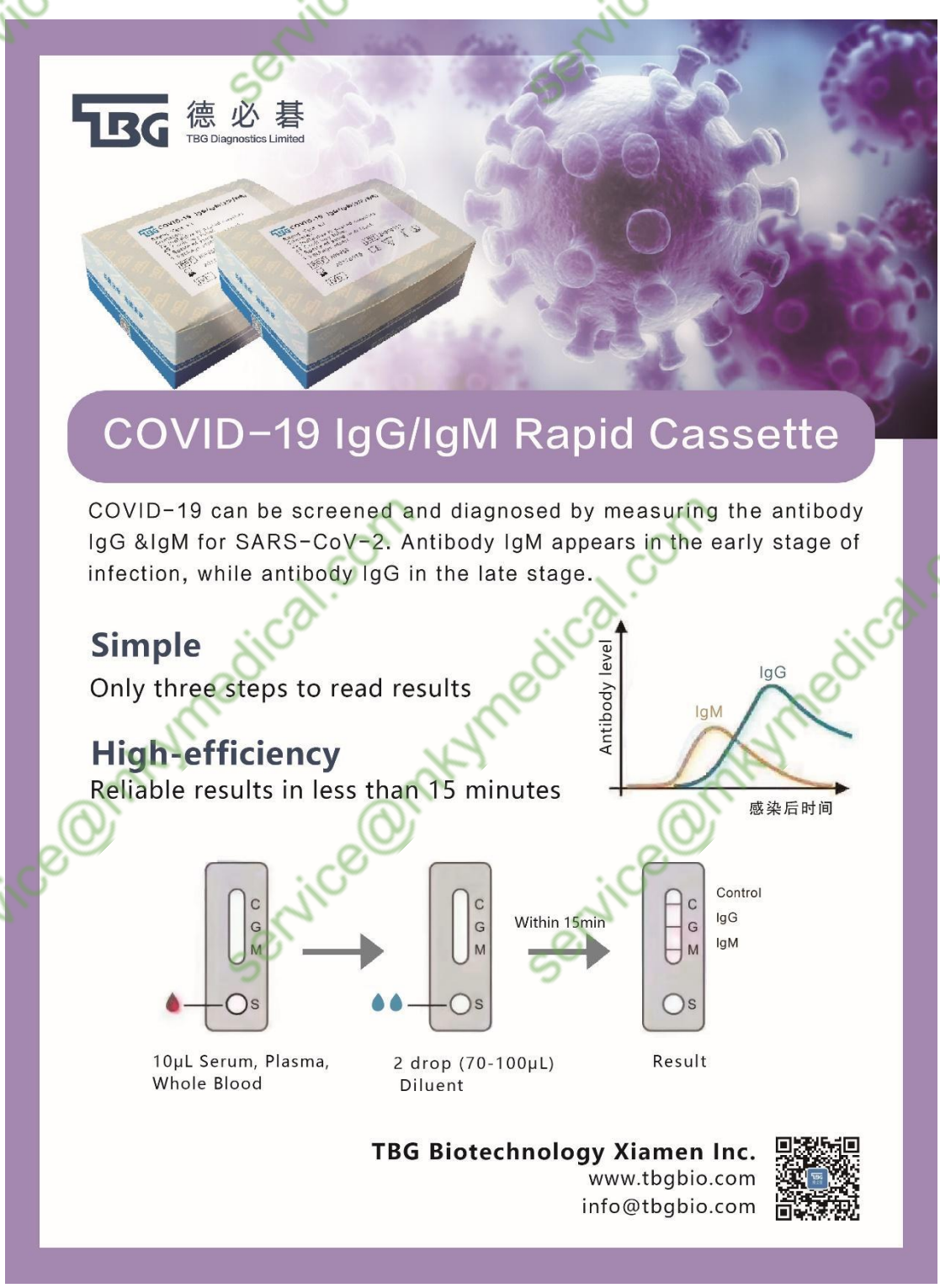
100000 Up

Press Reference (in Chinese):

https://money.udn.com/money/story/11074/4424882

https://ctee.com.tw/news/stock/237906.html

Product Information



Certification

# Test validation report (summary)

| | |
|---|---|
| Product name | Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold) |
| Verification unit | Yueyang first people's Hospital;<br>The Second Affiliated People's Hospital of traditional Chinese medicine of Hunan Province;<br>Chenxi County People's Hospital; |
| Summary unit | TBG Biotechnology Xiamen Inc. |
| Report date | March 18, 2020 |
| Validation summary | Expected Use: Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold) is a rapid detection kit developed which manufactured by TBG Biotechnology Xiamen Inc.. It uses the principle of double antigen sandwich method to qualitatively detect new coronavirus (2019-nCoV) IgM antibodies and IgG antibodies in blood samples in vitro.<br>Clinical validation method: This validation test is based on a number of clinical institutions, using multi-center clinical samples for validation, through the examination system ((Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold)) test results compared with the new coronavirus nucleic acid test results for analysis, statistics and calculation of the detection coincidence rate, in order to assess Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold) which produced by TBG Biotechnology Xiamen Inc.. It's qualitative detection of the performance of new coronavirus (2019-nCoV) antibodies (IgM/IgG) in blood samples.<br>Validation conclusion: The results show that the quality of Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold) produced by TBG Biotechnology Xiamen Inc. is stable and can be used to qualitatively detect new coronavirus (2019-nCoV) antibodies (IgM/IgG) in blood samples in vitro, which can meet the current detection needs of new coronavirus (2019-nCoV). |
| Data analysis | As of March 18, 2020, a total of 580 samples were enrolled in this validation test, including 97 confirmed positive samples and 483 negative samples of new coronavirus nucleic acid test. The above samples were detected by Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold). Among them:<br>(1) Among 97 new coronavirus nucleic acid positive samples, 95 were positive by Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold), with a positive detection rate of 97.9%.<br>(2) One of 483 negative control samples were positive for Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold), the |

<table>
<tr><td></td><td>total negative coincidence rate was 99.80%.<br>(3) Total coincidence rate: 98.85%.<br>See the table below for details:
<table>
<tr><td rowspan="2">Confirmed samples</td><td colspan="4">TBG Biotechnology Xiamen Inc.</td></tr>
<tr><td>Total antibody detection positive</td><td>Total antibody detection negative</td><td>Total samples</td><td>Coincidence rate</td></tr>
<tr><td>Confirmed positive samples</td><td>95</td><td>2</td><td>97</td><td>97.9%</td></tr>
<tr><td>Confirmed negative samples</td><td>1</td><td>482</td><td>483</td><td>99.8%</td></tr>
<tr><td>total</td><td>96</td><td>484</td><td>580</td><td>98.85%</td></tr>
</table></td></tr>
<tr><td>Verification conclusion</td><td>This project is an in vitro diagnostic reagent urgently needed for public health emergencies.<br>A total of 580 serum and plasma samples were tested in this validation test. The positive coincidence rate, negative coincidence rate and total coincidence rate of sample detection were 97.9%, 99.8% and 98.85%, respectively.<br>During the test, Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold) showed no abnormalities, which was easy to operate and stable, and met the needs of clinical application. Combined with the above analysis, the detection quality of Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold) for blood samples reaches the current level of clinical use, which can be used for emergency prevention and control of epidemic detection.</td></tr>
<tr><td>Verification unit</td><td>The key Changsha Changye medical laboratory<br>March 18, 2020<br><br>TBG Biotechnology Xiamen Inc.<br>March 18, 2020</td></tr>
</table>

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

# DECLARATION OF NOTIFICATION

As the EU Representative, SUNGO Europe B.V., hereby declare that:

**TBG BIOTECHNOLOGY XIAMEN INC.**

**Building 3 ,2004 wengjiao west Road, Haicang District, Xiamen, 361027, China.**

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

| Name Device | Reference Numbers |
|---|---|
| Corona Virus Disease-19(COVID-19) IgG/IgM Rapid Cassette(S/P/WB) | 20200961 |

The notification to the Netherlands Competent Authorities has been carried out on March 26, 2020 by SUNGO Europe B.V., the appointed Authorized Representative of TBG BIOTECHNOLOGY XIAMEN INC.

Information on the notification to the competent Authorities of other European countries is available upon request.

SUNGO Europe B.V.
Authorized Representative

SUNGO Europe B.V. | Office Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

TBG Biotechnology Xiamen Inc.

# Corona Virus Disease-19(COVID-19)

## IgG/IgM Rapid Cassette ( S/P/WB )

**【 Package Specification 】**

35 tests/kit

**【 Intended Use 】**

The COVID-19 IgG/IgM rapid test is used to qualitatively detect IgG and IgM antibodies of corona virus disease-19 in human serum, plasma or whole blood. This device is intended to be used by professionals as a screening test and as an aid in the diagnosis of infection with 2019 Corona Virus. Any reactive specimen with the COVID-19 IgG/IgM rapid test must be confirmed with alternative testing method(s).

***For in vitro diagnostic use only. For professional use only.***

**【 Summary 】**

The definitions of "suspected cases" and "suspected clusters of patients" shall be defined by referring to the "Pneumonia Diagnosis and Treatment Program for Novel Coronavirus Infection" and "Pneumonia Case Monitoring Program for Novel Coronavirus infection" issued by China CDC (the current version).

Corona Virus Disease-19 (COVID-19) IgG/IgM Rapid Cassette (S/P/WB) is only used for the auxiliary diagnosis of related cases and the emergency reserve for in vitro diagnosis during the outbreak of Corona Virus Disease (COVID-19) since December 2019, this kit shouldn't be used as routine in vitro diagnostic in clinical practice. Please follow the relevant requirements of the "Pneumonia Diagnosis and Treatment Program for Novel Coronavirus Infection", "Pneumonia Prevention and Control Program for Novel Coronavirus infection" and other documents in use.

**【 Test Principle 】**

The COVID-19 IgG/IgM rapid test is a qualitative membrane-based immunoassay for the detection of COVID-19 antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to COVID-19, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to COVID-19, if present in the specimen, reacts with the anti-human IgM and the COVID-19 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region. Therefore, if the specimen contains IgG antibodies to COVID-19, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to COVID-19, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to COVID-19, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

**【 Components 】**

1. Disposable test card
2. Disposable plastic capillary tubes (or sampling gun)
3. Sample Diluent (5mL x 1)
4. Instructions for use

【 Storage and Stability 】

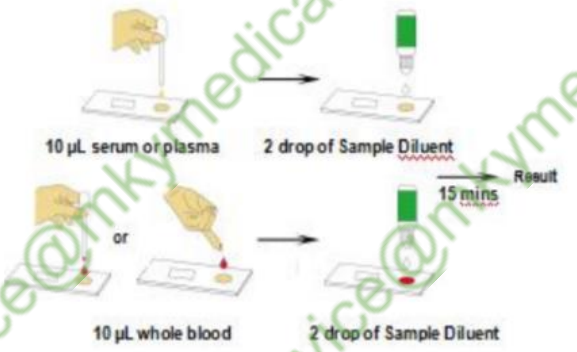
Store at 2℃ ~ 30℃ in a dry place and avoid direct sunlight. The test card will be invalid due to moisture absorption after opening the inner package, please use it within 1 hour. It is valid for 18 months from date of manufacturing.

【 Specimen Requirements 】

1. Applicable specimen type: Serum, plasma and whole blood, including those prepared by commonly used anticoagulants (EDTA, heparin, sodium citrate).
2. After the sample is collected, it shall be tested immediately. If immediate detection is not possible, the serum and plasma samples to be tested can be stored for 5 days at 2 ~ 8°C. For long-term storage, place at -20°C. Avoid repeated freeze-thaw samples. Anticoagulant whole blood sample should not be stored for more than 72 hours at room temperature; Do not exceed 7 days at 2 ~ 8°C.
3. Before testing, slowly return the refrigerated or refrigerated samples to room temperature and carefully mix them. In the presence of clearly visible particulate matter in the sample, the precipitate should be removed by centrifugation prior to testing.
4. If the sample contains a large amount of lipid, hemolysis or turbidity, please do not use it to avoid affecting the judgment of the result.

【 Test Method 】

Step 1: If the sample is refrigerated, the sample to be tested and the required reagent are removed from the storage condition and balanced to room temperature (15-30 ℃). After melting, mix the sample well before testing.
Step 2: When preparing for testing, open the foil bag from the tear. Remove the test card and place it flat on the horizontal table.
Step 3: Mark the sample number on the test card.
Step 4: Holding the capillary tubes (or sampling gun) vertically, dispense 10 μL of serum, plasma or whole blood into the sample well on the test card making sure that there are no air bubbles. Immediately add 2 drop (about 70-100 μL) of Sample Diluent to the sample well.
Step 5: Set up timer. Results can be read in 15 minutes.
*Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result. If you want to keep it for a long time, please take a photo of the result.*




【 Interpretation of Results 】

**1. Negative:**

If only the C line is present, the absence of any burgundy color in both test lines (M and G) indicates that no COVID-19 antibody is detected. The result is non-reactive.

**2. Positive:**

2.1 In addition to the presence of the C line, if only the M line is developed, the test indicates the presence of COVID-19 IgM. The result is IgM reactive.

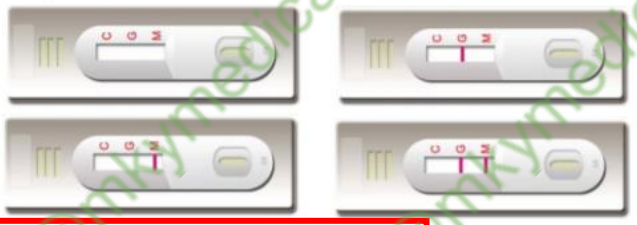
2.2 In addition to the presence of the C line, if only the G line is developed, the test indicates the presence of COVID-19 IgG. The result is IgG reactive.

2.3 In addition to the presence of the C line, if both the M and the G lines are developed, the test indicates the presence of COVID-19 IgG and IgM. The result is also reactive.

*Samples with reactive results should be confirmed with alternative testing method(s) and clinical Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.*

**3. 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 device.



**【 Clinical Performance 】**

A total of 97 positive samples and 483 negative samples were tested by the COVID-19 IgG/IgM rapid test. The test results are shown in below:

Sensitivity = 95/97*100% = 97.9%

Specificity = 482/483*100% = 99.8%

**【 Precautions 】**

1. This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.

3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Hemolytic samples cannot be used for testing.
6. Do not use turbid contaminated samples for testing.
7. Do not dilute the sample for testing, or you may get inaccurate results.
8. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning. Users must strictly follow the instructions for the operation and result interpretation.
9. The testing results should be read within 15 minutes after a specimen is applied to the sample well. Reading result after 20 minutes may give erroneous results.

**【 Limitations of Test 】**

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to COVID-19 in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

1. The COVID-19 IgG/IgM rapid test is limited to the qualitative detection of antibodies to COVID-19 in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.

2. A nonreactive result for an individual subject indicates absence of detectable COVID-19 antibodies. However, a nonreactive test result does not preclude the possibility of exposure to COVID-19.

3. A nonreactive result can occur if the quantity of COVID-19 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.

4. Samples containing high titers of heterophobic antibodies or rheumatoid factors may affect the expected results.

5. If the symptoms persist while the result from COVID-19 IgG/IgM rapid test is nonreactive, it is recommended to re-sample the patient a few days later or test with an alternative test method.

6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

**【 Symbols 】**

| | | |
|---|---|---|
| *In Vitro* Diagnostic Use | See Instruction for Use | Expiry Date |
| Tests per Kit | Manufacturing Date | Keep Dry |
| Batch Number | Authorized Representative | Keep away from Sunlight |
| Manufacturer | Do not reuse | Catalog # |
| Store between 2~30 ℃ | | |

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