

DPP® COVID-19 IgM/IgG System

For Detection of SARS-CoV-2 IgM and IgG Antibodies in Fingerstick Whole Blood, Venous Whole Blood, Serum and Plasma

Read this Product Insert completely before using the product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate test results.

STORAGE: Store at 2 to 30°C (36 to 86°F)

NAME AND INTENDED USE

The Chembio DPP® COVID-19 IgM/IgG System 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 fingerstick whole blood, venous whole blood, serum, or plasma (lithium heparin or EDTA) samples from patients suspected of COVID-19 infection by a healthcare provider. The DPP COVID-19 IgM/IgG System is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Results from the DPP COVID-19 IgM/IgG System should not be used as the sole basis for diagnosis. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests.

Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Results must be combined with clinical observations, patient history, and epidemiological information. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the DPP COVID-19 IgM/IgG System 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.

At this time, it is unknown for how long IgM or IgG antibodies may persist following infection.

The DPP COVID-19 IgM/IgG System is only for use under the Food and Drug Administration's Emergency Use Authorization. For prescription use only. For in vitro diagnostic use only.

SUMMARY AND EXPLANATION

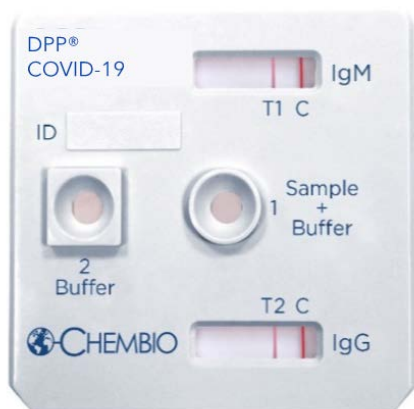
Coronaviruses are a large family of viruses that are common in people and many different species of animals. There are seven known types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV- NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and the novel "coronavirus disease 2019" (abbreviated "COVID-19"). COVID-19, discovered in 2019 in Wuhan, China, is caused by infection with the virus "SARS- CoV-2". Reported illnesses have ranged from very mild

(including some with no reported symptoms) to severe. Symptoms of COVID-19 are fever, fatigue, dry cough, and other symptoms which can rapidly develop into severe pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. which can be life-threatening.

BIOLOGICAL PRINCIPLES OF THE TEST

The DPP COVID-19 IgM/IgG System includes the DPP COVID-19 IgM/IgG Test Devices and the DPP Micro Reader or DPP Micro Reader 2 for use with the DPP COVID-19 IgM/IgG System. The device employs Chembio's patented DPP (Dual Path Platform) technology and consists of a sample path that distributes sample onto two assay paths (strips), which include antibody detection test and process control areas in each readout window of the test cassette (Figure 1).

Figure 1: DPP® COVID-19 IgM/IgG Test Device



The top test strip is for the detection of IgM antibodies to SARS CoV- 2 and the bottom test strip is for the detection of IgG antibodies to SARS CoV-2. To initiate the test, a 10 μ L specimen is diluted with buffer and applied to the SAMPLE+BUFFER well located in the middle of the sample transfer strip of the DPP COVID-19 IgM/IgG Test Device. The sample flows in both directions along the sample path membrane and is delivered to the Top and Bottom test (T1 and T2) and process control (C) areas. SARS CoV-2 antibodies, if present in the sample, bind to the immobilized Nucleocapsid Protein (NP) antigen on the test areas, while non-specific antibodies bind to the Protein A in the control areas. Five minutes after adding the sample/buffer mix, 9 drops (~250 μ L) DPP IgM/IgG Buffer is added to the BUFFER Well. The buffer flows onto both test strips, hydrates the two dried antibody- binding colored conjugates, which migrate to the two test areas. If the sample contains SARS CoV-2 antibodies, the conjugate binds to the antibodies (IgM or IgG or both if present) captured in the test areas. If only one of the two species of antibodies is present (IgM or IgG), the conjugate will be captured only at the location of the IgM (top strip) or IgG (bottom strip) test line.

At the time of reading the results, the DPP Micro Reader or DPP Micro Reader 2 **MUST BE USED** to obtain the test results and reports a reactive, nonreactive, or invalid result for the IgM and IgG test lines. The results must **not** be visually interpreted.

MATERIALS PROVIDED

Each kit contains the items to perform 20 tests:

- 20 Individually Pouched DPP COVID-19 IgM/IgG Test Devices, each containing a Desiccant Pouch
- 20 Disposable 10 μ L Sample Loops
- 20 Sample Vials/Tubes

- 20 Transfer Pipets (100 µL)
- 20 Bandages
- 20 Sterile Safety Lancets
- 1 DPP IgM/IgG Buffer
 - 9.5 mL, a phosphate buffer containing sodium chloride, EDTA, NP-40, Tween 20, and chicken serum, urea, antimicrobials and sodium azide as preservative
- 1 Product Insert for the DPP COVID-19 IgM/IgG System
- 1 Fact Sheet for Health Care Providers
- 20 Fact Sheets for Patients

ACCESSORIES AVAILABLE AND REQUIRED

DPP Micro Reader Kit for use with DPP COVID-19 IgM/IgG System Catalog Number 70-1069-0 or 70-1070-0.

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, watch, or other timing device
- Pipettor capable of delivering 10-100 µL of sample may be used in lieu of the disposable 10 µL Sample Loop or 100 µL Transfer Pipets supplied with the Kit (for venous whole blood, serum or plasma specimens)
- Disposable gloves, Biohazard disposal container, Collection devices (for venous whole blood, serum, plasma)
- Sterile gauze and antiseptic wipes (for fingerstick whole blood specimens)

WARNINGS

For *IN VITRO* Diagnostic Use under Emergency Use Authorization only.

1. Use of this product is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests.
2. Read the Product Insert completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate test results.
3. Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate test results.
4. This test should be performed at 18 to 30°C (64 to 86°F). If stored refrigerated, ensure that the pouch and buffer are brought to operating temperature before performing testing.

PRECAUTIONS

SAFETY PRECAUTIONS

1. Specimens may be infectious. Use Universal Precautions when performing this assay.
2. Use routine laboratory precautions. Do not eat, drink or smoke in the area where samples and kit reagents are handled. Avoid any contact between hands, eyes or mouth during sample collection and testing.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient samples. Wash hands thoroughly after handling specimens and kit reagents.
4. Dispose of all samples and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. Proper handling and disposal methods should be established according to local regulations.

HANDLING PRECAUTIONS

1. If Desiccant Packet is missing, DO NOT USE. Discard test device and use a new test device.
2. Do not use any test device if the pouch has been perforated.
3. Each test device is for single use only.
4. Do not use the test beyond the expiration date printed on the pouch. Always check expiration date prior to testing.

5. Do not mix reagents from different lot numbers of kits.
6. Ensure finger is completely dry before performing fingerstick.
7. Perform test procedure and read results in a well-lit area.

STORAGE AND STABILITY

The DPP COVID-19 IgM/IgG Test Devices should be stored in unopened pouches at 2 to 30°C (36 to 86°F). Do not freeze. Do not open pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch. The DPP IgM/IgG Buffer should be stored at 2 to 30°C (36 to 86°F) in its original container.

SPECIMEN COLLECTION

The DPP COVID-19 IgM/IgG System must be performed on fingerstick whole blood, venous whole blood, serum, or plasma samples (lithium heparin or EDTA).

FINGERSTICK WHOLE BLOOD

Please refer to Test Procedure for collection instructions.

After mixing the fingerstick whole blood specimen with the DPP IgM/IgG Buffer, as described in the Test Procedure, the sample should be tested immediately.

VENOUS WHOLE BLOOD:

- Draw blood following laboratory procedure for obtaining venous whole blood samples.
- Collect samples in tubes containing anticoagulant (Lithium Heparin or EDTA).
- Collect specimen in a clean container following standard laboratory procedures.
- Be sure the tube of blood is well mixed before sampling.
- If tested the same day, venous whole blood may be kept at room temperature. Venous whole blood may be stored for up to 3 days between 2 and 8°C (36 to 46°F) before testing.
- DO NOT FREEZE WHOLE BLOOD! Allow refrigerated sample to reach room temperature and mix gently before testing.

SERUM OR PLASMA:

- Draw blood following laboratory procedure for obtaining serum or plasma samples.
- Collect samples in tubes that do not contain any anticoagulant (serum), or in a tube containing anticoagulant (plasma).
- Be sure that the tube of serum or plasma is well mixed before sampling.
- Serum and plasma specimens may be tested immediately after collection. If specimens are not tested immediately, refrigerate them at 2 to 8°C (36 to 46°F) following collection. These specimens should be tested within 3 days of collection. If specimens are not tested within 3 days of collection, serum or plasma specimens should be frozen at -20°C (-4°F) or colder.

SPECIMEN SHIPPING

If venous whole blood, serum, or plasma specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents. Venous whole blood, serum and plasma specimens should be shipped refrigerated with cold packs or wet ice. Fingerstick specimens must be tested immediately after collection.

TEST PROCEDURE

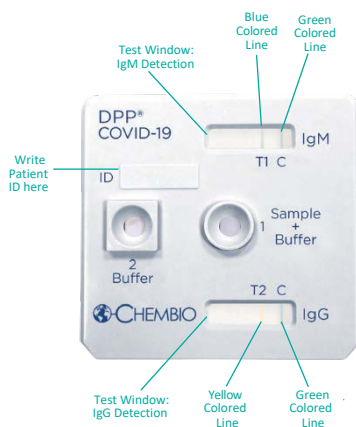
All components for the DPP COVID-19 IgM/IgG System are ready to use as supplied. Follow directions as indicated. If the sample and / or kit components have been refrigerated, remove them from the refrigerator and allow them to come to a temperature of 18 to 30°C (64 to 86°F) prior to testing.

1. Remove the DPP COVID-19 IgM/IgG Test Device from its pouch and place it on a flat surface (it is not necessary to remove the Desiccant Packet from the pouch). Note: If Desiccant Packet is missing, DO NOT USE, discard Test Device and use a new Test Device.

Label the Test Device with patient ID or identification number.

There are 2 colored lines in each of the Test Windows. For IgM one is blue and the other is green. For IgG, one is yellow and the other is green.

If any of the colored lines are absent from one or both windows, DO NOT USE, discard Test Device and use a new Test Device.



2. Transfer 5 drops (~150 μ L) of the DPP IgM/IgG Buffer (Blue cap) into the supplied Sample Vial.

For fingerstick whole blood samples, proceed to 3.a.

For venous whole blood, serum or plasma, proceed to 3.b.



FINGERSTICK WHOLE BLOOD COLLECTION

- 3a. Prepare to perform the fingerstick collection procedure. Clean the finger of the person being tested with an antiseptic wipe. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.

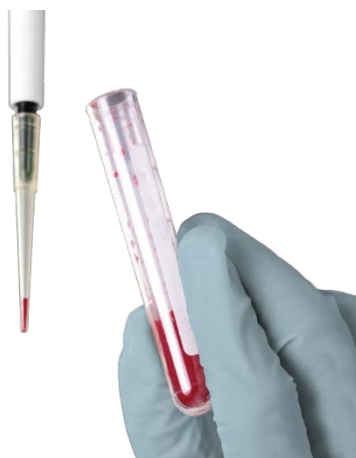
Using a sterile lancet, puncture the skin just off the center of the finger and wipe away the first drop of blood with sterile gauze. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.

Collect the sample from the second drop, laying the disposable sample loop provided against the drop of blood until the sample loop is full as shown below.



VENOUS WHOLE BLOOD, SERUM OR PLASMA COLLECTION

- 3a. For whole blood, serum or plasma samples, use a laboratory pipette to draw 10 μ L of the sample from the sample collection tube.



FINGERSTICK WHOLE BLOOD TRANSFER

- 3b Immerse the end of the loop filled with blood into the buffer in the sample vial; mix the contents well with the loop; remove and discard the empty loop in the biohazardous waste container.



- 3c Fill the transfer pipette up to the black line (100 μ L) ensuring there are no air bubbles in the pipette.



With the transfer pipette, transfer 100 μ L of the sample/buffer mixture from the sample vial into Well 1 (Sample+Buffer).



WHOLE BLOOD, SERUM OR PLASMA TRANSFER

- 3b Immerse the end of the laboratory pipette tip containing the 10 μ L into the buffer in the sample vial; mix the contents well.



- 3c With the calibrated pipette, Transfer the 100 μ L of sample/buffer mixture into Well 1 (Sample+Buffer).



4. Wait 5 minutes. The blue (IgM) and yellow (IgG) colored lines should have disappeared from the rectangular TEST and CONTROL windows. The green colored line may or may not disappear.

If the BLUE and YELLOW colored lines do not disappear, DO NOT USE, discard Test Device and use a new Test Device.

5. Invert the DPP IgM/IgG Buffer bottle (Blue Cap) and hold it VERTICALLY (not at an angle) over Well 2 (Buffer).

Add 9 drops of Buffer (~250 μ L) slowly, dropwise, into Well 2 (Buffer).

A reddish color should begin to flow across both strips within 2-3 minutes. Otherwise, stop and repeat the test with a new test device.



6. Read the test results using the DPP Micro Reader or DPP Micro Reader 2 between 10 and 15 minutes from the addition of the DPP IgM/IgG Buffer to Well 2 (Buffer) following the instructions outlined in the DPP Micro Reader or DPP Micro Reader 2 Manual.

NOTE: Discard the used Sample Loop, Test Device, and any other test materials into a biohazard waste container.

INTERPRETATION OF TEST RESULTS

DO NOT ATTEMPT TO INTERPRET RESULTS OF THE DPP COVID-19 IgM/IgG SYSTEM VISUALLY. ALWAYS USE THE DPP MICRO READER (OR DPP MICRO READER II) FOR USE WITH THE DPP COVID-19 IgM/IgG SYSTEM TO OBTAIN RESULTS.

MANUALLY RECORD RESULTS IMMEDIATELY UPON DISPLAY BY THE READER. THE DPP MICRO READER AND DPP MICRO READER II WILL AUTOMATICALLY SHUT OFF WITHIN 50 SECONDS AND 90 SECONDS, RESPECTIVELY, OF INACTIVITY. RESULTS CANNOT BE RECALLED.

Read the Product Insert accompanying the DPP Micro Reader (or DPP Micro Reader II) completely before using the product.

IgM and IgG NON-REACTIVE

A NON-REACTIVE Test Result for both IgM and IgG means that antibodies to SARS-CoV-2 were not detected in the specimen.

The Test Result is interpreted as NON-REACTIVE (i.e. negative). However, a negative result does not exclude possible infection with COVID-19, particularly in those who have been in contact with the virus, and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection

IgM REACTIVE (R) and IgG NON-REACTIVE (NR)

A REACTIVE IgM test result (i.e., presumed SARS-CoV-2 IgM positive) from the DPP® COVID-19 IgM/IgG System indicates that IgM antibodies to SARS-CoV-2 were detected in the specimen.

If only IgM antibodies were detected, the result is consistent with an active or recent SARS-CoV-2 virus infection.

IgM NON-REACTIVE (NR) and IgG REACTIVE (R)

A REACTIVE IgG test result (i.e., presumed SARS-CoV-2 IgG positive) in the IgG test window means that IgG antibodies to SARS-CoV-2 were detected in the specimen.

If only IgG antibodies were detected, the result is consistent with a recent or previous infection.

IgM and IgG REACTIVE (R)

A REACTIVE IgM and a REACTIVE IgG test result means that IgM and IgG antibodies to SARS-CoV-2 have been detected in the specimen. The result suggests a current or recent SARS-CoV-2 virus infection.

INVALID

If the reader returns an INVALID result for IgM OR for IgG, the entire test results are INVALID. An INVALID test cannot be interpreted. It is recommended that the specimen be re-tested with a new test device.

If the problem persists, please contact Customer Support: +001 631 924 1135 or 1-844-Chembio

Please also refer to the Fact Sheet for Health Care Providers for More Information

QUALITY CONTROL

Built-in Process Control Feature

The DPP COVID-19 IgM/IgG System uses an algorithm including assay-specific cut-off values that verifies and gives confirmation of sample addition and proper test procedure. Results will be displayed if the test procedure has been correctly performed. If the test procedure has not been performed correctly, the results will be displayed on the DPP Micro Reader as Invalid and new test must be performed. See Test Interpretation Section provided in the DPP Micro Reader or DPP Micro Reader II Manual. If the problem persists, please contact Chembio Customer Support at +001 631 924 1135 or 1-844-CHEMBIO.

Good laboratory practice suggests that positive and negative controls are run routinely to ensure that test reagents are working and that the test is correctly performed. External positive and negative controls should be used in accordance with local, state, federal accrediting organizations, or your lab's standard Quality Control procedures, as applicable.

LIMITATIONS OF THE PROCEDURE

- 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 immune response.
- False positive results due to cross-reactivity with antibodies to other coronaviruses, (e.g., HKU1, 229E, NL63, OC43) can occur.
- The DPP COVID-19 IgM/IgG System must ONLY be used with capillary (fingerstick) whole blood, venous whole blood, serum or plasma (lithium heparin or EDTA). Using other types of samples may not yield accurate results. For serum samples, collect blood without anticoagulant.
- The DPP COVID-19 IgM/IgG System must be used in accordance with the instructions in this product insert to obtain accurate results.
- Reading test results earlier than 10 minutes or later than 15 minutes after the addition of Buffer to Well 2 may yield erroneous results.
- 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 the screening of donated blood.
- The DPP COVID-19 IgM/IgG System 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.
- 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 utilized in the test.
- If symptoms persist and the result from the DPP COVID-19 IgM/IgG System is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The DPP COVID-19 IgM/IgG System 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/emergency-situations-medical-devices/emergency-use-authorizations# covid19ivd>. However, to assist clinical laboratories using the DPP COVID-19 IgM/IgG System ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories¹ 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, 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) and Chembio Diagnostics, Inc. (CustomerService@chembio.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.
- Chembio Diagnostics, Inc., 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.

¹ The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests" as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

POSITIVE AGREEMENT

Endemic, Symptomatic Subjects

Positive agreement was evaluated using plasma or venous whole blood samples collected from symptomatic subjects. All subjects were confirmed positive for 2019 Novel Coronavirus by RT-PCR. The positive population consisted of the following subjects.

- Living in New York during the 2020 COVID-19 pandemic.
- Living in East Asia during the 2020 COVID-19 pandemic.

Table 1: Positive Agreement of the DPP COVID-19 IgM/IgG System According to Days Post Onset of Symptoms: Endemic Symptomatic Subjects

Days from Symptom Onset to Blood Collection*	Number of Samples	2019-nCoV RT-PCR Result	DPP COVID-19 IgM/IgG System Result as compared to PCR		
			IgM (+)	IgG (+)	IgM (+) and/or IgG (+)
≤6 days	4	Pos	1/4=25%	4/4=100%	4/4=100%
7-10 days	10	Pos	7/10=70%	6/10=60%	8/10=80%
11-14 days	4	Pos	3/4=75%	4/4=100%	4/4=100%
15-18 days	11	Pos	11/11=100%	11/11=100%	11/11=100%
19-21 days	2	Pos	2/2=100%	2/2=100%	2/2=100%
Total	31	N/A	24/31=77.4% 95% CI: 60.2% - 88.6%	27/31=87.1% 95% CI: 71.1% - 94.9%	29/31=93.5% 95% CI: 79.3% - 98.2%

*Development of an antibody response to SARS-COVID-2 can take up to 14 or more days post symptom onset¹.

Seroconversion

The DPP COVID-19 IgM/IgG System was evaluated using serial plasma (lithium heparin) samples collected from symptomatic subjects. All subjects were confirmed positive for 2019 Novel Coronavirus by an FDA EUA RT-PCR. The positive population consisted of 9 subjects from the United States (New York), from whom 22 specimens were drawn. Plasma samples were collected and tested 1-22 days after onset of symptoms and within 1 to 16 days after the respiratory specimen was collected for PCR. Test evaluation results are presented in Table 2.

Table 2: Testing Seroconversion Samples from USA using the DPP COVID-19 IgM/IgG System. Results are presented as Reflectance Units where ≥25 is reactive and < 25 is nonreactive

Patient ID #	nCoV-2 PCR Result	Days Between Symptom Onset & Blood Collection	DPP COVID-19 IgM/IgG System		
			IgM (+)	IgG (+)	IgM (+) and/or IgG (+)
022-01	POS	2	7	2	NR
022-02	N/A	11	129	364	R
027-01	POS	15	4	3	NR
027-02	N/A	20	72	260	R
033-01	POS	9	12	3	NR
033-02	N/A	14	172	87	R
057-01	POS	1	4	6	NR
057-02	N/A	5	57	297	R
081-01	POS	10	13	10	NR
081-02	N/A	14	110	107	R
081-03	POS	17	158	360	R
093-01	POS	15	12	7	NR
093-02	N/A	19	7	10	NR
093-03	N/A	22	163	387	R
114-01	POS	9	8	5	NR
114-02	N/A	13	26	131	R
118-01	POS	9	10	10	NR
118-02	N/A	13	36	136	R
118-03	N/A	15	158	363	R
119-01	POS	12	6	5	NR
119-02	N/A	16	11	5	NR
119-03	N/A	19	107	192	R

R = Reactive, NR = Nonreactive; N/A= Not Applicable

NEGATIVE AGREEMENT

Endemic, Symptomatic Subjects

Negative agreement of the DPP COVID-19 IgM/IgG System was evaluated using 41 samples collected from symptomatic subjects; two (2) subjects were residing in East Asia (venous whole blood samples were collected) and thirty-nine (39) subjects were residing in New York (plasma samples were collected). Samples were collected during the 2020 COVID-19 pandemic and all were confirmed negative for 2019 Novel Coronavirus by RT-PCR. Results are shown in Table 3a below.

Table 3a: Negative Agreement of the DPP COVID-19 IgM/IgG System: Endemic, Symptomatic Subjects

Number of Samples	Origin	2019-nCOV RT-PCR Result	DPP COVID-19 IgM/IgG System results as compared to PCR		
			IgM (-)	IgG (-)	IgM (-) and IgG (-)
2	East Asia	Neg	2/2 = 100%	2/2 = 100%	2/2=100%
39	NY, USA	Neg	38/39 = 97.4%	36/39=92.3%	35/39=89.7%
TOTAL = 41	N/A	N/A	40/41 = 97.6% 95% CI: 87.4% - 99.6%	38/41=92.7% 95% CI: 80.6% - 97.5%	37/41=90.2% 95% CI: 77.5% - 96.1%

Endemic, Asymptomatic Subjects

The specificity of the DPP COVID-19 IgM/IgG System was also evaluated using 49 presumed negative EDTA venous whole blood specimens collected from asymptomatic individuals from the United States. The samples were commercially sourced from a blood donation center and collected during the 2020 COVID-19 pandemic. The resulting negative agreement of the DPP® COVID-19 IgM/IgG System compared to the expected result was 100% (49/49 = 100%) for IgM and 95.9% (47/49 = 95.9%) for IgG. Results are shown in Table 3b below.

Table 3b: Negative Agreement of the DPP COVID-19 IgM/IgG System for Presumed Negative Samples: Endemic, Asymptomatic Subjects

Number of Samples	DPP COVID-19 IgM/IgG System results as compared to expected		
	IgM (-)	IgG (-)	IgM (-) and IgG (-)
49	49/49=100%	47/49=95.9%	47/49=95.9%
	95% CI: 92.7% - 100.0%	95% CI: 86.3% - 98.9%	95% CI: 86.3% - 98.9%

Non-Endemic Subjects, Asymptomatic Subjects

The specificity of the DPP COVID-19 IgM/IgG System was evaluated using 25 presumed negative plasma specimens collected from asymptomatic individuals from the United States. The samples were commercially sourced from a blood donation center and collected in 2016 before the COVID-19 outbreak. The resulting negative agreement of the DPP COVID-19 IgM/ IgG System compared to the expected result was 100% (25/25 = 100%) for IgM and 100% (25/25 = 100%) for IgG and as shown in Table 4.

In addition, the specificity of the DPP COVID-19 IgM/IgG System was evaluated using 32 presumed negative plasma specimens and 68 presumed negative serum specimens collected from asymptomatic individuals residing in Brazil. The samples were collected prior to March 2019 before the COVID-19 outbreak. The resulting negative agreement of the DPP COVID-19 IgM/IgG System compared to the expected result was 97% (97/100 = 97%) for IgM and 96% (96/100 = 96%) for IgG and as shown in Table 4.

Table 4: Negative Agreement of the DPP COVID-19 IgM/IgG System: Non-Endemic, Asymptomatic Subjects

Number of Samples	Origin	Matrix	DPP COVID-19 IgM/IgG System results as compared to expected		
			IgM (-)	IgG (-)	IgM (-) and IgG (-)
25	USA	Plasma	25/25 = 100%	25/25 = 100%	25/25 = 100%
32	Brazil	Plasma	32/32 = 100%	30/32 = 93.4%	30/32 = 93.4%
68		Serum	65/68 = 95.6%	66/68 = 97.1%	63/68 = 92.6%
Total = 125	N/A	N/A	122/125 = 97.6% 95% CI: 93.2% - 99.2%	121/125 = 96.8% 95% CI: 92.1% – 98.7%	118/125 = 94.4% 95% CI: 88.9% – 97.3%

FINGERSTICK SAMPLE

The performance of the DPP COVID-19 IgM/IgG System was evaluated using fresh, fingerstick samples prospectively-collected from 11 individuals, 7 of whom were presenting with symptoms. All samples were collected from hospital workers in the United States (New York), an area endemic for COVID-19 during the 2019 Novel Coronavirus outbreak. Samples had confirmed results with an FDA-authorized RT-PCR. Test evaluation results are presented in Table 5.

Table 5: Performance of DPP COVID-19 IgM/IgG System with Fingerstick Samples with Confirmed nCoV-2 PCR results: Endemic, Hospital Workers

Number of Samples	nCoV-2 RT-PCR Result	Days Between Symptom Onset and Blood Collection	DPP COVID-19 IgM/IgG System		
			Result as compared to PCR		
			IgM (+)	IgG (+)	IgM (+) and/or IgG (+)
6	Positive	14-17 ²	3/6=50%	6/6=100%	6/6=100%
			IgM (-)	IgG (-)	IgM (-) and IgG (-)
5	Negative	7-17 ¹	5/5=100%	5/5=100%	5/5=100%
			Total Agreement		
Total=11	N/A	N/A	8/11=72.7% 95% CI: 43.4% – 90.3%	11/11=100% 95% CI: 74.1% - 100.0%	11/11=100% 95% CI: 74.1% - 100.0%

¹ For 2 samples the day of symptom onset is unknown

² For 4 samples the day of symptom onset is unknown

MATRIX COMPARISON

The performance of the DPP COVID-19 IgM/IgG System was evaluated using prospectively-collected matched EDTA venous whole blood, EDTA plasma and capillary (fingerstick) whole blood samples from a total of 15 individuals, 6 of whom were presenting with symptoms. All samples were collected from hospital workers in the United States (New York), an area endemic for COVID-19 during the 2019 Novel Coronavirus outbreak. Five (5) of the samples from those presenting with symptoms had PCR-positive confirmed results with an FDA-authorized RT-PCR and are also discussed in Table 5 above. The results of the plasma and fingerstick samples are compared to the matched venous whole blood result for each subject. Test evaluation results are presented in Table 6.

Table 6: DPP COVID-19 IgM/IgG System: Matched venous whole blood, plasma and fingerstick specimens: Endemic, Hospital Workers

	DPP COVID-19 IgM/IgG System		
	Venous Whole Blood (n)	Plasma	Fingerstick
IgM (+) only	3	3/3=100%	3/3=100%
IgG (+) only ¹	7	7/7=100%	7/7=100%
IgG (+) and IgM (+) ²	5	5/5=100%	4 ³ /5=80%
Total	15	15/15=100% 95% CI: 79.6% - 100.0%	14/15=93.3% 95% CI: 70.2% - 98.8%

¹ nCoV-2 PCR+ results were available for 2 IgG (+) only subjects. The fingerstick results are also presented in Table 5 above.

² nCoV-2 PCR+ results were available for and 3 IgM (+) and IgG (+) subjects. The fingerstick results are also presented in Table 5 above.

³ One specimen was IgM negative. A PCR result was not available for the subject with the discordant (IgM(-)) fingerstick result.

Cross Reactivity

The DPP COVID-19 IgM/IgG System did not cross react with samples positive for: antibody to Dengue virus, Chikungunya virus, Zika virus, or Yellow fever virus (post-immunization); human coronaviruses (NL63 and OC43), antigen to Flu A, Flu B; heterophile antibodies for mononucleosis. Cross reactivity was observed on the DPP COVID-19 IgM/IgG System with one specimen positive for

Table 7: Cross Reactivity of the DPP COVID-19 IgM/IgG Assay System

Organisms/Conditions	Number of Samples	DPP COVID-19 IgM/IgG System					
		IgM			IgG		
		POS	NEG	%CR	POS	NEG	%CR
Anti-Dengue virus (IgM and IgG)	5	0	5	0%	0	5	0%
Anti-Chikungunya virus (IgM and IgG)	5	0	5	0%	0	5	0%
Anti-Zika virus (IgM)	5	0	5	0%	0	5	0%
Yellow fever virus post-immunization	5	0	5	0%	0	5	0%
Human coronavirus HKU1 ¹	5	0	5	0%	1	4	20%
Human coronavirus 229E	1	0	1	0%	1	0	100%
Human coronavirus NL63	2	0	1	0%	0	2	0%
Human coronavirus OC43	1	0	1	0%	0	1	0%
Influenza A	5	0	5	0%	0	5	0%
Influenza B	5	0	5	0%	0	5	0%
Mononucleosis	5	0	5	0%	0	5	0%

¹The sample that was IgG-antibody reactive on the DPP COVID-19 IgM/IgG System, was confirmed positive for COVID-19 by a FDA-authorized RT-PCR; a second sample that was found IgM and IgG-antibody non-reactive on the DPP System was also confirmed positive for COVID-19 by the same FDA-authorized RT-PCR.

DILUTION OF POSITIVE SAMPLES

Two (2) plasma samples were prospectively-collected from symptomatic patients confirmed positive by nCoV-2 RT-PCR. Samples were serially-diluted and tested on the DPP COVID-19 IgM/IgG System. IgM and IgG data are presented in the Table 8 below. This information can also be seen in graph format, in Figures 1 and 2.

Table 8: Testing of serially-diluted plasma samples on the DPP COVID-19 IgM/IgG System. Results are presented as Reflectance Units where ≥25 is reactive and <25 is nonreactive.

Dilution	DPP COVID-19 IgM/IgG System – Sample 1		DPP COVID-19 IgM/IgG System – Sample 2	
	IgM Result	IgG Result	IgM Result	IgG Result
1:15	36	290	128	310
1:30	16	197	223	348
1:60	11	66	140	302
1:120	16	66	62	237
1:240	16	32	49	218
1:580	24	15	49	85
1:1160	12	23	14	54
1:2320	17	9	19	74
1:4640	NT	NT	8	21
1:9280	NT	NT	11	11

█ = R, for Reactive; NT= Not Tested

Figure 1: Dilution of IgM-Antibody Positive Samples

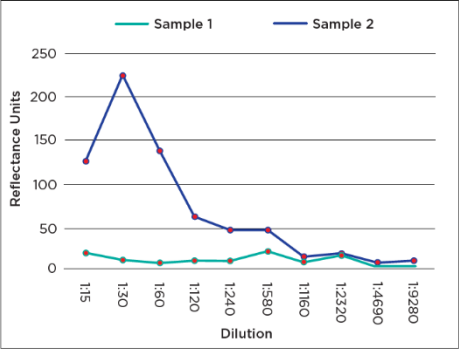
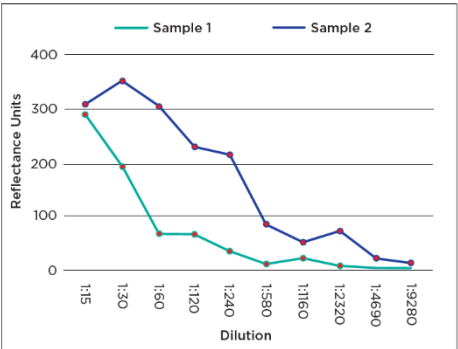



Figure 2: Dilution of IgG-Antibody Positive Samples



Ordering Information












Product	Catalog Number
DPP® COVID-19 IgM/IgG System	65-9569-0
DPP® Micro Reader Kit for Use with DPP COVID-19 IgM/IgG System	70-1069-0
DPP® Micro Reader II Kit for Use with DPP COVID-19 IgM/IgG System	70-1070-0

For Product Information, Literature
and/or SDS please email:
info@chembio.com

 **Manufactured by:**
CHEMBIO DIAGNOSTIC SYSTEMS, INC.
3661 HORSEBLOCK ROAD
MEDFORD, NY 11763
USA

Tel: +001 631 924 1135

Email: info@chembio.com
Web Site: www.chembio.com

SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	WARNING
	DO NOT RE-USE
	FOR USE WITHIN TEMPERATURE LIMITS
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	BATCH CODE
	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE
	CONTAINS SUFFICIENT FOR 20 TESTS

DPP® Micro Reader

70-1069-0

For Use with the DPP COVID-19 IgM/IgG System

Read this Product Insert completely before using the product.

STORAGE: Store between -20 to 80°C (-4 to 176°F)

NAME AND INTENDED USE

The DPP® Micro Reader is for use with DPP COVID-19 IgM/IgG System.

SUMMARY AND EXPLANATION

The DPP® Micro Reader is a reflectance reader used to obtain test results from DPP® COVID-19 IgM/ IgG System test devices. The DPP Micro Reader minimizes human errors due to subjective visual reading of IgM and IgG results; therefore, the DPP COVID-19 IgM/ IgG System was made specifically to be read with the DPP Micro Reader or the DPP Micro Reader II (refer to the Product Insert for the DPP Micro Reader II).

PRINCIPLES OF THE PROCEDURE

The DPP Micro Reader is a portable, battery-powered instrument that captures an image of the test strip surface, verifies the presence and intensity of the control line and measures the line intensity at each of the test line positions; it interprets the results using a scoring algorithm, and reports a REACTIVE, NON-REACTIVE or INVALID result after approximately 3 seconds. A 14-segment liquid crystal display (LCD) on the top of the instrument shows the status of the instrument and displays the test results to the operator.

The DPP Micro Reader is maintenance free and not configurable by the user and is operated by a single, multi-function button.

MATERIALS PROVIDED

DPP Micro Reader Kit for use with DPP COVID-19 IgM/IgG System (Catalog 70-1069-0) Each kit contains:

- 1 DPP Micro Reader (includes 3 batteries)
- 1 Holder for use with DPP Test Device
- 1 Microfiber cloth
- 1 Adapter Cable (5V/1000mA)
- 1 RFID Card for use with DPP COVID-19 IgM/IgG System
- 1 User Manual

WARNINGS

For *IN VITRO* diagnostic use

The DPP COVID-19 IgM/IgG Assay System test results **must** be read using the DPP Micro Reader. The DPP COVID-19 IgM/IgG Assay System test results and must not be visually interpreted.

- The DPP Micro Reader is calibrated and checked before shipping under strict quality control measures in order to guarantee a high degree of quality. Do not attempt to open, re-configure or re-calibrate the DPP MicroReader.
- The correct RFID cards are required for running the DPP COVID-19 IgM/IgG System tests. Each RFID card is specific to the assay type being conducted and will transfer test specific information to the reader before each measurement. Using an RFID card intended for a different test type than the one performed can result in incorrect test results.
- The DPP Micro Reader requires three (3) CR2032 (3 V/230 mAh) batteries to operate. Alternatively, it can be powered through the adaptor cable connected to an external power source.
- Do not use the DPP Micro Reader in direct sunlight or exposed to bright light while reading results.
- The DPP Micro Reader is designed for use on a clean, flat, horizontal, surface.
- Always ensure that the DPP Micro Reader is positioned correctly in the DPP test device holder, as described in Operation of the Micro Reader below. Incorrect positioning may lead to incorrect results.
- The DPP Micro Reader should be operated at 18 to 30°C (64 to 86°F) and between 20% and 85% humidity. Ensure that the DPP Micro Reader is brought to operating temperature before use.
- Protect the DPP Micro Reader from liquids. Any liquid entering the DPP Micro Reader may damage it permanently.
- Please follow the instructions in the product insert provided with the test kit regarding the disposal of DPP test devices containing hazardous or infectious material.
- The DPP Micro Reader itself contains no biological hazards. However, contamination during use with biological hazards is possible. For cleaning and maintenance, refer to section CLEANING AND MAINTENANCE.


STORAGE AND STABILITY

The DPP Micro Reader should be stored at temperatures between -20 and 80°C (-4 to 176°F) and between 20% and 85 % humidity. It should be operated at temperatures between 18 and 30°C (64 to 86°F) and between 20% and 85% humidity.

BATTERY LIFE


Under continuous use, one set of batteries will last for approximately 250- 300 reads (exact number may vary depending on battery quality, temperature, and length of storage between uses). The status of the batteries is being monitored and shown on the reader display every time the reader is turned ON. Verify that the battery symbol is not blinking nor has any bars left. Replace the batteries when the battery symbol starts to blink. The batteries cannot be recharged and have to be disposed according to local regulations. Always have a spare set of three batteries. Please see section on BATTERY INSTALLATION below. Alternatively, the DPP Micro Reader can be powered using the USB power cable connected to a power source.

BATTERY INSTALLATION




Battery compartment

To replace batteries, use three (3) CR2032 (3V/230mAh) Lithium-ion Coin Cell batteries




OPERATION OF THE DPP MICRO READER


1. Ensure that the reader and components are clean. Remove any dust or debris from bottom camera window. Insert DPP Micro Reader into the supplied holder as shown.



DPP Micro Reader

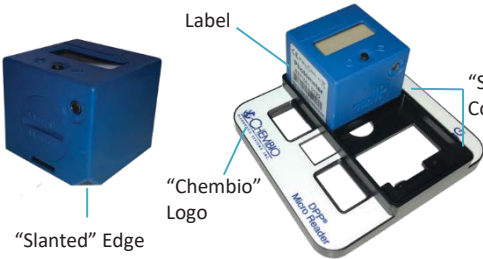


DPP Test Device Holder



DPP Micro Reader with Holder

a. Connect the DPP Micro Reader to the supplied holder. Insert the base of the reader so that the “slanted” edge meets the corresponding “slanted” corner in the holder cavity. The reader should lay flat in the holder and the button and battery compartment should face the user. The label on the reader should face the “Chembio” logo on the test device holder, as shown in this figure.



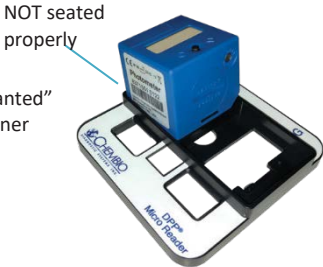
CORRECT

Label

“Slanted” Edge

“Chembio” Logo


“Slanted” Corner



INCORRECT

NOT seated properly

b. At the time indicated for reading the test results, place the reader and holder on the TOP IgM Test Window of the device and push the button. “ON” will appear in the display window.



IgM TEST PROCEDURE

Ensure that the DPP Micro Reader is seated in the IgM test window before proceeding. Press the black button. "ON" will appear on the display and a beep will sound.



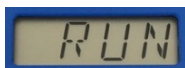
Press the button again; the display will read "RFID". Place the DPP COVID-19 IgM/IgG RFID card on top of the reader and a beep will sound.



Remove the card from the top of the reader and "TEST" will appear in the display window.



Press the button and "RUN" will appear in the display window.



After approximately 3 seconds, R or NR letters and a numerical value for the IgM results will be displayed; **IMMEDIATELY RECORD THE IgM TEST RESULT** (refer to INTERPRETATION OF TEST RESULTS).

IgG TEST PROCEDURE

Move the reader to the BOTTOM IgG Test Window. Ensure that the DPP Micro Reader is seated in the IgG test window before proceeding. Press the black button. "ON" will appear on the display and a beep will sound.



Press the button again; the display will read "RFID". Place the DPP COVID-19 IgM/IgG RFID card on top of the reader and a beep will sound.



Remove the card from the top of the reader and "TEST" will appear in the display window.



Press the button and "RUN" will appear in the display window.



After approximately 3 seconds, R or NR letters and a numerical value for the IgG results will be displayed; record the IgG results; **IMMEDIATELY RECORD THE IgG TEST RESULT** (refer to INTERPRETATION OF TEST RESULTS).

WARNING: The reader will turn off automatically after approximately 50 seconds of inactivity. PREVIOUS TEST RESULTS CANNOT BE RECALLED.

There is no active function to shut off the DPP Micro Reader or to recall the last test results.

INTERPRETATION OF TEST RESULTS

DO NOT ATTEMPT TO INTERPRET RESULTS OF THE DPP COVID-19 IgM/IgG SYSTEM VISUALLY. ALWAYS USE THE DPP MICRO READER FOR USE WITH THE DPP COVID-19 IgM/IgG SYSTEM TO OBTAIN RESULTS. CONSULT DPP MICRO READER USER MANUAL.

THE FOLLOWING WILL
SCROLL ACROSS THE
READER DISPLAY

IgM and IgG NON-REACTIVE

If the numerical results displayed for BOTH IgM and IgG are less than 25, the specimen test result is interpreted as NON-REACTIVE for both IgM and IgG.

IgM 24/NR

A NON-REACTIVE Test Result means SARS-CoV-2 specific antibodies were not detected in the specimen.

IgG 24/NR

The Test Result is interpreted as NON-REACTIVE (i.e. negative). However, a negative result does not exclude possible infection with COVID-19, particularly in those who have been in contact with the virus, and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection.

Please also refer to the Fact Sheet for Health Care Providers for More Information.

IgM REACTIVE (R) and IgG NON-REACTIVE (NR)

If the numerical result displayed for IgM is greater than or equal to 25, the specimen test result indicates a REACTIVE SARS-CoV-2 IgM Antibody Test Result.

IgM 25/R

A REACTIVE IgM test result (i.e. presumptive SARS-CoV-2 IgM positive) from the DPP® COVID-19 IgM/IgG System indicates that IgM antibodies to SARS-CoV-2 were detected in the specimen.

IgG 24/NR

If only IgM antibodies were detected, the result is consistent with an active or recent SARS-CoV-2 virus infection.

Please also refer to the Fact Sheet for Health Care Providers for More Information.

IgM NON-REACTIVE (NR) and IgG REACTIVE (R)

If the numerical result displayed for IgG is greater than or equal to 25, the specimen test result indicates a REACTIVE SARS-CoV-2 IgG Antibody Test Result.

IgM 24/NR

A REACTIVE IgG test result (i.e. presumptive SARS-CoV-2 IgG positive) in the IgG test window means that IgG antibodies to SARS-CoV-2 were detected in the specimen.

IgG 25/R

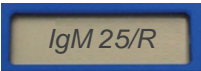
If only IgG antibodies were detected, the result is consistent with a recent or previous infection.

Please also refer to the Fact Sheet for Health Care Providers for More Information.

INTERPRETATION OF TEST RESULTS, continued

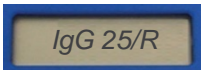
IgM and IgG REACTIVE (R)

If the numerical result displayed for both IgM and IgG is greater than or equal to 25, the specimen test result indicates a REACTIVE SARS-CoV-2 IgM and IgG Antibody Test Result.



IgM 25/R

A REACTIVE IgM and a REACTIVE IgG test result means that IgM and IgG antibodies to SARS-CoV-2 have been detected in the specimen. The result is IgM and IgG reactive, suggesting current or recent SARS-CoV-2 virus infection.



IgG 25/R

Please also refer to the Fact Sheet for Health Care Providers for More Information.

INVALID

If the reader returns an INVALID result for IgM OR for IgG, the entire test results are INVALID. An INVALID test cannot be interpreted. It is recommended that the specimen be re-tested with a new test device.



INV

If the problem persists, please contact Customer Support: +001-631-924-1135 or 1-844-CHEMBIO.

TURNING OFF THE READER

There is no active function to shut off the DPP Micro Reader; it will turn off automatically after approximately 50 seconds of inactivity.

CLEANING AND MAINTENANCE

The outer case and display may be cleaned with the enclosed microfiber cloth lightly moistened with 70% isopropyl alcohol (IPA), 10% bleach solution, or mild soap solution. Do not introduce cleaning solution or any liquid into the unit. Do not use a saturated towel, which may leak liquid into the case or display seams. Ensure that the DPP Micro Reader is dry and the surface is free of fluid prior to returning to use. It is recommended to clean the reader daily.

Before each use, make sure that the window under the reader is clean of finger marks, dust and lint, which may interfere with the results. It can be wiped with the provided dry microfiber cloth, or the microfiber cloth lightly moistened with 70% isopropyl alcohol (IPA).

SERVICING AND RE-ORDERING

There are no user serviceable components in the unit with the exception of the replaceable batteries. For technical issues or questions, and to order a new reader, please contact Chembio Diagnostic Systems, Inc.

Customer Service Department
Call: 1-844-CHEMBIO or +001 631 924 1135
Email: customerservice@Chembio.com

DISPOSAL

As the DPP Micro Reader may be contaminated by infectious material, it should be disinfected according to the CLEANING AND MAINTENANCE section above before disposal. Remove the batteries before disposing of the expired device and dispose of the batteries in accordance with local regulations.

MESSAGES

Messages displayed by the DPP Micro Reader are described in the table below. For assay-specific messages, see the appropriate product insert.

Message	Type	Meaning	Action Recommended
ON	Status	Reader is ready for use	None
RFID	Status	Reader is ready for RFID card	The RFID sticker is attached to the reader to allow the reader to obtain assay information. Press the button and the reader will show TEST
TEST	Status	Reader is ready to run a DPP test device	Press the button and the reader will show RUN
RUN	Status	Reader is reading test results	None
INV	Status	Test results cannot be interpreted.	Re-test the specimen with a new test device
OK	Status	Reader has recorded date and time information	Press the button one more time, the reader will show ON and is now ready for use
ERR	Error	The device could not read the information from the RFID card	(1) Press the button briefly (<1 second), the display will show ON. (2) Verify that the correct RFID card is being used. (3) Make sure the RFID card is on top of the reader after you press the button when the RFID word is in the display. If the error occurs again, please contact Chembio Diagnostic Systems, Inc..
DATE	Error	An expiration date appears to be exceeded	Check the expiration date of the reader, RFID card and the test device in use

SPECIFICATIONS

Dimensions:	L x W x H: Approx. 1.6 x 1.6 x 1.6 in. (41 x 41 x 40 mm)
Weight:	Approx. 1.4 oz (40 g)
Operation:	One button operation
Display:	14-segment LCD
Storage capacity:	None
Device measurement period:	Approx. 3 seconds
Power supply:	3 batteries CR2032 (3 V/230 mAh) Or Micro-Reader power cord/USB cable
Interface:	4 pole – 0.1 in (2.5 mm) jack plug for power supply (instead of battery)
Configuration:	Specific configuration program; RFID technology
Measuring field:	Min. 0.2 in. (4 mm) width; Max. 0.7 in. (18 mm) length
Lighting:	Wavelength 525 nm
Signaling device:	Buzzer
Operating conditions:	Between 18 and 30°C (64 to 86°F); between +20 % and +85 % humidity
Storage conditions:	Between -20 to 80°C (-4 to 176°F) between +20 % and 85 % humidity
Degree of protection:	IP 20
Lifetime:	3,000 reads

Ordering Information

Product	Catalog Number
DPP® COVID-19 IgM/IgG System	65-9569-0
DPP® Micro Reader Kit for Use with DPP® COVID-19 IgM/IgG System	70-1069-0

For Product Information, Literature and/or SDS please email: info@chembio.com



Manufactured by:

CHEMBIO DIAGNOSTIC SYSTEMS, INC.
3661 HORSEBLOCK ROAD
MEDFORD, NY 11763 USA
Tel: +001 631 924 1135

Email: info@chembio.com
Web Site: www.chembio.com

SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	WARNING
	DO NOT RE-USE
	FOR USE WITHIN TEMPERATURE LIMITS
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	BATCH CODE
	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE

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DPP® Micro Reader II

70-1070-0

For Use with the DPP COVID-19 IgM/IgG System

Read this Product Insert completely before using the product.

STORAGE: Store between -20 to 80°C (-4 to 176°F)

NAME AND INTENDED USE

The DPP® Micro Reader II is for use with the DPP COVID-19 IgM/IgG System test cassettes.

SUMMARY AND EXPLANATION

The DPP Micro Reader II is a reflectance reader used to obtain test results from DPP COVID-19 IgM/IgG System test cassettes. The DPP Micro Reader II minimizes human errors due to subjective visual interpretation; therefore, the DPP COVID-19 IgM/ IgG System was made specifically to be read with the DPP Micro Reader II (or DPP Micro Reader).

PRINCIPLES OF THE PROCEDURE

The DPP Micro Reader II is a portable, battery-powered instrument that captures an image of the test strip surface, verifies the presence and intensity of the control line and measures the line intensity at each of the test line positions; it interprets the results using a test-specific algorithm, and reports a REACTIVE, NON-REACTIVE or INVALID result in about ten seconds. A liquid crystal display (LCD) on the top of the instrument shows the status of the instrument and displays the test results to the operator.

The DPP Micro Reader II is maintenance-free, is not configurable by the user and is operated with a single, multi-function button.

MATERIALS PROVIDED

DPP Micro Reader II Kit for use with DPP COVID-19 IgM/IgG System (Catalog 70-1070-0) Each kit contains:

- 1 DPP Micro Reader II
- 3 AA batteries (1.5 V)
- 1 Battery Holder
- 1 RFID card specific for use with the DPP COVID-19 IgM/IgG System
- 1 Micro-USB Cable
- 1 Cleaning brush (for use on the glass of the camera unit under the bottom cover)
- 1 User Manual

WARNINGS AND PRECAUTIONS

For *IN VITRO* Diagnostic Use

- DPP COVID-19 IgM/IgG System test results **must** be read using the DPP Micro Reader II (or DPP Micro Reader) and cannot be visually interpreted.
- The DPP Micro Reader II is calibrated and checked before shipping under strict quality control measures in order to guarantee a high degree of quality. Do not attempt to open, re-configure or re-calibrate the DPP Micro Reader II.
- The correct RFID cards are required for running the DPP COVID-19 IgM/IgG System tests. Each RFID card is specific to the assay type being conducted and will transfer test specific information to the reader before each measurement. Using an RFID card intended for a different test type than the one performed can result in incorrect test results.
- The DPP Micro Reader II requires three (3) AA (1.5 V) batteries to operate. Alternatively, it can be powered through the Micro-USB Cable connected to an external power source.
- Do not use the DPP Micro Reader II in direct sunlight or exposed to bright light while reading results.
- The DPP Micro Reader II is designed for use on a clean, flat, horizontal surface.
- The DPP Micro Reader II should be operated at 18 to 30°C (64 to 86°F) and between 20% and 85% humidity. Ensure that the DPP Micro Reader II is brought to operating temperature before use.
- Protect the DPP Micro Reader II from liquids. Any liquid entering the DPP Micro Reader II may damage it permanently.
- Please follow the instructions in the product insert provided with the test kit regarding the disposal of DPP devices containing hazardous or infectious material.
- The DPP Micro Reader II itself contains no biological hazards. However, contamination during use with biological hazards is possible. For cleaning and maintenance, refer to section [CLEANING AND MAINTENANCE](#).

STORAGE AND STABILITY

The DPP Micro Reader II should be stored at temperatures between -20 and 80°C (-4 to 176°F) and between 20% and 85 % humidity. It should be operated at temperatures between 18 and 30°C (64 to 86°F) and between 20% and 85% humidity.

BATTERY LIFE

The DPP Micro Reader II is powered by 3 AA (1.5 V) batteries. Whereas the batteries should allow to read well over 1,000 tests, always have a spare set of three batteries available. Please see section on [BATTERY INSTALLATION](#) below. Alternatively, the DPP Micro Reader II can be powered using the Micro-USB cable and USB power source, like a computer USB outlet connection.

UNPACKING AND SET-UP

- 1 Before using the DPP Micro Reader II, visually inspect the contents for damage. If damage is apparent, contact Chembio Diagnostic Systems, Inc at +001 631 924 1135 or 1-844-CHEMBIO.
- 2 Remove the reader from its protective wrapping. It is recommended that the packaging materials be retained for later use.
- 3 Ensure that the reader and components are clean. Remove any dust or debris with a smooth, dry cloth.

BATTERIES INSTALLATION AND REPLACEMENT

The reader requires three (3) AA (1.5 V) batteries. Follow the directions below for battery installation and replacement. Replace the batteries if the battery symbol is blinking. To replace the batteries, turn the reader upside down and open the maintenance and battery hatch. Remove the battery holder from the DPP Micro Reader II. Replace the spent batteries with three fresh AA batteries, properly orienting them to match their poles with the polarity signs inside the holder. Once the batteries have been replaced, insert the holder back into the DPP Micro Reader II: the battery holder only fits one way: with the round corners pointing towards the back of the device, and a crease in the holder fitting with a fin inside the holder cavity. The holder will make an audible “click” when inserted correctly into place. Once the battery holder is installed, replace the hatch. See Figure 1 for more clarification.

NOTE: In order to maintain Date and Time settings during battery replacement, it is recommended to replace the batteries within 5 minutes from removal. If the date and time is present on the display at the time the batteries are removed for replacement, the date and time settings will not be affected. If incorrect date and time settings are observed after battery replacement, refer to the following instructions in the section on [SETTING THE DATE AND TIME](#) to correct the Date and Time settings.

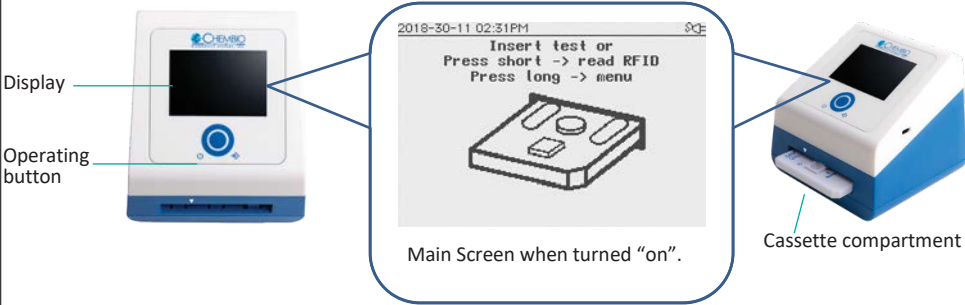
If you have any questions, please contact Chembio Customer Support at: +001 631 924 1135 or 1-844-CHEMBIO.

Figure 1: Battery installation and replacement in the DPP Micro Reader II

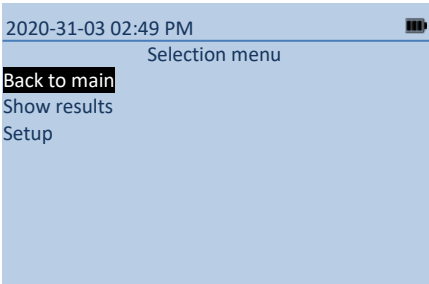


SETTING THE DATE AND TIME

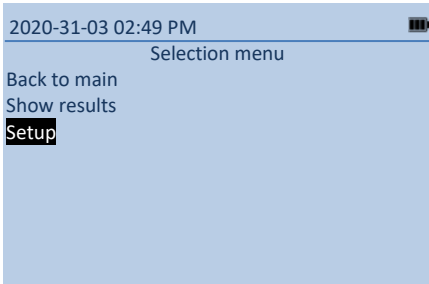
1 To set the date and time, if the instrument is off, briefly press the operating button (less than one second) or insert a DPP test. The display turn will turn on.



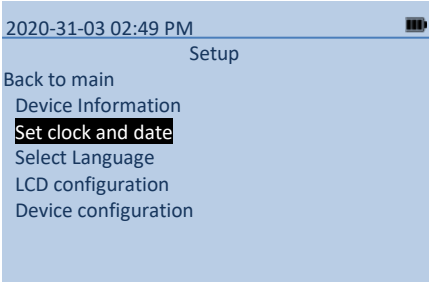
2 Hold the button down for >1 second. The menu "option" will appear on the screen.



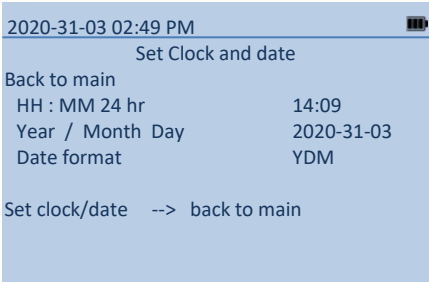
3 Use the single operating button to scroll down to "Setup" in 3 short presses (<1 second).



4 Hold the button down for >1 second to enter "Set-up" mode. Use the single operating button to scroll down to "Set clock and date" in 2 short presses (<1 second).



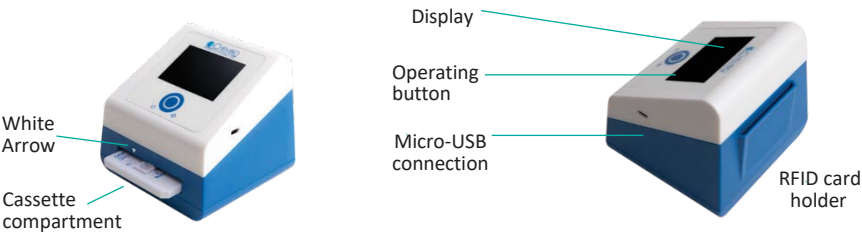
5 Hold the button down for >1 second to enter "Set clock and date" mode. Using short presses (<1 second), set the clock and date.



5 After setting the clock and date, hold the button down for >1 second to go "back to main" screen.

PROCEDURE: READING DPP IgM/IgG SYSTEM TESTS ON THE DPP MICRO READER II

- 1 Ensure that the reader and components are clean (use supplied cleaning brush). The DPP Micro Reader II is designed for use on a straight, horizontal, and non-metallic surface.



- 2 For one-step reading of the test results: insert the RFID card in the holder on the back of the instrument.

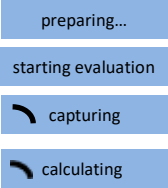


- 3a Insert the cassette fully in the front opening. The IgM and IgG Test Windows and Well 1 (Sample + Buffer) should be completely embedded in the DPP Micro Reader II. Only Well 2 (Buffer) should remain visible. The white arrow on the instrument should line up with the area for writing the patient ID.

The instrument will turn on automatically when the cartridge is fully and correctly inserted. It will then read the RFID card, display the test name and information, start the reading sequence and display the test results.



- 3b The following will be displayed on the screen:



- 4 When the read is complete, the test results will appear on the display for each line. See [INTERPRETATION OF TEST RESULTS](#)

If the line in the IgM and/or IgG CONTROL (C) area is too weak or absent, the DPP Micro Reader II will display "INV", indicating that the test is INVALID.

An invalid result indicates a problem with running the test, either related to the specimen, the device, or the procedure followed. An invalid test cannot be interpreted; it is recommended that the specimen be retested with a new device.

Record the IgM and IgG test result according to the laboratory policy (refer to [INTERPRETATION OF TEST RESULTS](#)) as the **DPP Micro Reader II does NOT record or store results for future reference.**

The results will remain visible for 90 seconds or until another cassette is inserted.

The reader will automatically shut off after 90 seconds if another cassette is not inserted.



INTERPRETATION OF TEST RESULTS

DO NOT ATTEMPT TO INTERPRET RESULTS OF THE DPP COVID-19 IgM/IgG SYSTEM VISUALLY. ALWAYS USE THE DPP MICRO READER II (OR DPP MICRO READER) FOR USE WITH THE DPP COVID-19 IgM/IgG SYSTEM TO OBTAIN RESULTS. USING AN RFID CARD INTENDED FOR A DIFFERENT TEST TYPE THAN THE ONE PERFORMED CAN RESULT IN INCORRECT TEST RESULTS.

IgM and IgG NON-REACTIVE

If the numerical results displayed for BOTH IgM and IgG are less than 25, the specimen test result is interpreted as NON-REACTIVE for both IgM and IgG.

A NON-REACTIVE Test Result means that antibodies to SARS- CoV-2 were not detected in the specimen.

The Test Result is interpreted as NON-REACTIVE (i.e. negative). However, a negative result does not exclude possible infection with COVID-19, particularly in those who have been in contact with the virus, and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection

Please also refer to the Fact Sheet for Health Care Providers for More Information

IgM REACTIVE (R) and IgG NON-REACTIVE (NR)

If the numerical result displayed for IgM is greater than or equal to 25, the specimen test result indicates a REACTIVE SARS-CoV-2 IgM Antibody Test Result.

A REACTIVE IgM test result (i.e., presumptive SARS-CoV-2 IgM positive) from the DPP® COVID-19 IgM/IgG System indicates that IgM antibodies to SARS-CoV-2 were detected in the specimen.

If only IgM antibodies were detected, the result is consistent with an active or recent SARS-CoV-2 virus infection.

Please also refer to the Fact Sheet for Health Care Providers for More Information

IgM NON-REACTIVE (NR) and IgG REACTIVE (R)

If the numerical result displayed for IgG is greater than or equal to 25, the specimen test result indicates a REACTIVE SARS-CoV-2 IgG Antibody Test Result.

A REACTIVE IgG test result (i.e., presumptive SARS-CoV-2 IgG positive) in the IgG test window means that IgG antibodies to SARS-CoV-2 were detected in the specimen.

If only IgG antibodies were detected, the result is consistent with a recent or previous infection.

Please also refer to the Fact Sheet for Health Care Providers for More Information

IgM and IgG REACTIVE (R)

If the numerical result displayed for both IgM and IgG is greater than or equal to 25, the specimen test result indicates a REACTIVE SARS-CoV-2 IgM and IgG Antibody Test Result

A REACTIVE IgM and a REACTIVE IgG test result means that IgM and IgG antibodies to SARS-CoV-2 have been detected in the specimen. The result suggests a current or recent SARS-CoV-2 virus infection.

Please also refer to the Fact Sheet for Health Care Providers for More Information

INTERPRETATION OF TEST RESULTS, continued

INVALID

If the reader returns an INVALID result for IgM OR for IgG, the entire test results are INVALID. An INVALID test cannot be interpreted. It is recommended that the specimen be re-tested with a new test device.

If the problem persists, please contact Customer Support: +001 631 924 1135 or 1-844-ChemBio

TURNING OFF THE READER

There is no active function to shut off the DPP Micro Reader II; it will turn off automatically after approximately 90 seconds of inactivity.

CLEANING AND MAINTENANCE

The outer case and display may be cleaned with the enclosed microfiber cloth lightly moistened with 70% isopropyl alcohol (IPA) or mild soap solution. Do not introduce cleaning solution or any liquid into the unit. Do not use a saturated towel, which may leak liquid into the case or display seams. Ensure that the DPP Micro Reader II is dry and the surface is free of fluid prior to returning to use. It is recommended to clean the reader daily.

If the inside of the DPP Micro Reader II becomes contaminated by a DPP test, a cotton swab with IPA or 10% bleach solution may be used to clean hard to reach surfaces. Be sure that the windows (accessed through the hatch on the bottom of the reader) are clear of dust and lint, and use provided brush to clean if required.

SERVICING AND RE-ORDERING

The reader does not need calibration, there are no user serviceable components in the unit with the exception of the replaceable batteries. For technical issues or questions, and to order a new reader, please contact ChemBio Diagnostic Systems, Inc.

Customer Service Department
Call: 1-844-CHEMBIO or +001 631 924 1135
Email: customerservice@ChemBio.com

DISPOSAL

As the DPP Micro Reader II may be contaminated by infectious material, it should be disinfected according to the [CLEANING AND MAINTENANCE](#) section above before disposal. Remove the batteries before disposing of the expired device and dispose of the batteries in accordance with local regulations.


SPECIFICATIONS

Description:	Reader for quantifying lateral flow assays from ChemBio
Test format:	Test cassette DPP
Measurement:	Device for quantification, semi-quantification or qualification of test-line intensity – also adaptable for multiple test-line measurements
Dimensions:	L x W x H: Approx. 3.9 x 3.9 x 4.2 in. (100 x 98 x 106 mm)
Weight:	9.4 oz (267.6 g); with batteries inserted: 11.9 oz (337 g)
Operation:	One button operation
Display:	240x160 pixel, monochrome LCD
Storage capacity:	7000 test results
Device measurement period:	Approx. 90 seconds
Power supply:	3 AA batteries (1.5 V), or DPP Micro Reader II-Micro-USB cable

Ordering Information











Product	Catalog Number
DPP® COVID-19 IgM/IgG System	65-9569-0
DPP® Micro Reader II Kit for Use with DPP® COVID-19 IgM/IgG System	70-1070-0

For Product Information, Literature
and/or SDS please email:
info@chembio.com

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Email: info@chembio.com
Web Site: www.chembio.com

SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	WARNING
	DO NOT RE-USE
	FOR USE WITHIN TEMPERATURE LIMITS
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	BATCH CODE
	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE