# COVID-19 IgG/IgM CONTROL Kit

**For use under an Emergency Use Authorization (EUA) Only**

**For *In Vitro* Diagnostic Use Only**

Instructions for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions.

For professional use only.

## NAME

COVID-19 IgG/IgM CONTROL Kit

## INTENDED USE

The COVID-19 IgG/IgM CONTROL Kit is an external qualitative quality control for anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG for use with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma), a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma to aid in the diagnosis of COVID-19 infection.

## CONTENTS

Human plasma based negative control. Volume: 0.1 mL.

Positive control containing SARS-CoV-2 Spike protein specific recombinant human IgG and SARS-CoV-2 Spike protein specific recombinant human IgM diluted with human plasma. Volume: 0.1 mL.

Preservatives: sodium azide, 0.02%

## PRECAUTIONS

1. For Emergency Authorization Use only.
2. For *in vitro* diagnostic use only
3. For professional use only.
4. Do not use after expiration date.
5. If there is evidence of microbial contamination or excessive turbidity in the product discard the vial.
6. Only use with Healgen's COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma). Incompatibilities between this product and other manufacturer test kits may occur.
7. Follow Good Laboratory Practices, wear protective clothing, use disposable gloves, do not eat or drink in the area.
8. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
9. The control and test device should be discarded in a proper biohazard container after testing.

## Safety Precautions

1. **CAUTION:** This product contains human-sourced and/or potentially infectious components. Refer to the CONTENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that this product, human specimens, and all consumables contaminated with potentially infectious materials be handled in accordance

with the OSHA Standard on Blood borne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[1-4]

2. The human-sourced materials used in the positive control have been tested and found to be reactive both for anti-SARS-CoV-2 IgG and anti-SARS-CoV-2 IgM and nonreactive for HBsAg, Syphilis, anti-HIV-1/HIV-2, and anti-HCV.

3. The human-sourced material used in the negative control have been tested and found to be nonreactive for anti-SARS-CoV-2 IgG, anti-SARS-CoV-2 IgM, HBsAg, Syphilis, anti-HIV-1/HIV-2, and anti-HCV.

## STORAGE

1. This product is shipped on ice packs.
2. Store at -20°C for long-term storage. Once opened, the remaining controls may be stored at 2-8°C/36-46°F for up to 30 days. Controls should avoid repeated freeze and thaw cycles.
3. Do not use past the expiration date.
4. Vials should always be stored upright.

## PREPARATION FOR USE

Allow controls to equilibrate to room temperature (15-30°C/59-86°F) prior to testing.

Prior to each use, mix by gentle inversion.

## CONTROL KIT TEST PROCEDURE

Allow test cassette, buffer, and controls to equilibrate to room temperature (15 to 30°C/59-86°F) prior to testing.

### Negative Control Testing

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

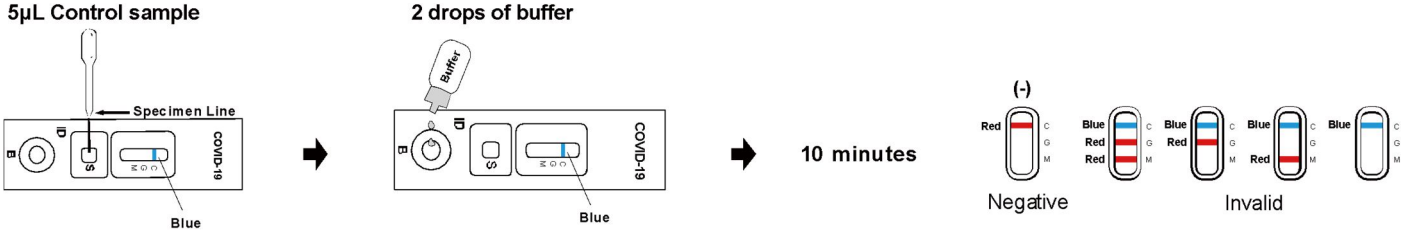
2. Place the test device on a clean and level surface.

3. With the 5 µL mini plastic dropper provided with the test, draw negative control specimen to exceed the specimen line as shown in the following image and then transfer drawn negative control specimen into the sample well ( S ). Then add 2 drops (about 80 µL) of sample buffer to the buffer well ( B ) immediately. Avoid air bubbles.

*Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimens by pipette capable of delivering 5 µL of volume.*

4. Wait for the colored line(s) to appear. After 2 minutes, if the red color has not moved across the test window, add 1 additional drop of the sample buffer to the buffer well ( B ).

5. The result should be read in 10 minutes. Do not interpret the result after 15 minutes.




### Positive Control Testing

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

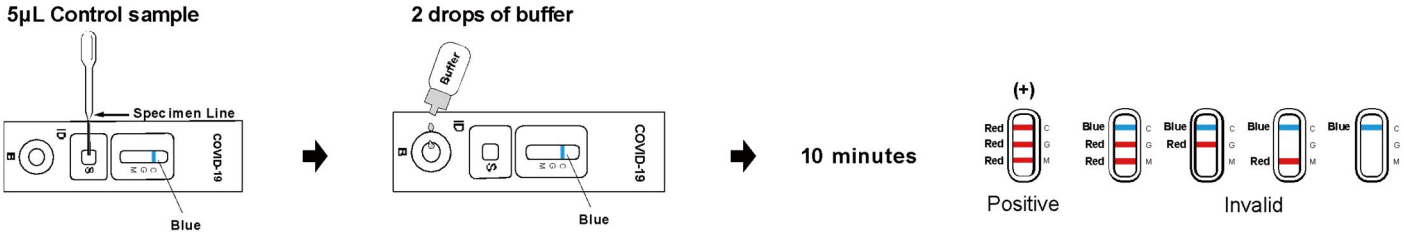
2. Place the test device on a clean and level surface.

3. With the 5 µL mini plastic dropper provided with the test, draw positive control specimen to exceed the specimen line as shown in the following image and then transfer drawn positive control specimen into the sample well ( S ). Then add 2 drops (about 80 µL) of sample buffer to the buffer well ( B ) immediately. Avoid air bubbles.

*Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimens by pipette capable of delivering 5 µL of volume.*

4. Wait for the colored line(s) to appear. After 2 minutes, if the red color has not moved across the test window , add 1 additional drop of the sample buffer to the buffer well ( B ).

5. The result should be read in 10 minutes. Do not interpret the result after 15 minutes.




## INTERPRETATION OF RESULTS

**NEGATIVE:** The colored line in the control line region (C) changes from blue to red. No line appears in the test line regions M or G. The result is negative.

**IgG and IgM POSITIVE:**

The colored line in the control line region (C) changes from blue to red, and two colored lines appear in test line regions M and G. The result is anti-COVID-19 IgM and IgG positive.

**INVALID:**

Control line is still completely or partially blue and fails to completely change from blue to red. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## BIBLIOGRAPHY


1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Blood borne pathogens.
2. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.
3. World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.
4. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition. CLSI Document M29-A4. Wayne, PA: CLSI; 2014.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