AmeriDx® SARS-CoV-2 IgG/IgM-T Antibody Rapid Test Kit

Cat # R30143012

IVD See external Label 4-30°C Σ 10 Tests

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INTENDED USE

The AmeriDx® SARS-CoV-2 IgG/IgM-T Antibody Rapid Test Kit is an in vitro diagnostic test for the qualitative detection of total IgG and IgM antibodies to the SARS-CoV-2 in human finger stick blood collected in CLIA certified laboratories and/or by healthcare workers at the point-of-care.

SUMMARY AND EXPLANATION

The typical symptoms of coronavirus infection include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, the infection can cause pneumonia, and even death. Coronavirus can be excreted through respiratory secretions or transmitted through oral fluids, sneezing, physical contact, and through air droplets.

TEST PRINCIPLE

AmeriDx® SARS-CoV-2 IgG/IgM-T Antibody Rapid Test Kit is a visual one step in vitro assay. The conjugate pad harboring the recombinant virus spike S1 protein (detection antigen) grasps the novel coronavirus antibodies in the sample fluid, and moves toward the captured line (virus spike S1 protein) via capillary action to form a horizontal color line, in which case, the test is positive. If there is no SARS-CoV-2 coronavirus specific antibodies in the sample flow, only a control line (C, IgG antibody) displays the purple color line, then the test results is negative.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. Detection Cassette, 1 unit/kit, 10 kits/box, including the following components:
   1) Colloidal gold-labeled SARS-CoV-2 virus N protein (fixed on conjugation pad).
   2) Goat anti-mouse IgG antibody (fixed on porous capillary membrane).
   3) Mouse anti-human IgG antibody (fixed on porous capillary membrane).
   4) Mouse anti-human IgM antibody (fixed on porous capillary membrane).

   Note: The components in different batches cannot be used interchangeably.
2. Plastic pipette dropper, 10 units/box.
3. Sample diluent dropper bottle, 5 mL/bottle. 1 bottle per box.
4. Lancet, 10 units/box.
5. Bandage, 10 units/box.
6. Alcohol swab, 20 units/box.
7. Manual instruction for use.

Materials required but not provided

1.Timer clock.

Kit STABILITY

Store kit in a cool and dry place at 2 – 30°C. Do not freeze the individual components and/or box. Properly stored kits are valid for 18 months (see the kit box for expiration information).

SPECIMEN COLLECTION WITH SAMPLE TUBE

Assay is for use with human whole blood from a finger prick as indicated below:

1. Wash your hands with warm water.
2. Select the finger pad you are going to prick and choose a puncture site off center of the fingertip.
3. Massage and/or shake to stimulate blood flow towards the collection area.
4. Clean the collection area and the pipet provided in cartridge bag with an alcohol swab (provided in kit).
5. Place the finger with the chosen collection site on a flat surface facing up.
6. Twist the cap off the Lancet (provided in kit) and press firmly against the collection site to puncture the finger.
7. Create a large drop of blood by applying pressure at the base of the finger and massaging upward.
8. Squeeze the pipette bulb to expel air. Draw fingertip blood into the pipet by gently releasing the bulb. The pipet should be filled just up to 2-3 millimeter. Avoid bubbles.
9. Expel the collected blood onto the Sample section (S) on the Detection Cassette, then use sample diluent bottle to release 2-3 drops on the collected blood in Sample section (S). The blood sample will move toward the release pad section of the Detection Cassette.

SPECIMEN STORAGE

Samples should be used immediately after collection.

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ASSAY PROCEDURE

Read the instructions carefully before using. Bring the Detection Cassette, Sample Diluent, and sample to room temperature before testing.

1. Add 2-3 drops of the prepared sample to the release pad section (S) of the Detection Cassette.
2. The results can be interpreted in 8-10 minutes. Results measured after 20 minutes are invalid and should be discarded.

RESULTS

Positive: If both C and T lines are visible within 10 minutes, the test result is positive and valid.

Note: Specimens containing very low levels of target antibodies may develop two colored lines over 10 minutes.

Negative: If test area (T line) has no color and the control area displays a colored line, the result is negative and valid.

Invalid result: The test result is invalid if a colored line does not form in the control region. The sample must be re-tested, using a new test strip.

PERFORMANCE CHARACTERISTICS

A. Sensitivity:

Sensitivity: 100% (12/12).

B. Specificity:

97.8% (93/95).

Table. Finger-prick Data

	Positive Sample	**Negative Sample**	**Total**
Detected Positive	12	2	14
Detected Negative	0	93	93
Total	12	95	107

Estimated Sensitivity = 100% x 12/12 = 100%
Estimated specificity = 100% x 93/95 = 97.8%

LIMITATIONS OF PROCEDURE

1. This product is designed to use human whole blood from finger prick, serum or plasma as testing sample for the qualitative detection of novel coronavirus (SARS-CoV-2).
2. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnosis should be considered to rule out infection in these individuals.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4. 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.
5. This product is designed only for use with finger-prick and serum samples for the qualitative detection of novel coronavirus (SARS-CoV-2).
6. Coronavirus may not be detected even though coronavirus antibodies are present in the sample, leading to a false negative. This may occur if the amount of coronavirus antibodies is below the detection level of the kit.
7. If the product gets wet prior to use, or is stored improperly, it may cause incorrect results.
8. This test has not been reviewed by the FDA.
9. This product is for *in vitro* diagnostic use only, both CE approved and per FDA policy under Section IV.D of "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency," issued March 16, 2020.
10. This is not for the screening of donated blood.
11. This assay should be performed as outlined in this manual, and in accordance with all instructions.
12. Only use the matching diluent in the kit package. Diluents from different kit lots cannot be mixed.
13. This test should be used within 1 hour after opening.
14. If there is no movement of the liquid after 30 seconds of beginning the test, 1 additional drop of sample solution should be added.
15. Take care to prevent the possibility of virus infection when collecting samples. Wear disposable gloves, masks, etc., and wash your hands afterwards.
16. This test card is designed for one-time use. After use, the test and sample should be regarded as medical waste with risk of biological infection and properly disposed of in accordance with government regulations.

Date Adopted	**Reference No. Cat # R**30143012
2020-3-28	**AmeriDx® SARS-CoV-2 IgG/IgM-T Antibody Rapid Test Kit**
Revision Date: 04-22-2020	

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