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DIAQUICK COVID-19 Ag Cassette

For the detection of nucleocapsid protein antigen in nasopharyngeal swab specimen

REF	Content
Z20401CE	- 20 test cassettes, individually packed in foil pouches with a desiccant (20x REF GCCOV-502a) - 2 Buffer - 20 sterile swabs - 20 extraction tubes - 1 paper stand - 1 package insert

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method	Immunochromatographic assay
Shelf life	24 months from date of production
Storage	2-30°C

INTENDED USE

The DIAQUICK COVID-19 Ag Cassette is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab specimens. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. The DIAQUICK COVID-19 Ag Cassette does not differentiate between SARS-CoV and SARS-CoV-2.

DIAGNOSTIC SIGNIFICANCE

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, dry cough, and loss of taste and smell. Nasal congestion, runny nose, sore throat, myalgia and diarrhoea are found in some cases. This test is for detection of SARS-CoV-2 nucleocapsid protein antigen which is generally detectable in upper respiratory specimens during the acute phase of infection.

TEST PRINCIPLE

The DIAQUICK COVID-19 Ag Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip is composed of the following parts: sample pad, reagent pad, reaction membrane and absorbing pad. The reagent pad contains colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2. The reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen is present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

REAGENT COMPOSITION

Buffer: Sodium azide, NaCl, Tris, Purified water
Cassette: monoclonal antibodies, colloidal-gold, secondary antibodies

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer

REAGENT PREPARATION

The test is ready to use.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- Do not freeze any of the test kit components.
- Do not use test devices and reagents after expiration date.
- Test devices that have been outside of the sealed desiccated pouch for more than 1 hour should be discarded.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- The test device should remain in the sealed pouch until use.
- Do not use kit past its expiration date.
- Swabs, tubes and test devices are for single use only.
- The extraction buffer contains a solution with a preservative (0.09% sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
- Do not interchange or mix components from different kit lots.
- When collecting a nasopharyngeal swab sample, use the swab supplied in the kit.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

SPECIMEN COLLECTION AND STORAGE

- Use the nasopharyngeal swab supplied in the kit.
- Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion under visual inspection.
- Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
- Withdraw the swab from the nasal cavity.

Specimen Transport:
Specimens should be tested as soon as possible after collection. If transport of samples with viral transport medium (VTM) is required, minimal dilution of the sample is recpmmended, as dilution may result in reduced test sensitivity. While holding the swab, remove the cap from the tube.

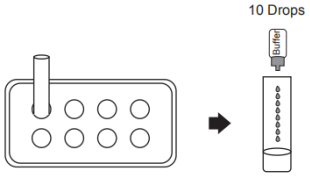
Insert the swab into the tube until the breakpoint is level with the tube opening. Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. You may need to gently rotate the swab shaft. Based on data generated with influenza virus, nasopharyngeal swabs in VTM are stable for up to 72 hours at 2° to 8°C.

Note: When using viral transport medium (VTM), it is important to ensure that the VTM containing the sample is warmed to room temperature. Cold samples will not flow correctly and can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.

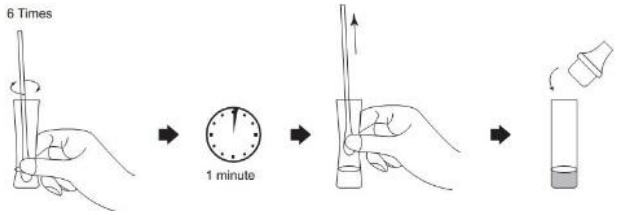
TEST PROCEDURE

Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

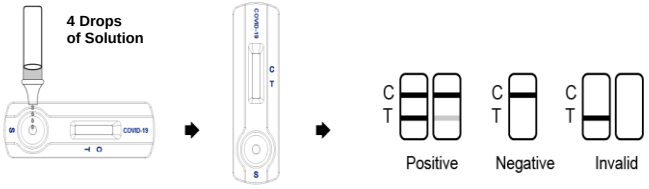
1. Insert the test extraction tube into the paper stand delivered with the kit. Make sure that the tube is standing firm and reaches the bottom of the stand.
2. Add 0.3 ml (about 10 drops) of the sample extraction buffer into the extraction tube.



3. Insert the swab with the sample (see SAMPLE COLLECTION) into the extraction tube which contains the extraction buffer.
4. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5. Leave the swab in the extraction tube for 1 minute.
6. Squeeze the tube several times with fingers from outside of the tube while immerseing the swab. Remove the swab. The extracted solution will be used as test sample.



7. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
8. Insert a nozzle with filter into the sample extraction tube tightly.
9. Reverse the sample extraction tube and add 4 drops (about 100 µl) of test sample by squeezing the extracted solution tube into the sample window (S) of the cassette.
10. Wait for the colored band(s) to appear. The result should be read within 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

1. POSITIVE:
The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.
2. NEGATIVE:
The presence of only control line (C) within the result window indicates a negative result.
3. INVALID:
If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure. It is recommended to re-test the specimen using a new test.

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NOTE:
1.The intensity of color in the test line region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. Please note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.

QUALITY CONTROL AND CALIBRATION

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Good laboratory practice (GLP) recommends the use of external control materials to ensure proper test kit performance.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy
The DIAQUICK COVID-19 Ag Cassette (Swab) has been evaluated with specimens obtained from patients. A commercial molecular assay was used as the reference method. The results are presented in the following table.

Table 1: The DIAQUICK COVID-19 Ag Cassette vs PCR

Method		PCR		Total Results
DIAQUICK COVID-19 Ag Cassette	Results	Positive	Negative	
	Positive	39	0	39
	Negative	6	116	122
Total Results		45	116	161

Relative Sensitivity: 86.7% (95% CI*: 73.2%-95.0%) * Confidence Interval
Relative Specificity: 100% (95% CI*: 96.9%-100%)
Accuracy: 96.3% (95% CI*: 92.1%-98.6%)

In addition, another study was performed using clinical samples from patients with pneumonia or respiratory symptoms. A commercial molecular assay was used as a reference method. The results are shown in the table below.

Table 2: The DIAQUICK COVID-19 Ag Cassette vs PCR

Method		PCR		Total Results
DIAQUICK COVID-19 Ag Cassette	Results	Positive	Negative	
	Positive	71	0	71
	Negative	2	130	132
Total Results		73	130	203

Relative Sensitivity: 97.3% (71/73)
Relative Specificity: 100% (130/130)
Accuracy: 99.0% (201/203)

The sensitivity for strongly positive PCR samples with a Ct-Value of ≤30 is 100%.

LIMITATIONS

- The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test. The DIAQUICK COVID-19 Ag Cassette (Swab) is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the DIAQUICK COVID-19 Ag Cassette (Swab) depends on antigen load and may not correlate with viral culture results performed on the same specimen.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of SARS-CoV-2 antigens in the sample, as they may be present below the minimum detection level of the test. Also improper sampling and/or improper transport condition can lead to erroneous results.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative results should be treated as presumptive and confirmed with an authorized molecular assay, if necessary, for clinical management, including infection control.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1.Rothan HA, Byrareddy SN. The epidemiology and pathogenesis of coronavirus disease (COVID-19) outbreak. J Autoimmun. 2020; Feb 26:102433. doi: 10.1016/j.jaut.2020.102433.
2.Guo YR, Cao QD, Hong ZS, et al. The origin, transmission and clinical therapies on coronavirus disease 2019 (COVID-19) outbreak-an update on the status. Mil Med Res. 2020; Mar 13; 7(1):11.doi:10.1186/s40779-020-00240-0.
3.Lai CC, Shih TP, Ko WC, et al. Severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges. Int J Antimicrob Agents. 2020; Mar 55(3): 105924.doi:10.1016/j.ijantimicag.2020.105924.
4.In Vitro Diagnostic Assays for COVID-19: Recent Advances and Emerging Trends (Sandeep Kumar Vashist, 2020 April 05: diagnostics)
5.Nano Research for COVID-19 (http://dx.doi.org/10.1021/acsnano.0c02540)

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