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# DIAQUICK COVID-19 Ag Cassette

***English:*** *Chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human nasopharyngeal and nasal swabs*

| REF | Content |
|---|---|
| Z20601CE | - 20 test cassettes, individually packed in foil pouches with a desiccant (20x REF Z20601B)<br>- 2 extraction buffer á 10 mL<br>- 20 extraction tubes and tips<br>- 20 sterile swabs<br>- 1 positive control<br>- 1 workstation<br>- 1 package insert<br>- 1 procedure card |

**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 a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2 infection in conjunction with the clinical presentation and the results of other laboratory tests.
Results are for the detection of SARS-CoV-2 antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of an infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease.
Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
The DIAQUICK COVID-19 Ag Cassette is intended for use by trained clinical laboratory personnel.

## 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 and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhoea are found in a few cases.

## TEST PRINCIPLE

The DIAQUICK COVID-19 Ag Cassette is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antigens in human nasopharyngeal swab specimen. SARS-CoV-2 antibodies are coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibodies in the test line region. If the specimen contains SARS-CoV-2 antigens, a coloured line will appear in the test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no coloured line will appear in the test line region, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

## REAGENT COMPOSITION

Buffer: NaCl, Tris, 0.02% Proclin 300, BSA, 2 g/L Triton X-100
Cassette: Chloroauric acid, filter paper, nitrocellulose membrane, fiberglass, polyester, streptavidin, biotin, SARS-CoV-2 antibody
Positive control: contains freeze-dried COVID-19 antigen and Proclin 300 as the preservative on the swab.

## MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Negative Control Swab

## REAGENT PREPARATION

The test is ready to use.

## STORAGE AND STABILITY

- Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C).
- The test is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use beyond the expiration date.

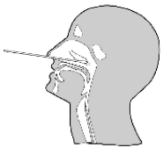
## WARNINGS AND PRECAUTIONS

- This package insert must be read completely before performing the test. Failure to follow the directions in the package insert may yield in inaccurate test results.
- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the collection, handling, storage, and disposal of patient samples and used kit contents.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Wash hands thoroughly after handling.
- Please ensure that an appropriate amount of sample is used for testing. Too much or too little sample size may lead to a deviation of results.
- Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect the results.

## SPECIMEN COLLECTION AND STORAGE

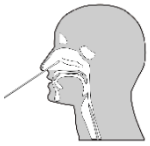
Specimen Collection
1) Nasopharyngeal swab specimen

- Insert a sterile swab into the nasopharynx securely from a nostril and collect mucoepidermis wiping posterior nasopharynx 5-10 times. Avoid excess volume and highly viscous nasopharyngeal discharge.



2) Nasal swab specimen

- Insert a sterile swab less than one inch (about 2 cm) into a nostril (until resistance is met at the turbinates). Rotate the swab 5-10 times against the nasal wall. Using the same swab repeat the collection procedure with the other nostril. Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.



**Specimen Storage:**
Specimens should be tested as soon as possible after collection.
If swabs are not processed immediately, it is highly recommended to place the swab sample in a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in dry and sterile conditions is stable for up to 8 hours at room temperature and 24 hours at 2-8°C.

## TEST PROCEDURE

**Specimen Preparation:**

Only the Extraction Buffer and the tubes provided in this kit are used for the swab specimen preparation.

Please refer to the Procedure Card for detailed information of specimen extraction.

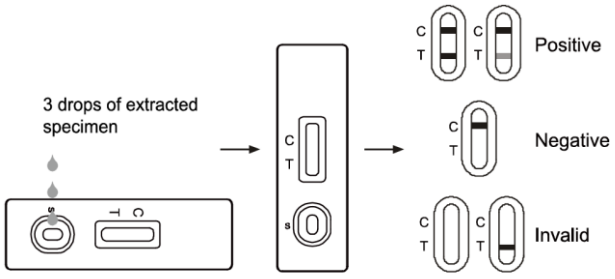
1. Place the swab specimen in the Extraction tube with Extraction Buffer (approx. 350 µL). Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
2. Remove the swab while squeezing the swab head against the inside of the Extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

**Note:** The specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8°C.

**Directions for Use:**

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Invert the specimen extraction tube and add **3 drops of extracted specimen** (75-100 µL) to the specimen well (S) and then start the timer.
3. Wait for the coloured line(s) to appear. Read the result after **15 minutes**. Do not interpret the result after 20 minutes.




## INTERPRETATION OF RESULTS

*Please refer to the illustration above.*

**POSITIVE**:* Two distinct coloured lines appear. One coloured line should be in the control region (C) and another coloured line should be in the test region (T). A positive result in the test region indicates detection of SARS-CoV-2 antigens in the sample.

***NOTE**:* The intensity of the colour in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So, any shade of colour in the test region (T) should be considered positive.

**NEGATIVE**: One coloured line appears in the control region (C). No apparent coloured line appears in the test line region (T).

**INVALID**: Control line fails to appear. 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL AND CALIBRATION

**Internal Quality Control:**
Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal

negative procedural control. If the test is working properly, the background in the result area should be white to light pink and should not interfere with the ability to read the test result.

**External Quality Control:**
A positive control is included in this kit.

## PERFORMANCE CHARACTERISTICS

**Sensitivity, Specificity and Accuracy**:
The DIAQUICK COVID-19 Ag Cassette has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the DIAQUICK COVID-19 Ag Cassette. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

Nasopharyngeal Swab Specimens:

| DIAQUICK COVID-19 Ag Cassette | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| COVID-19 Antigen | Positive | 84 | 3 | 87 |
| | Negative | 6 | 348 | 354 |
| Total | | 90 | 351 | 441 |
| Relative Sensitivity | | 93.3% (95%CI*: 86.1%-97.5%) | | |
| Relative Specificity | | 99.1% (95%CI*: 97.5%-99.8%) | | |
| Accuracy | | 98.0% (95%CI*: 96.2%-99.1%) | | |

* Confidence Interval

**Specificity Testing with Various Viral Strains:**
The DIAQUICK COVID-19 Ag Cassette was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations:

| Description | Test Level |
|---|---|
| Adenovirus type 3 | 3.16 x $10^4$ $TCID_{50}$/mL |
| Adenovirus type 7 | 1.58 x $10^5$ $TCID_{50}$/mL |
| Human coronavirus OC43 | 2.45 x $10^6$ $LD_{50}$/mL |
| Influenza A H1N1 | 3.16 x $10^5$ $TCID_{50}$/mL |
| Influenza A H3N2 | 1 x $10^5$ $TCID_{50}$/mL |
| Influenza B | 3.16 x $10^6$ $TCID_{50}$/mL |
| Human Rhinovirus 2 | 2.81 x $10^4$ $TCID_{50}$/mL |
| Human Rhinovirus 14 | 1.58 x $10^6$ $TCID_{50}$/mL |
| Human Rhinovirus 16 | 8.89 x $10^6$ $TCID_{50}$/mL |
| Measles | 1.58 x $10^4$ $TCID_{50}$/mL |
| Mumps | 1.58 x $10^4$ $TCID_{50}$/mL |
| Parainfluenza virus 2 | 1.58 x $10^7$ $TCID_{50}$/mL |
| Parainfluenza virus 3 | 1.58 x $10^8$ $TCID_{50}$/mL |
| Respiratory syncytial virus | 8.89 x $10^4$ $TCID_{50}$/mL |

**$TCID_{50}$** = Tissue Culture Infectious Dose is the dilution of virus, that under the conditions of the assay, can be expected to infect 50% of the inoculated culture vessels.
**$LD_{50}$** = Lethal Dose is the dilution of virus, that under the conditions of the assay, can be expected to kill 50% of the inoculated suckling mice.

**Precision – Inter-Assay & Intra-Assay:**
Within-run and Between-run precision has been determined by using three specimens of COVID-19 standard control. Three different lots of DIAQUICK COVID-19 Ag Cassette have been tested using negative, SARS-CoV-2 antigen weak positive and SARS-CoV-2 antigen strong positive samples. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

**Cross-Reactivity:**
The following organisms were tested at 1.0 x $10^8$ org/mL and all found to be negative when tested with the DIAQUICK COVID-19 Ag Cassette:

| | |
|---|---|
| *Arcanobacterium* | *Pseudomonas aeruginosa* |
| *Candida albicans* | *Staphylococcus aureus subspaureus* |
| *Corynebacterium* | *Staphylococcus epidermidis* |
| *Escherichia coli* | *Streptococcus pneumoniae* |
| *Moraxella catarrhalis* | *Streptococcus pygenes* |
| *Neisseria lactamica* | *Streptococcus salivarius* |
| *Neisseria subflava* | *Streptococcus sp group F* |

**Limit of Detection:**
The minimal detection limit of the DIAQUICK COVID-19 Ag Cassette is 100 pg/mL for the recombinant SARS-CoV-2 protein.

**Interfering Substances:**
The interfering substances below were spiked with negative and SARS-CoV-2 antigen weak positive samples. No substances showed any interference with the DIAQUICK COVID-19 Ag Cassette.

| Substance | Concentration |
|---|---|
| Whole Blood | 20 µL/mL |
| Mucin | 50 µg/mL |
| Budesonide Nasal Spray | 200 µL/mL |
| Dexamethasone | 0.8 mg/mL |
| Flunisolide | 6.8 ng/mL |
| Mupirocin | 12 mg/mL |
| Oxymetazoline | 0.6 mg/mL |
| Phenylephrine | 12 mg/mL |
| Rebetol | 4.5 µg/ mL |
| Relenza | 282 ng/ mL |
| Tamiflu | 1.1 µg/mL |
| Tobryamycin | 2.43 mg/mL |

## EXPECTED VALUES

The DIAQUICK COVID-19 Ag Cassette has been compared with a leading commercial RT-PCR test. The correlation between these two systems is no less than 98%.

## LIMITATIONS

- The test procedure and the interpretation of results must be followed closely when testing for the presence of SARS-CoV-2 antigens in human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
- The performance of the DIAQUICK COVID-19 Ag Cassette was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for this test.
- The DIAQUICK COVID-19 Ag Cassette is for in vitro diagnostic use only. This test should be used for detection of SARS-CoV-2 antigens in human nasopharyngeal specimens as 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. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
- The DIAQUICK COVID-19 Ag Cassette will only indicate the presence of SARS-CoV-2 antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
- Results obtained with the test should be compared with other clinical findings from other laboratory tests and evaluations.
- If the test result is negative or non-reactive and clinical symptoms persist, it is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic method to rule out infection in these individuals.
- The test will show negative results under the following conditions: The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
- 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 diagnostic method should be considered to rule out infection in these individuals.
- Excess blood or mucin on the swab specimen may interfere with test performance and may yield in a false positive result.
- The accuracy of the test depends on the quality of the swab sample. False negative results may result from improper sample collection or storage.
- Positive results may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
- The positive control is a qualitative reagent and is not to be used as quantitative calibrator.
- The positive control can only be used to validate the performance of the DIAQUICK COVID-19 Ag Cassette.

## WASTE MANAGEMENT

Please refer to local legal requirements.

## LITERATURE

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4. 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.
5. In Vitro Diagnostic Assays for COVID-19: Recent Advances and Emerging Trends (Sandeep Kumar Vashist, 2020 April 05: diagnostics).
6. Nano Research for COVID-19 (http://dx.doi.org/10.1021/acsnano.0c02540).