IVD 2℃ 30℃ COV04S-1T-IFU-001

REF COV04S-1T

# PCL COVID19 Ag Gold

**Instructions for use**

Please read the instructions carefully before performing the test. Follow the instructions, and do not modify the process. Strict adherence to the guidelines will avoid inaccurate results and achieve optimal performance of PCL COVID19 Ag Gold.

## Product name

PCL COVID19 Ag Gold

## Intended use

**PCL COVID19 Ag Gold is a rapid Immunochromatographic assay (ICA) for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human saliva, nasal or nasopharyngeal specimens from individuals who are suspected of COVID-19 by a healthcare provider within the first 7 days of symptom onset.** PCL COVID19 Ag Gold is intended for use by trained healthcare professionals. The assay is intended for use at the point-of-care (near patient) setting. It is intended for serial testing of symptomatic individuals for use at least twice with 48 hours between tests. The test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasal, nasopharyngeal swab and saliva specimens during the acute phase of 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 coinfection with other viruses. The agent detected may not be the definite cause of disease.

**Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.** 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, and confirmed with a molecular assay, if necessary, for patient management

## Special conditions for use

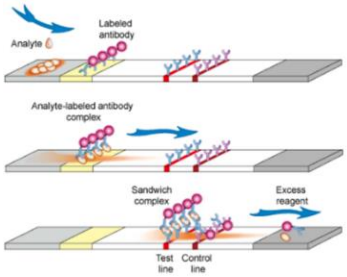
- For professional use & point-of care (near patient) only
- For *in vitro* diagnostic use only

## Summary and explanation of the test

COVID19 is a respiratory disease caused by a new type of coronavirus (SARS-CoV-2) first identified in December 2019 in Wuhan, China. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath, and more. In severe cases, the infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and death. Coronaviruses are a group of viruses that cause symptoms from the common cold to more severe illnesses such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

## Principle of the procedure

PCL COVID19 Ag Gold detects the N protein (nucleocapsid protein) of SARS-CoV-2. The test uses COVID19 antibodies, which are labeled with small gold particles and are attached to a nitrocellulose membrane near the sample hole of the test card (see also illustration below). After its application, capillary forces are pulling the sample from the sample hole to the test region of the device. When the liquid of the sample reaches the COVID19 antibodies, they detach from the membrane and are moved along the test card.




If the sample contains SARS-CoV-2 antigens ("analyte"), these bind to the labelled antibodies to form analyte-labeled antibody complexes. When these complexes reach the test line of the test card, they are retained on the test line by another set of COVID19 antibodies, which are immobilized on the nitrocellulose membrane. These so-called sandwich complexes appear as a color band on the test line. If the sample does not contain SARS-CoV-2 antigens, no sandwich complexes are formed and no color band appears on the test line.

Regardless of the presence or absence of SARS-CoV-2 antigens in the sample, a color band will appear on the control line of the test card. If no color band appears on the control line, the test card has not worked as intended.

## Kit Components

**Materials provided**

| Component | Description | Unit (Kit) |
|---|---|---|
| | | 1 |
| Test card | Test card with antibody coating and built-in strip (pouch sealed) | 1 ea. |
| Extraction buffer tube | Liquid reagent for sample extraction and development | 1 buffer tube with 500 µL |
| Filter cap | Disposable lid for depositing a certain amount of sample on the test card | 1 ea. |
| IFU | Instructions for use | 1 ea. |

**Required materials not included**

- Timer or stopwatch

**Nasal swab used in the preclinical and clinical studies: COPAN Diagnostics – Flexible Minitip Flocked Swab, Sterile Single Wrapped (BD Cat. No. 220250)*

**Nasopharyngeal swab used in the preclinical and clinical studies: COPAN Diagnostics – Regular Flocked Swab, Sterile Single Wrapped (BD Cat. No. 220252)*

## Kit storage and stability

- PCL COVID19 Ag Gold should be stored at **2-30 ℃ in a dry place**. When stored and handled as directed, the test cards and reagents are stable until expiration date indicated on kit labels.
- Test card should be used immediately after opening the pouch.
- **DO NOT FREEZE**

*Watch the tutorial video https://youtu.be/zlgu8wy9mtw and read the instructions for use prior to performing the test.

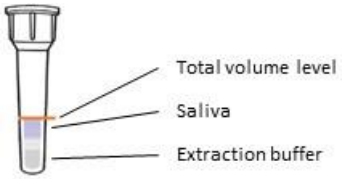
## Sample collection

- Different specimen types have been validated with the PCL COVID19 Ag Gold.
- Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.

**Saliva specimens**

- The person to be tested collects saliva in the mouth on the tip of the tongue for 30 seconds (approximately 0.5 mL); see also illustration below.

- Spit the collected saliva into the extraction buffer tube directly for immediate use. Fill the tube with saliva up to the indicated line. By adding the saliva, the volume in the tube should approximately double.




- Do not use stored specimens. Long-term storage may result in a signal decrease.
- Do not freeze the sample. Multiple freeze/ thaw cycles may result in a signal decrease.

**Nasal swab specimens**

- Insert the sampling swab through one nostril and the swab tip shall be inserted until resistance reaches (approximately 2~4 cm depth).
- Rotate the sampling swab five times.
- Repeat the above in the other nostril with the same swab.
- Put the swab into the extraction buffer tube for immediate use.
- Do not freeze the sample. Multiple freeze/ thaw cycles may result in a signal decrease.

**Nasopharyngeal swab specimens**

- Insert the sampling swab through the nostril and gently push the swab into the posterior nasopharynx.
- Rotate the sampling swab three times.
- Put the swab into the extraction buffer tube for immediate use.
- Do not freeze the sample. Multiple freeze/ thaw cycles may result in a signal decrease.

## Warnings and precautions

- This product is intended for in vitro diagnostic use.
- This product is intended for single use.
- This product is intended for professional use.
- This product is intended for POCT use with human saliva, nasal, and nasopharyngeal swab specimens.
- Assay should be performed as directed in the instructions for use to obtain accurate results.
- Do not use beyond the expiration date or damaged products.
- Do not use any other reagents that are not provided in this kit and do not mix components of different lots.
- This reagent can be stored at room temperature (15~25°C). Reagents stored or samples collected at lower temperatures should be allowed to come to room temperature before use.
- Remove the test card from the pouch and use it as soon as possible to avoid prolonged exposure to air. Prolonged exposure to air affects the test results.
- Follow laboratory test procedures for infectious diseases. Waste after use should be treated as infectious material and not disposed of randomly.
- Appropriate safety assurance procedures should be in place for infectious agents and materials.
- Wear gloves to handle samples and reagents.
- Do not suck the samples and reagents.
- Do not eat, drink, smoke, use cosmetic or touch contact lenses while handling the product.
- Do not eat, drink, smoke, chew gum, brush or floss for 30 minutes before collection.
- Spilled samples or reagents should be cleaned with disinfectants.
- Disinfect and dispose of all samples, reagents, and potential contaminants following applicable local regulations.
- Sodium azide is present in the extraction buffer and is harmful if swallowed. The extraction buffer vial should only be used as directed; do not ingest; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, consult a doctor.

## Preparation for use

⚠ *Reagents should be allowed to stand at room temperature for 20-30 minutes before testing. Do not use samples, which have been stored for prolonged times after collection.*

## Assay procedure for saliva specimens

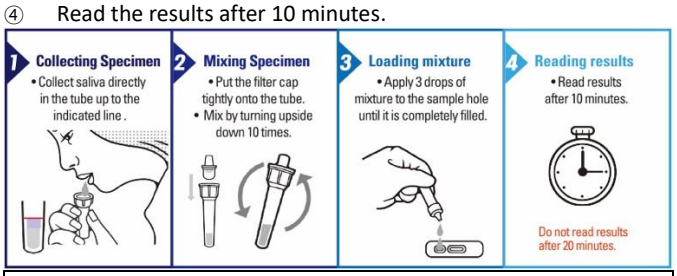
① Collect the sample as directed in the "Sample collection" section.

② Cover the tube with a filter cap and tighten the lid. Mix the contents by turning the tube upside down 10 times.

⚠ *Open the test card pouch just before use. If the pouch is left unused after opening, it may cause inaccurate results.*

③ Open the test card pouch and place the test card on a flat surface. Apply 3 drops of the saliva extraction buffer mix into the sample hole of the test card. The sample hole should almost be completely filled.

④ Read the results after 10 minutes.




⚠ *Reading the test card later than 20 minutes after applying the sample diluent may give inaccurate results.*

## Assay procedure for nasal and nasopharyngeal swab specimens

① Collect the sample as directed in the "Sample collection" section.

② Swirl the swab 10 times then remove it while squeezing the liquid from the swab.

③ Cover the tube with a filter cap and tighten the lid. Mix the contents by turning the tube upside down 10 times.

⚠ *Open the test card pouch just before use. If the pouch is left unused after opening, it may cause inaccurate results.*

④ Open the test card pouch and place the test card on a flat surface. Apply 3 drops of the nasal/nasopharyngeal swab extraction buffer mix into the sample hole of the test card. The sample hole should almost be completely filled.

⑤ Read the results after 10 minutes.

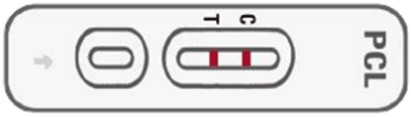
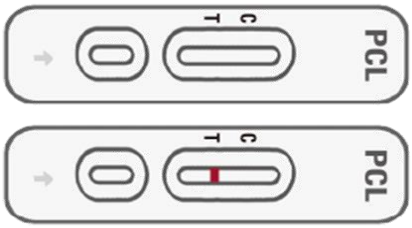

⚠ *Reading the test card later than 20 minutes after applying the sample diluent may give inaccurate results.*

## Interpretation of results

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

| Status on First Day of Testing | First Result Day 1 | Second Result Day 3 | Third Result Day 5 | Interpretation |
|---|---|---|---|---|
| With Symptoms | Positive | N/A | N/A | Positive for COVID-19 |
| | Negative | Positive | N/A | Positive for COVID-19 |
| | Negative | Negative | N/A | Negative for COVID-19 |

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

| | |
|---|---|
| COVID-19 Ag non-reactive |  |
| COVID-19 Ag reactive |  |
| Invalid |  |

Using the test card can lead to three different results:

① If a single color band appears in the test region near the letter "C", the result is valid and "non-reactive", meaning no SARS-CoV-2 antigens could be detected. **To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing.**
A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.
All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

② If a second color band appears in the test region near the letter "T", the result is valid and "reactive", meaning SARS-CoV-2 antigens were detected. Repeat testing does not need to be performed if the patient has a positive result at any time.

③ If no color band appears or if a single color band appears near the letter "T", the result is invalid. In this case the result cannot be used, because the test did not work as intended. See section "Internal Control" for details.

## Internal Control

The PCL COVID19 Ag Gold test contains a built-in internal control in the test card. A color band appearing in the control region (C) is designed as an internal control. The appearance of the control line confirms that sufficient flow has occurred, and that the test card is working normally. If the control line does not appear within 10 minutes, it is considered an error in the test result and it is recommended to test again with the same sample and a new device. If there is again no color band on the internal control line on the retest, contact the manufacturer or distributor.

## External Controls

- External positive and negative controls may be used with the test kit. These controls provide additional quality control material to assess that the test reagents react as expected. Positive controls shall lead to "reactive" results and negative controls shall lead to "non-reactive" results.
- Controls are recommended to be run once for each new kit lot. It is advised to follow storage and handling instruction of the controls for proper use.
- Prepare solutions for positive controls following the instructions provided with the control material.
- For external negative controls, it is recommended to use the extraction buffer included in the kit.
- Perform controls using the same procedure as used for patient specimens.
- If the kit controls do not perform as expected, do not report patient results. Contact the manufacturer or distributor.

## Limitations of the procedure

- It is important for operators to understand the test procedure indicated in the IFU, failure to follow the steps may produce invalid test results.
- The results of PCL COVID19 Ag Gold should not be considered as absolute, and shall not be the sole basis for treatment or patient management. The infection should be confirmed by a specialist along with other experimental results, clinical symptoms, epidemiology, and additional clinical data.
- This kit detects both SARS-CoV and SARS-CoV-2, regardless of their viability. This kit does not differentiate between SARS-CoV and SARS-CoV-2.
- In the early stages of infection, low levels of antigen expression can result in non-reactive results.
- Due to the limitation of the assay methods, non-reactive results cannot entirely rule out the possibility of infection.
- This product can qualitatively detect SARS-CoV or SARS-CoV-2 antigens in human saliva, nasal or nasopharyngeal specimens and cannot determine the specific antigen quantity in the sample.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern.
- Based on the *in-silico* analysis results performed with the UK (B.1.1.7) & South Africa (B.1.351) derived SARS-CoV-2 variants, the risk of obtaining false negative results in patients who are positive for these strains is low.

## Serial Testing (Repeat Testing) Information and Limitations

- Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.

- A negative result should be followed up with repeat, or serial testing at least twice over three days with at least 48 hours between tests for symptomatic individuals.
- Serial testing has not been validated with saliva samples. However, a clinical study conducted with nasal samples (Please include the following reference to the study: "Performance of Screening for SARS-CoV-2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort study." Soni A. et al. medRxiv 2022.08.05.22278466; doi: https://doi.org/10.1101/2022.08.05.22278466) has shown that antigen tests more accurately determine whether the individual is infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

## Performance characteristics

**Limit of detection (LoD)**

The LoD was determined using limiting dilutions of inactivated SARS-CoV-2 (ZeptoMetrix, #0810587CFHI) in two separate methods.
For LoD screening, positive samples serially diluted 1/2 from $1.15x10^5$ $TCID_{50}$/ml to $2.25x10^2$ $TCID_{50}$/ml.
For confirmation LoD study, 5 points are set as the interval estimated as LoD. Select the lowest concentration marked as positive (≥95%) and one marked negative and proceed to the next test.
As a result of LoD confirmation test based on the selected point, the lowest concentration marked positive (≥95%) at $5.62 \times 10^2$ $TCID_{50}$/ml for saliva and $8.98 \times 10^2$ $TCID_{50}$/ml for nasal/nasopharyngeal swabs was determined.

- Saliva LoD: $5.62 \times 10^2$ $TCID_{50}$/ml
- Nasal/Nasopharyngeal LoD: $6.74 \times 10^2$ $TCID_{50}$/ml

**Cross-reactivity/ Microbial interference**

Viruses/bacteria listed below were confirmed not to have cross-reactivity or cause interference with PCL COVID19 Ag Gold.

- Virus ($10^5$ $TCID_{50}$/mL): Adenovirus type 1, Adenovirus type 7, Coronavirus 229E, Coronavirus NL63, Coronavirus OC43, MERS-CoV, SARS-CoV, Cytomegalovirus, Influenza A H3N2, Influenza A H1N1, Influenza B, Enterovirus type 71, Parainfluenza type 1, Parainfluenza type 2, Parainfluenza type 3, Parainfluenza type 4A, Measles virus, Human Metapneumovirus, RSV type A, RSV type B, Rhinovirus, Epstein Barr virus and Mumps virus
- Bacteria ($10^6$ CFU/mL): B. pertussis, C. pneumoniae, E. coli, H. influenzae, M. catarrhalis, L. pneumophila, M. pneumoniae, M. tuberculosis, N. meningitidis, P. aeruginosa, S. epidermidis, S. pneumoniae, S. pyogenes, S. salivarius and S. aureus
- P. jirovecii (in silico), C.albicans (in silico)
- Pooled human nasal wash
- For Human Coronavirus HKU1, homology exists between the SARS CoV-2 nucleoprotein and Human Coronavirus HKU1. "BLAST" results showed Sequence ID Query_30767 had the highest alignment score and was found to be 36.74% homologous across 82% of the sequences.

**Endogenous interference**

Potential interfering substances listed below were confirmed not to have a response with PCL COVID19 Ag Gold.

- Mucin (5mg/ml), Human Blood (4%), 4-Acetamidopheno (10 mg/ml), Acetylsalicylic Acid (20mg/ml), Chlorpheniramine (5mg/ml), Diphenhydramine (5mg/ml), Guaiacol glyceryl ether (20mg/ml), Oxymetazoline (15%), Phenylephrine (15%), Fexofenadine (500mg/ml), Amantadine (500mg/ml), Ribavirin (500mg/ml), Pseudoephedrine HCl (20mg/ml), Ibuprofen (10mg/ml), Tamiflu (5mg/ml), Naso GEL (5%), Chloraseptic (1.5mg/ml), Cromolyn (15%), Zicam (5%), Homeopathic (1:10 dilution), Sore Throat Phenol Spray (15%), Tobramycin (4μg/ml), Mupirocin (10mg/ml), Fluticasone Propionate (5%), and Heparin (10%), α-Amylase (0.2U/ml), IgA (500ug/ml), Listerine Mouth Wash (50%), Colgate Toothpaste (200mg/ml), Coffee – Caffeine (73.5mg/ml), Redbull Energy Drink – Taurine (500mg/ml), Sprite (50%).

**Precision / Repeatability study**

The precision / repeatability study, consisting of one negative control and three positive control of each of the saliva, nasal, and nasopharyngeal swab specimens, showed consistent results on each panel regardless of lot, operator, testing site and the test date.

**Clinical accuracy**

The clinical performance of the PCL COVID19 Ag Gold in saliva, nasal or nasopharyngeal swab specimens was evaluated in comparison to Real Time PCR results. Saliva, nasal and nasopharyngeal swab samples for COVID-19 were collected from individuals diagnosed as positive or negative by RT-PCR testing.

- Saliva specimen (retrospective)

Positive percent agreement, PPA is 89.38 % (95% CI: 82.35% - 93.82%) and negative percent agreement, NPA is 99.53 % (95% CI: 97.41% - 99.92%) with PCL COVID19 Ag Gold.

| PCL COVID19 Ag Gold | RT-PCR* | | PPA (%) | NPA (%) |
|---|---|---|---|---|
| | Positive | Negative | | |
| Positive | 101 | 1 | 89.38 | 99.53 |
| Negative | 12 | 214 | | |
| Total | 113 | 215 | | |

*Real-Q 2019-nCoV Detection Kit: FDA-EUA, MFDS-EUA authorized and CE marked test

- Saliva specimen (prospective)

Positive percent agreement, PPA is 94.44% (95% CI: 81.34% - 99.32%) and negative percent agreement, NPA is 100% (95% CI: 94.72% - 100%) with PCL COVID19 Ag Gold.

| PCL COVID19 Ag Gold | RT-PCR* | | PPA (%) | NPA (%) |
|---|---|---|---|---|
| | Positive | Negative | | |
| Positive | 34 | 0 | 94.44 | 100 |
| Negative | 2 | 68 | | |
| Total | 36 | 68 | | |

*Real-Q 2019-nCoV Detection Kit: FDA-EUA, MFDS-EUA authorized and CE marked test

- Nasal specimen (retrospective)

Positive percent agreement, PPA is 88.50 % (95% CI: 81.31% - 93.15%) and negative percent agreement, NPA is 100 % (95% CI: 98.24% - 100%) with PCL COVID19 Ag Gold.

| PCL COVID19 Ag Gold | RT-PCR* | | PPA (%) | NPA (%) |
|---|---|---|---|---|
| | Positive | Negative | | |
| Positive | 100 | 0 | 88.50 | 100 |
| Negative | 13 | 215 | | |
| Total | 113 | 215 | | |

*Real-Q 2019-nCoV Detection Kit: FDA-EUA, MFDS-EUA authorized and CE marked test

- Nasal specimen (prospective)

Positive percent agreement, PPA is 91.67 % (95% CI: 77.53% - 98.25%) and negative percent agreement, NPA is 100 % (95% CI: 94.72% - 100%) with PCL COVID19 Ag Gold.

| PCL COVID19 Ag Gold | RT-PCR* | | PPA (%) | NPA (%) |
|---|---|---|---|---|
| | Positive | Negative | | |
| Positive | 33 | 0 | 91.67 | 100 |
| Negative | 3 | 68 | | |
| Total | 36 | 68 | | |

*Real-Q 2019-nCoV Detection Kit: FDA-EUA, MFDS-EUA authorized and CE marked test

- Nasopharyngeal specimen (retrospective)

Positive percent agreement, PPA is 90.27 % (95% CI: 83.41% - 94.48%) and negative percent agreement, NPA is 100 % (95% CI: 98.24% - 100%) with PCL COVID19 Ag Gold.

| PCL COVID19 Ag Gold | RT-PCR* | | PPA (%) | NPA (%) |
|---|---|---|---|---|
| | Positive | Negative | | |
| Positive | 102 | 0 | 90.27 | 100 |
| Negative | 11 | 215 | | |
| Total | 113 | 215 | | |

*Real-Q 2019-nCoV Detection Kit: FDA-EUA, MFDS-EUA authorized and CE marked test

- Nasopharyngeal specimen (prospective)

Positive percent agreement, PPA is 91.67 % (95% CI: 77.53% - 98.25%) and negative percent agreement, NPA is 100 % (95% CI: 94.72% - 100%) with PCL COVID19 Ag Gold.

| PCL COVID19 Ag Gold | RT-PCR* | | PPA (%) | NPA (%) |
|---|---|---|---|---|
| | Positive | Negative | | |
| Positive | 33 | 0 | 91.67 | 100 |
| Negative | 3 | 68 | | |
| Total | 36 | 68 | | |

*Real-Q 2019-nCoV Detection Kit: FDA-EUA, MFDS-EUA authorized and CE marked test

※ PPA and NPA is interpreted as sensitivity and specificity, respectively.

This clinical performance data reflects the accuracy of the test when testing once. This test was not clinically validated for serial testing. The serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

- **Serial-testing clinical performance**

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in below table. The data in this table establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

| DAYS AFTER FIRST PCR POSITIVE TEST RESULT | ASYMPTOMATIC ON FIRST DAY OF TESTING | | | SYMPTOMATIC ON FIRST DAY OF TESTING | | |
|---|---|---|---|---|---|---|
| | Ag Positive/PCR Positive (Antigen Test Performance % PPA) | | | | | |
| | 1 Test | 2 Tests | 3 Tests | 1 Test | 2 Tests | 3 Tests |
| 0 | 9/97 (9.3%) | 35/89 (39.3%) | 44/78 (56.4%) | 34/57 (59.6%) | 47/51 (92.2%) | 44/47 (93.6%) |
| 2 | 17/34 (50.0%) | 23/34 (67.6%) | 25/32 (78.1%) | 58/62 (93.5%) | 59/60 (98.3%) | 43/43 (100%) |
| 4 | 16/21 (76.2%) | 15/20 (75.0%) | 13/15 (86.7%) | 55/58 (94.8%) | 53/54 (98.1%) | 39/40 (97.5%) |
| 6 | 20/28 (71.4%) | 21/27 (77.8%) | 16/18 (88.9%) | 27/34 (79.4%) | 26/33 (78.8%) | 22/27 (81.5%) |
| 8 | 13/23 (56.5%) | 13/22 (59.1%) | 4/11 (36.4%) | 12/17 (70.6%) | 12/17 (70.6%) | 7/11 (63.6%) |
| 10 | 5/9 (55.6%) | 5/8 (62.5%) | | 4/9 (44.4%) | 3/7 (42.9%) | |

1 Test = one(1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Test = two(2) test performed an average of 48 hours apart. The first test performed on the indicated day and second test performed 48 hours later.
3 Test = three(3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

**Key to symbols used**

| | | | |
|---|---|---|---|
| REF | Catalog number | IVD | *In vitro* diagnostics medical device |
| LOT | Lot number | | Consult instructions for use |
| Σ n | Sufficient for n tests | | Do not reuse |
| 2℃ 30℃ | Store at 2-30℃ | | Manufacturer |
| | Expiration Date | | Caution |

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