MONOCENT
Innovation & Excellence

ENGLISH

SARS-CoV2 ANTIGEN RAPID TEST SYSTEM

CE

REF **RT45-2214** Σ **25 TESTS** **IVD**

INTENDED USE

The Monocent, Inc.'s SARS-CoV2 Antigen Rapid Test System is a qualitative and immunochromatographic in vitro assay for the detection of the nucleocapsid protein antigen from SARS-CoV2 in anterior nasal and nasopharyngeal swab specimen obtained from patients suspected of COVID-19 within five days of symptom onset. The device provides an aid in the determination of SARS-CoV-2 virus acute infection.

PRINCIPLE OF THE TEST

The principle of COVID-19 Coronavirus Rapid Test System is an antibody-antigen-antibody gold conjugate immunochromatographic assay for the detection of COVID-19 virus from nasal swab. Anti SARS-CoV2 virus antibodies are conjugated to a colloidal gold and deposited on the conjugate pad. Another antibody is immobilized on the test lines of the nitrocellulose membrane. When the sample is added, the antibody gold conjugate is rehydrated and COVID-19 virus, if present in the sample, will react to the gold conjugate to form an antigen-antibody-gold complex. The complex will migrate towards the test window (T) where they will be captured by the other antibodies immobilized on the test lines to form a visible solid or faint pink line to indicate positive results. If COVID-19 Coronavirus is absent in the sample, no pink line will appear in the test lines, to indicate a negative result. To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

MATERIALS AND COMPONENTS

- Individual test cassette with a desiccant in foiled pouch
- 25 reagent tubes with pre-dispensed extraction buffer
- 25 dropper caps
- 25 sterilized nasal swabs
- Tube Rack
- Positive control swab (+) in foiled pouch
- Negative control swab (-) in foiled pouch
- Test instruction (IFU)

MATERIALS REQUIRED BUT NOT PROVIDED

- Gloves
- Clock or timer

PRECAUTIONS

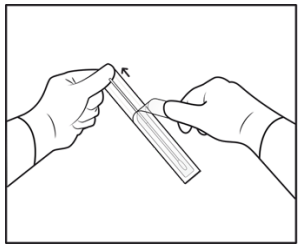
- For professional in vitro diagnostic use only. Do not reuse.
- Do not use if the pouch is open or its packaging is damaged.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations.

SPECIMEN COLLECTION

Note: It is important to obtain as much secretion as possible. Freshly collected specimens should be processed as soon as possible, within one hour after the collection. It is essential that correct specimen collection and preparation method be strictly followed. If not tested immediately, swab specimens may be stored at 2-8°C for 24 hours after collection.

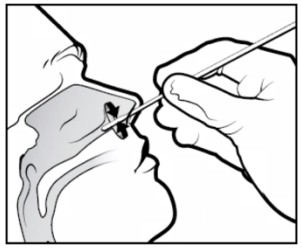
Viral Transport Medium Sample Collection:
If viral transport medium (VTM) is required, minimal dilution of the sample is recommended. If possible 0.5 mL is recommended to avoid excessive dilution of each sample. Specimens in VTM may be stored at 2-8°C for 72 hours if not tested immediately.

Anterior Nasal Swab Sample Collection:



1. Remove the sterile swab from the pouch.

2. Carefully insert the sterile swab into the nostril up to until resistance is met at the turbinate (about 1 inch).



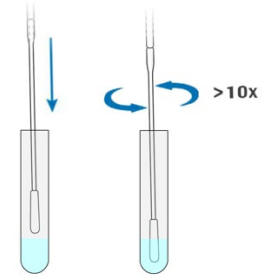
3. Rotate the swab 5 times against the nasal wall. Using the same swab repeat the collection process with the second nostril.

4. Remove the swab slowly from the nostril; avoid high-viscous nasal discharge.

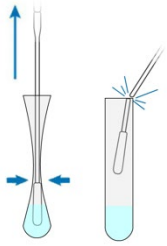
TEST PROCEDURE

Bring devices, extraction buffer, and specimens and/or controls to room temperature (15~30°C) before use.

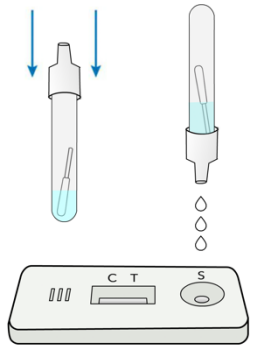
1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a flat, dry surface.
2. Remove a reagent tube from the container and pill open the aluminum seal.



3. Insert the sampled swab into the tube.
4. Vigorously rotate and twist the swab against the side of the tube at least 10 times for at least a minute.



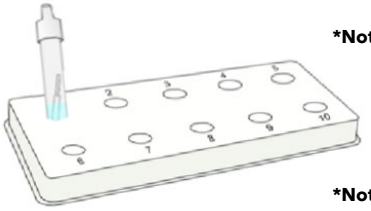
5. Squeeze the swab against inner wall of the tube to drain out as much solution as possible.
6. Press the swab at the breakpoint position against the opening edge of the tube to break the handle and leave the tip in the tube.



7. Apply the dropper cap to close the tube.
8. Turn the tube upside down vertically and squeeze 3 drops (100 µl) of the solution into the sample well.
9. Dispose the extraction buffer tube properly.

10. Observe results in 15 minutes. Do not try to interpret results after 30 minutes.

***Note:** For condensed samples, if the sample does not migrate to the membrane within 20 seconds, to apply additional one drop of extraction buffer to the sample well.



***Note:** For your convenience and ease of the test procedure a Tube Rack is provided in the kit.

***Note:** The extraction buffer tube may vary.

USE OF POSITIVE & NEGATIVE CONTROLS

Use the negative and positive control to ensure the validity of the test and if the test was performed correctly.

Negative control: Use a blank swab provided as negative control without collecting any sample following the assay procedure.

Positive Control: Non-infectious recombinant SARS-CoV2 N protein antigen dried swab. Use the positive control swab following the assay procedure.

Use of external positive and negative controls is recommended with every new shipment or every new lot number.

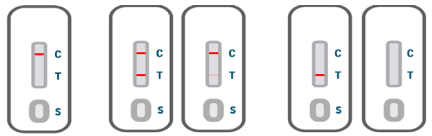
INTERPRETATION OF RESULTS

Negative: No band in the test region (T), only one pink band appears in the control region (C). This indicate that no detectable Covid-19 virus in the tested sample.

Positive: In additional to the band in the control region, another one solid or faint pink bands appears in the test region. This indicates that the sample contains Covid-19 Coronavirus antigens.

Invalid: There is no control band.

Test results are illustrated in pictures below:



PERFORMANCE CHARACTERISTICS

Detection limit:
The detection limit was determined with a quantified SARS-CoV2 virus and evaluated at 1.0*10³ TCID50/ml. Monocent' s SARS-CoV2 Antigen Rapid Test can also detect recombinant N protein as low as 0.1 ng/ml.

Nasopharyngeal Swab Specimen Clinical Evaluation:
Performance Characteristic of Monocent, Inc.'s SARS-CoV2 Antigen Nasopharyngeal Swab Rapid Test System was established in a clinical site. A total of 134 patient specimens, 57 positive and 77 negatives confirmed by RT-PCR, were evaluated by Monocent' s SARS-CoV2 Antigen Rapid Test. Specimens consist of nasopharyngeal swabs from symptomatic patients used Monocent, Inc.'s SARS-CoV2 Antigen Rapid Test procedure.

Nasopharyngeal Swab Specimen Clinical Results

Monocent Nasopharyngeal SARS-CoV2 Antigen Rapid Test	Clinical RT-PCR		Total
	Positive	Negative	
Positive	56	0	56
Negative	1	77	78
Total	57	77	134

(Sensitivity) Positive Percent Agreement
PPA = 56 / (56+1) * 100% = **98.25%**
(95% confidence interval 91.23% ~ 99.62%)
(Specificity) Negative Percent Agreement
NPA =77 / (77+0) * 100% = **100%**
(95% confidence interval 92.82% ~ 100%)
Total Agreement = (56+77) / (56+77+1+0) = **99.25%**
(95% confidence interval 92.78% ~ 100%)

A total of 134 patient specimens were evaluated. Monocent's SARS- CoV2 Antigen Rapid Test picked up all Coronavirus antigen positive specimens. The sensitivity is 98.25% with one false negative. On the other hand, the assay has showed clean result on all negative specimens for specificity of 100%.

Anterior Nasal Swab Specimen Clinical Evaluation:
Performance Characteristic of Monocent, Inc.'s SARS-CoV2 Antigen Anterior Nasal Swab Rapid Test System was established in a clinical site. A total of 123 patient specimens, 45 positive and 78 negatives confirmed by RT- PCR, were evaluated by Monocent' s SARS-CoV2 Antigen Rapid Test. Specimens consist of nasal swabs from symptomatic patients used Monocent, Inc.'s SARS-CoV2 Antigen Rapid Test procedure.

Anterior Nasal Swab Specimen Clinical Results

Monocent Anterior Nasal SARS-CoV2 Antigen Rapid Test	Clinical RT-PCR		Total
	Positive	Negative	
Positive	44	0	44
Negative	1	78	79
Total	45	78	123

(Sensitivity) Positive Percent Agreement
PPA = 44/(44+1)*100% = **97.78%**
(95% confidence interval 91.23% ~ 99.62%)
(Specificity) Negative Percent Agreement
NPA =78 / (78+0) * 100% = **100%**
(95% confidence interval 92.82% ~ 100%)
Total Agreement = (44+78) / (44+78+1+0) = **99.19%**
(95% confidence interval 92.78% ~ 100%)

A total of 123 patient specimens were evaluated. Monocent's SARS- CoV2 Antigen Rapid Test picked up all Coronavirus antigen positive specimens except one specimen. The sensitivity is 97.78% with one false negative. The assay has showed clean result on all negative specimens for specificity of 100%.

Intra-lot Repeatability:
Variation within the lot was evaluated by running three spiked Covid-19 antigen negative, one weak positive, one strong positive on the same lot of Monocent's SARS-CoV2 Antigen test device for 9 times. All have been identified correctly.

Inter-lot Reproducibility:
To evaluate assay variation between lots, one negative, one weak positive, one strong positive, were tested on three lots of Monocent's SARS-CoV2 Antigen test devices, three times for each sample and each lot. All results were agreed with each run.

Interfering Substances
Substances commonly used to release symptoms of allergic rhinitis, Flu and other diseases may present in respiratory mucus were evaluated at the concentrations on the list below. There was no interference with Monocent's SARS-CoV2 Antigen test rapid Test.

List of Substances:

Oxymetazoline Hydrochloride	5mg/ml	Acetylsalicylic Acid	20mg/ml
Phenylephrine	10mg/ml	Albuterol	20mg/ml
Phenylpropanolamine	20mg/ml	Diphenhydramine	5mg/ml
Rimantadine	500ng/ml	Dextromethorphan	10mg/ml
Tobramycin	40mg/ml	Dexamethasone	5mg/ml
Camphor (Synthetic)	6.2%	Chlorpheniramine	5mg/ml
Afrin Nasal Spray	0.05%	4-acetamidophenol	10mg/ml
Sinus relief	0.05%		

Cross Reactivity:
Pathogens shown below were tested on Monocent's SARS-CoV2 Antigen Rapid Test and there was no cross-reaction observed.

Virus/Bacteria / Parasite	Strain	Concentration	Result	Result	Result
Corona virus	OC43	1.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
	NL63	1.0 x 10^4 TCID 50/mL	NEG	NEG	NEG
Adeno virus	Type 1	3.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
	Type 3	1.5 x 10^6 TCID 50/mL	NEG	NEG	NEG
	Type 5	4.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
	Type 7	1.5 x 10^6 TCID 50/mL	NEG	NEG	NEG
	Type 55	4.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
Influenza A	A/14160 (H1N1)	3.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
	A/44045 (H3N2)	1.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
	A/924 (H3N2)	4.0 x 10^6 TCID 50/mL	NEG	NEG	NEG
	A/Beijing/302/54(H5N1)	1.5 x 10^6 TCID 50/mL	NEG	NEG	NEG
Influenza B	B/1715	3.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
	B/1704	2.5 x 10^5 TCID 50/mL	NEG	NEG	NEG
	B/179	4.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
	B/668	1.5 x 10^6 TCID 50/mL	NEG	NEG	NEG
Respiratory syncytial virus	Type A	3.0 x 10^5 TCID 50/mL	NEG	NEG	NEG
Mycoplasma pneumoniae	Mutant 22	5.0 x 10^4 cells/mL	NEG	NEG	NEG
Streptococcus pneumonia	178 [Poland 23F-16]	5.0 x 10^4 cells/mL	NEG	NEG	NEG
Legionella pneumophila	Bloomington-2	5.0 x 10^4 cells/mL	NEG	NEG	NEG
Mycobacterium tuberculosis	HN878	5.0 x 10^4 cells/mL	NEG	NEG	NEG
RhinovirusA16	N/A	1.0 x 10^5 TCID 50/mL	NEG	NEG	NEG

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE CONDITIONS

- The bottle containing the buffer should be stored at 2-30℃.
- The test device should be kept away from direct sunlight, moisture, and heat.

LIMITATIONS OF THE TEST

1. The Monocent, Inc.'s SARS-CoV2 Antigen Rapid Test System is limited to the detection of COVID-19 virus from nasal swab and nasopharyngeal swab specimens that were collected and tested freshly. If viral transport medium (VTM) is required, minimal dilution of the sample is recommended.
2. The test is not intended for testing liquid samples such as wash or aspirate samples as results can be compromised by over dilutions.
3. A negative result may occur if the level of antigen in the sample is below the detection limit of the test.

REFERENCES

1. Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected. Interim guidance. WHO.2020.
2. Diagnosis and treatment of pneumonia caused by new coronavirus (tail version 4) National Health Commission. 2020.
3. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html Accessed March 30, 2020.

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