CE

PerkinElmer

PerkinElmer® COVID-19 Antigen Test (NS, NP)

Rapid Test for Detection of SARS-CoV-2 Antigen in Human Nasal Swab (NS) and Nasopharyngeal (NP) Swab Specimens

CASSETTE TEST

INTENDED USE

PerkinElmer® COVID-19 Antigen Test (NS, NP) is an invitro, rapid, qualitative immunoassay for the detection of nucleocapsid protein antigens expressed by the SARS-CoV-2 virus present in human nasopharyngeal swab and nasal swab specimens. It is to be used for screening or to aid in the diagnosis of COVID-19 disease. This rapid antigen detection test takes 15-30 minutes for producing a positive or negative test result. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The result of this test should not be the sole basis for the diagnosis. Presumptive positive or negative result may need to be further confirmed with a molecular test.

SUMMARY

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the strain of coronavirus that causes Coronavirus disease 2019 (COVID-19), the respiratory illness responsible for the COVID-19 pandemic. This virus was first identified in the respiratory tract of patients with pneumonia in Wuhan, Hubei China, in December 2019 which was then indicated as a newly identified β-coronavirus (nCoV). SAR-CoV2 is an enveloped, non-segmented, positive sense RNA virus that is included in the sarbecovirus, ortho corona virinae subfamily which is broadly distributed in humans and other mammals. Its diameter is about 65-125 nm, containing single strands of RNA and provided with crown-like spikes on the outer surface. SARS-CoV2 is a novel β-coronavirus after the previously identified SARS-CoV and MERS-CoV which led to pulmonary failure and potentially fatal respiratory tract infection and caused outbreaks mainly in Guandong, China and Saudi Arabia. Severe Acute Respiratory Syndrome Coronavirus 2 can attack lung cells because there are many conserved receptor entries, namely Angiotensin Converting Enzyme-2. The presence of this virus in host cells will initiate various protective responses leading to pneumonia and Acute Respiratory Distress Syndrome.

The most characteristic symptom of COVID-19 patients is respiratory distress. Most people infected with SARS-CoV-2 virus do not have symptoms, but when present they are usually mild and last less than seven days. Common symptoms of COVID-19 infection are fever, headache, nausea and vomiting. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death. Older people and people with severe chronic conditions are at higher risk of developing serious COVID-19 illness.

PRINCIPLE

PerkinElmer® COVID-19 Antigen Test (NS, NP) utilizes the principle of agglutination of antibodies with respective antigen in immuno-chromatography format along with use of nano indicator colloidal particles as agglutination revealing agent. Mouse monoclonal anti-SARS-CoV-2 antibodies are coated as capture in the Test region 'T, Goat anti-mouse IgG as assay control in the control region 'C and mouse monoclonal anti-SARS-CoV-2 antibodies conjugated with color particles are used as detectors in this cassette. As the test specimen flows through the membrane assembly within the cassette, the colored Mouse monoclonal anti-SARS-CoV-2 antibodies- indicator colloidal particle complexes with SARS-CoV-2 antigen, if present in the specimen. This complex moves further on the membrane to the Test region where it is immobilized by the Mouse monoclonal anti-SARS-CoV-2 antibodies coated as capture on the nitrocellulose membrane leading to formation of a colored band in the Test region 'T' which confirms a positive test result. Absence of the colored band in the Test region 'T' indicates a negative test result.

The unreacted conjugate and the unbound complex move further on the membrane and are subsequently immobilized by the Goat anti-mouse IgG coated at the control region 'C', forming a colored band.

This control band serves to validate the test results.

REAGENT AND MATERIAL SUPPLIED

PerkinElmer® COVID-19 Antigen Test (NS, NP) kit comprises of:

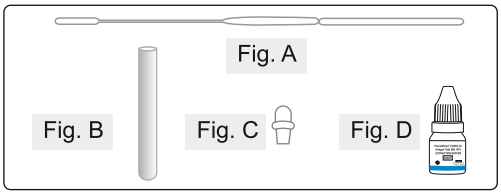
A. Individual pouches, each containing:
   1. CASSETTE : Membrane assembly pre-dispensed with Mouse monoclonal anti-SARS-CoV-2 antibodies -indicator colloidal particles, Mouse monoclonal anti- SARS-CoV-2 antibodies -capture at test region 'T' and Goat anti-mouse IgG at control region 'C'.
   2. Desiccant pouch.

B. Accessories box containing:

Size : 137 x 218 mm

- Sterile nasal/ nasopharyngeal swabs - **Fig. A**
- Extraction Buffer tubes - **Fig. B**
- Nozzles for Extraction Buffer tubes - **Fig. C**
- Stand for Extraction Buffer tubes

C. Extraction Buffer bottle - **Fig. D**
D. Package Insert.



REF	502120025
Σ	25 T

ADDITIONAL MATERIAL REQUIRED

Stop watch, Disposable gloves.

STORAGE AND STABILITY

The test kit (including sealed pouches) may be stored between 4ºC to 30ºC till the duration of the shelf life as indicated on the pouch/ carton. DO NOT FREEZE the kit or its components. After first opening of the extraction buffer bottle, it can be stored between 4ºC to 30ºC for remaining duration of its shelf life.

NOTE

1. For *in vitro* diagnostic use and for professional use only. NOT FOR MEDICINAL USE.
2. Do not use the kit beyond expiry date and do not re-use the cassette.
3. Read the instructions carefully before performing the test.
4. Any modification to the above procedure and / or use of other reagents will invalidate the test results.
5. Do not inter mix the reagent or cassettes from different lots.
6. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.
7. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
8. Clean up spills thoroughly using an appropriate disinfectant.
9. Handle all specimens as if potentially infectious. Follow standard bio-safety guidelines for handling and disposal of potentially infective material.
10. The Extraction buffer contains Sodium Azide (< 0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

SPECIMEN COLLECTION AND PREPARATION

1. Use the appropriate personal protective equipment while collecting specimen.

For nasopharyngeal swab specimen collection

2. Insert a sterile nasopharyngeal swab into the nostril of the patient, reaching the surface of the posterior nasopharynx. Refer **Fig.1**
3. Gently rotate the swab and slowly pushing the swab a little further, rotate the swab a few more times against the nasopharyngeal wall.
4. Remove the swab with specimen, from the nostril carefully.
5. The specimen should be tested as soon as possible after collection.
6. Specimens may be stored at room temperature for up to 1 hour or at 2-8°C/ 36-46°F for up to 4 hours prior to testing.

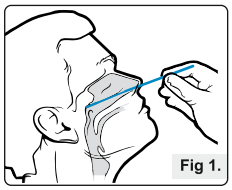


Fig 1.

For nasal swab specimen collection

2. Insert the entire absorbent tip of the swab into the patient's nostril, but do not insert the swab more than ¾ of an inch (1.5 cm) into the nose. Refer **Fig. 2.**
3. Slowly rotate the swab in a circular path against the inside of the nostril at least 4 times for a total of 15 seconds.
4. Follow steps 4-6 of the nasopharyngeal swab collection procedure.

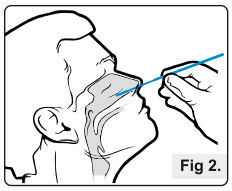


Fig 2.

TEST PROCEDURE

1. Bring the **PerkinElmer® COVID-19 Antigen Test (NS, NP)** kit components to room temperature before testing.
2. Place the required number of Extraction Buffer tubes, according to the number of specimens to be tested, in the tube stand provided.

3. Next open the Extraction Buffer bottle by tightening its cap in clockwise direction to pierce the bottle nozzle. Refer **Fig.3**
4. Dispense 8 drops of the Extraction Buffer into Extraction Buffer tube.
   Note: For each patient sample a new tube should be used.
5. Label each Extraction Buffer tubes with the patient's name/ id.
6. Using the swab provided, collect the specimen as mentioned in the **Specimen Collection and Preparation** section above.

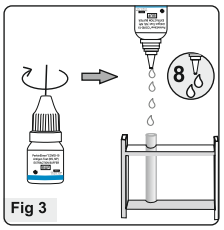


Fig 3

7. Insert the swab with collected specimen into the Extraction Buffer tube.
8. Roll the swab more than **5 times** within Extraction Buffer tube, squeeze against inside of tube, let stand for 1 minute, and squeeze several more times. Refer **Fig.4**

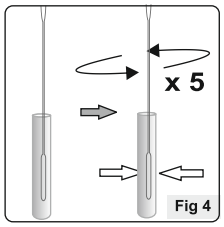


Fig 4

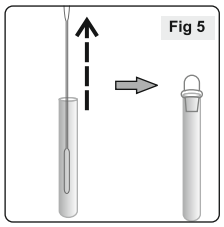


Fig 5

9. Safely remove the swab while squeezing the sides of the Extraction Buffer tube to extract the liquid from the swab completely. Discard the swab into gluteraldehyde or hypochlorite solution following Biohazard protocols.
10. Press the nozzle cap tightly onto the Extraction Buffer tube. The extracted specimen is ready for the test. Refer **Fig.5.**

Running the test

11. Next open a **PerkinElmer® COVID-19 Antigen Test (NS, NP)** cassette pouch by tearing along the "notch".
12. Retrieve the cassette and desiccant pouch. Check the color of the desiccant. It should be blue. If it has turned colorless or pink, discard that cassette and use another cassette.
    Note: ***Once opened, the cassette must be used immediately.***
13. Label the cassette with patient's identity.
14. Place the cassette on a flat horizontal surface.

Specimen addition

15. Add 4 drops of the extracted specimen into the specimen port of the cassette. Refer **Fig. 6**

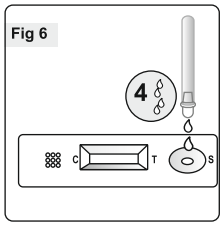
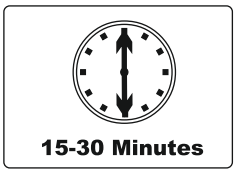


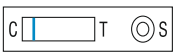
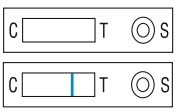
Fig 6

Read Results

16. Read the test results in 15-30 minutes. Do not read test results beyond 30 minutes.



INTERPRETATION OF RESULT

	**Negative result**: The presence of only one pink-purple coloured band in the control area marked 'C', indicates absence of SARS CoV-2 antigen in the specimen.
	**Positive Result:** In addition to the band in the control area marked 'C', appearance of a pink-purple coloured band in the test region 'T', indicates the presence of SARS-CoV-2 antigen in the specimen.
	**Invalid Result**: The test result is invalid if no bands appear on the cassette. The test should also be considered invalid if only the test band appears and no control band appears. In such cases, verify the test procedure and repeat the test with a new cassette.

Size : 137 x 218 mm

PERFORMANCE EVALUATION

a) In an independent evaluation performed in the USA, the performance of **PerkinElmer® COVID-19 Antigen Test (NS, NP)** was compared to RT-PCR (PerkinElmer® New Coronavirus Nucleic Acid Detection Kit)

Evaluation Summary			
	RT-PCR	PerkinElmer® COVID-19 Antigen Test	
		Sensitivity	Specificity
Positive	39	97.4 %	-
Negative	1	-	100%

	Nasal swab specimens			Nasopharyngeal swab specimens								
	Symptomatic Patients			Symptomatic Patients			Asymptomatic Patients			Total Patients		
	RT-PCR	PerkinElmer® Antigen Test		RT-PCR	PerkinElmer® Antigen Test		RT-PCR	PerkinElmer® Antigen Test		RT-PCR	PerkinElmer® Antigen Test	
		Sensitivity	Specificity		Sensitivity	Specificity		Sensitivity	Specificity		Sensitivity	Specificity
Positive	12	100%	-	23	95.7%	-	4	100%	-	27	96.3%	-
Negative	-	-	-	-	-	-	1	-	100%	1	-	100%

b) **Specificity**: In an in-house evaluation with 202 RT-PCR COVID-19 negative samples, **PerkinElmer® COVID-19 Antigen Test (NS, NP)** cassette showed 100% specificity.

c) **Limit of Detection (LoD):** The study used "SARS-Related Coronavirus 2 (SARS-CoV-2) Culture Fluid (Heat Inactivated) " USA-WA1/2020 strain (Zeptomatrix # 0810587CFHI). The inactivated virus is diluted in extraction buffer. Based on the study LoD observed is $1.4 \times 10^{3.0}$ $TCID_{50}$ / ml.

LIMITATIONS OF THE TEST

(1) **PerkinElmer® COVID-19 Antigen Test (NS, NP)** is used for the detection of SARS-CoV-2 antigen in human nasal and nasopharyngeal specimens. It should not be used as the sole criteria for diagnosis, treatment and/or management of COVID-19 infection. The result of this test should be confirmed with molecular assays and clinical findings as needed. (2) Negative results do not preclude SARS-CoV-2 infection and must be combined with clinical observations, patient history, and epidemiological information. (3) This is a qualitative test. Neither the quantitative value or change in SARS-CoV-2 antigen concentration can be determined by this qualitative test. (4) Cross reactivity across the other coronavirus group may occur in certain patients with prior exposure to HKU1 or NL63 or OC43 or 229E or SARS-CoV or MERS-CoV etc. (5) False results may occur due to presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing. (6) Do not interpret the test results beyond 30 minutes. (7) This test is meant for and validated for testing human nasal or nasopharyngeal samples only. This test is not meant for testing of pooled samples. (8) *Escherichia coli* ATCC 25922, *Staphylococcus aureus* ATCC 25923, *Pseudomonas aeruginosa* ATCC 27853, *Streptococcus pneumoniae* ATCC 6305, *Staphylococcus epidermidis* ATCC 12228 and *Streptococcus pyogenes* ATCC 19615 did not interfere with the results. (9) Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children. (10) Nasopharyngeal swab is the preferred specimen for testing due to higher recovery of the virus, sensitivity may be lower with nasal swab specimens.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1) Indwiani Astuti, Ysrafil, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2): An overview of viral structure and host response, Diabetes & Metabolic Syndrome: Clinical Research & Reviews, Volume 14, Issue 4, July–August 2020,Pages 407-412. (2) Interim Guidance for Rapid Antigen Testing for SARS-CoV-2, https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html. (3) Hélène Péré et al., Nasal Swab Sampling for SARS-CoV-2: a Convenient Alternative in Times of Nasopharyngeal Swab Shortage, Journal of Clinical Microbiology, June 2020 Volume 58 Issue 6 e00721-20, 1-2. (4) Data on file: Zephyr Biomedicals.

SYMBOL KEYS

	Temperature Limitation		Do not use if package is damaged		Consult Instructions for use	REF	Catalogue Number	Σ	Contains sufficient for <n> tests
	Manufacturer		Do not reuse	IVD	*In vitro* Diagnostic Medical Device	LOT	Batch Number / Lot Number		
	Use by		Date of Manufacture	CASSETTE TEST	Cassette		This side up	EC REP	Authorised Representative in the European Community

Manufactured for: **PerkinElmer, Inc.**

Zephyr Biomedicals

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M 46-47, Phase III B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

EC REP

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