Biolidics

ClearEpi™

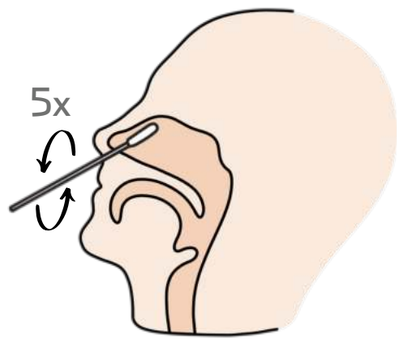
SARS-CoV-2 ANTIGEN RAPID TEST

CATALOGUE NUMBER:
CBB-F016028-BLD-C

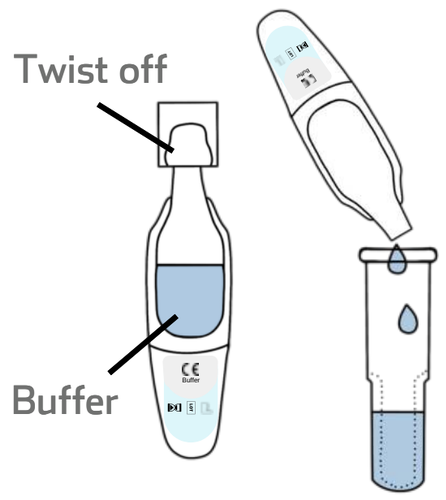
- Qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal specimen directly from individuals suspected of COVID-19 infection
- Clinical Data Performance
  - Sensitivity: 98.15 %
  - Specificity: 98.75 %
  - Accuracy: 98.60 %
- Convenient storage conditions: 2ºC-30ºC
- Deployed as point of care in a variety of setting
- Simplified protocol, with results in 15 minutes
- Accessible solution enables large-scale testing

TEST PROCEDURES

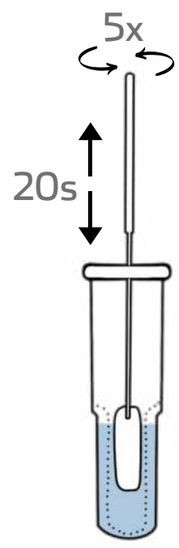
1 Insert the swab into the nostril of the patient. Swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab (5) times along the mucosa inside the nostril to ensure both mucus and cells are collected. * Repeat for other nostril



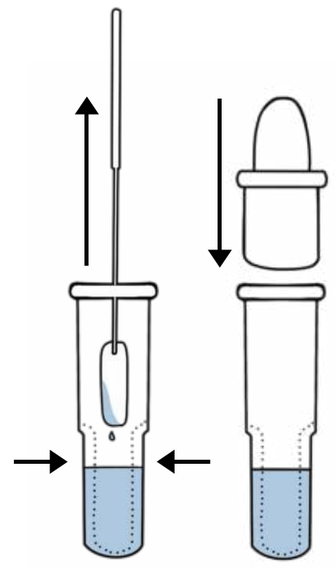
2 Twist off the top of the buffer bottle, slowly dispense all of the buffer into the extraction tube.



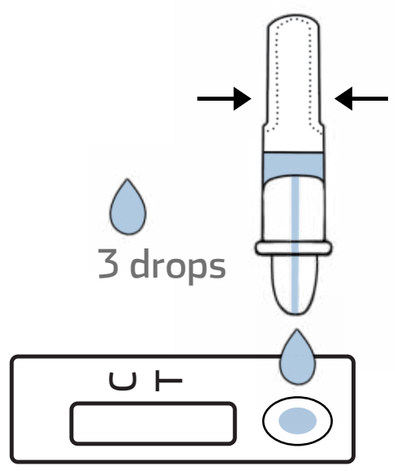
3 Insert collected nasal swab specimen into the tube and plunge the swab up and down in the fluid for a minimum of 20 seconds, then hold the swab against the bottom of the tube and roll 5 turns, taking care not to splash contents out of tube.



4 Remove swab while squeezing the sides of the tube to extract the liquid from the swab. Press the nozzle cap firmly onto the extraction tube containing the processed sample (threading or twisting not required). Mix thoroughly by swirling or flicking the bottom of the tube. Place the extraction tube(s) in a rack in the designated area of workspace.



5 Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and leveled surface. Label the test device and one extraction tube for each specimen or control to be tested. Gently squeeze the ridged body of the tube, dispensing (3) drops of the processed specimen into the sample well.



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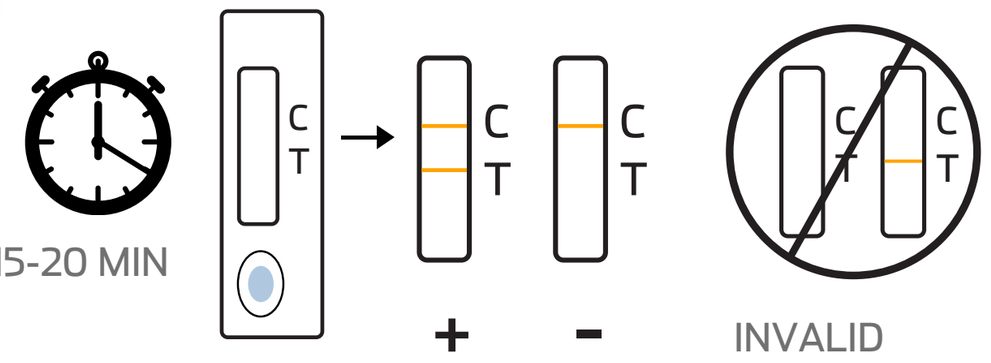

Read the test results between 15 and 20 minutes.
* Do not read the results after 20 minutes

PERFORMANCE

- Sensitivity: 98.15 %
- Specificity: 98.75 %
- Clinical Study Results from symptom onset

Reagent Test Results	RT-PCR Comparator		Subtotal
	Positive	Negative	
Positive	53	2	55
Negative	1	158	159
Subtotal	54	160	214

Accuracy=(53+158)/214×100% = 98.60%

SPECIFICATIONS

- Test time: 15 - 20 minutes
- Storage: 2°C - 30°C
- CE MARK
- Shelf life: 18 months
- Sample Type: Nasal swab

INTENDED USE:
For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal(NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days after onset of symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, not for at-home testing. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, or 2019-nCoV) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease 2019 (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M), and nucleocapsid (N). The antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results should be treated as presumptive, which 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. For in vitro diagnostic use only. For professional use only.

ORDER INFORMATION

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