COVID 19 RAPID ANTIGEN TEST

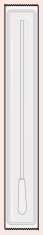
PLEASE READ IN FULL

APRIL 2021 (VERSION 5) | REF 11811125 | FOR PROFESSIONAL USE | CE

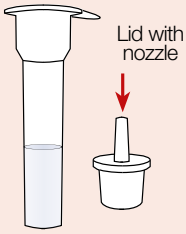
KIT COMPONENTS (ALL SINGLE USE ONLY)

- Lateral flow device
- Sterile swab
- Swab extraction buffer tube

X1
LATERAL FLOW DEVICE



X1
STERILE SWAB



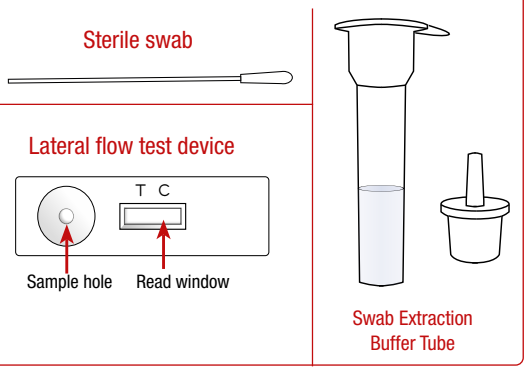
X1
SWAB EXTRACTION BUFFER TUBE

MATERIALS REQUIRED BUT NOT PROVIDED

- Tube stand
- Stopwatch/timer

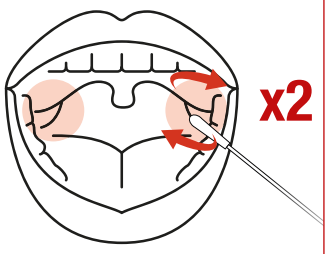
SPECIMEN COLLECTION AND HANDLING

1 Open kit components pictured above and lay on a clean, flat surface



IF SAMPLE FROM NOSE ONLY GO TO STEP 3; IF SAMPLE FROM NOSE AND THROAT GO TO STEP 2.

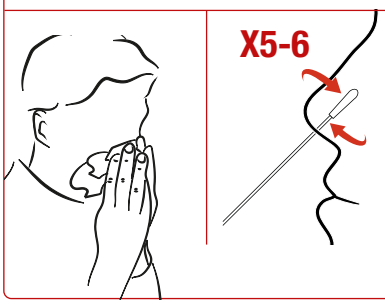
2 **THROAT SWAB SPECIMEN COLLECTION:** Open mouth, make "ah" sound, and run swab along **both tonsils** at least twice. Use the same swab for nasal specimen collection.



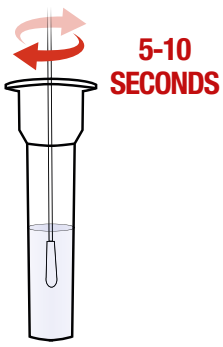
3 **NASAL SWAB SPECIMEN COLLECTION:**

1. Ask patient to blow their nose thoroughly to remove excess mucus.

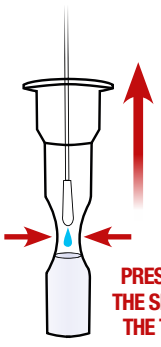
2. Insert swab 1-2cm into both nostrils one at a time and rotate the swab against the nasal wall 5-6 times and withdraw.



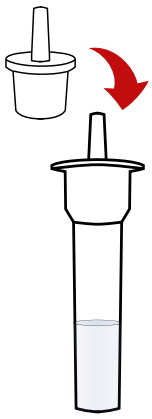
4 **TUBE:** Peel back and remove the foil, Lower the swab specimen into the tube. Submerge the swab in the buffer and mix thoroughly pressing the swab on the tube sides for 5 to 10 seconds.



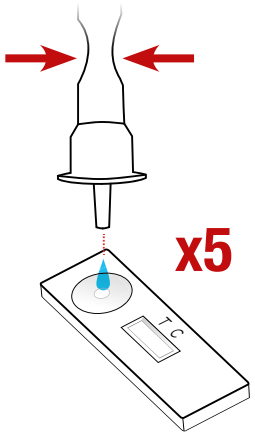
5 **SQUEEZE:** Extract as much fluid as possible by squeezing and twisting the swab head through your fingers as you draw it out from the tube.



CLOSE: Seal the tube by pushing the nozzle in place.



6 Ensure tube is **VERTICAL** and carefully dispense 5 continuous drops of extract into the sample hole on the lateral flow test device by gently squeezing the tube.



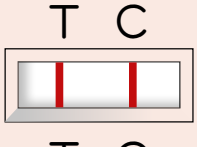
Read the TEST (T) visually at 10 minutes.

Discard extraction tube and swab.

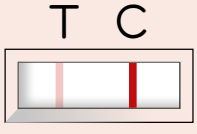
INTERPRETATION OF TEST RESULTS

DO NOT INTERPRET THE TEST AFTER 15 MINUTES. IF UNSURE, PLEASE REPEAT TEST ON NEW DEVICE AND INTERPRET AT 10 MINUTES

POSTIVE

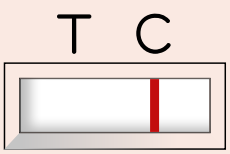


If the test line (T) is **visible**, this indicates a postive SARS-CoV-2 result.



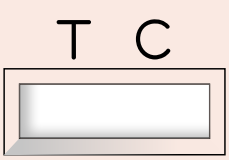
If the test line (T) is **faint**, this indicates a postive SARS-CoV-2 result.

NEGATIVE



If the test line (T) is not visible, this indicates a negative result.

INVALID



If the control line (C) is absent, the test is invalid.

COVID 19 RAPID ANTIGEN TEST: POOLED PERFORMANCE DATA

Prospective Recruitment		RT-qPCR		
		Pos	Neg	Total
Mologic Rapid Antigen Test	Pos	**130**	**5**	135
	Neg	**23**	**225**	248
	Total	153	230	383

Performance	Sensitivity 85%	Specificity 98%		

- Mologic COVID-19 Rapid Antigen Test uses a nose/throat (nostril/tonsil) or nose only (anterior nares) swab
- RT-qPCR platforms: Cepheid, Novacyt, ThermoFisher, Hologic/Panther
- Range Ct: 9.8 to Ct 43.0
- Panther score: 690-1299

Sensitivity stratified by RT-PCR cycle threshold value	
Ct	Sensitivity
<20	98.4% (61/62)
<25	93% (96/103)
<33	88% (115/131)

COVID-19 MICROBIAL INTERFERENCE AND CROSS REACTIVITY

Pathogen	Concerntration stock $TCID_{50}$ **Or CFU/mL	Reactive
hCoV-OC-43	4.17×10^5	No Cross-Reactivity
hCoV-229-E	1.70×10^5	No Cross-Reactivity
hCoV-NL-63	1.41×10^5	No Cross-Reactivity
Adenovirus 5	1.30×10^5	No Cross-Reactivity
hMPV-16	1.26×10^6	No Cross-Reactivity
Parainfluenza 1	5.01×10^5	No Cross-Reactivity
Parainfluenza 2	1.51×10^6	No Cross-Reactivity
Parainfluenza 3	1.70×10^5	No Cross-Reactivity
Parainfluenza 4A	4.17×10^5	No Cross-Reactivity
Influenza A H3N2	1.41×10^5	No Cross-Reactivity
Influenza A H1N1	1.41×10^5	No Cross-Reactivity
Influenza B	1.26×10^6	No Cross-Reactivity
Enterovirus type 68	1.26×10^6	No Cross-Reactivity
RSV-A	5.01×10^5	No Cross-Reactivity
Rhinovirus type 1A	1.41×10^5	No Cross-Reactivity
Haemophilus influenza	5.43×10^5	No Cross-Reactivity
Streptococcus pneumoniae	4.16×10^8	No Cross-Reactivity
Streptococcus pyogenes	2.66×10^9	No Cross-Reactivity
Candida albicans	4.50×10^8	No Cross-Reactivity
Bordetella pertussis	6.43×10^9	No Cross-Reactivity
Legionella pneumophila	1.42×10^{10}	No Cross-Reactivity
Pneumocystis jiroveci	6.34×10^8	No Cross-Reactivity

INTENDED USE

The Rapid Antigen Test is a qualitative point of care, lateral Flow immunoassay and is used as an aid to the qualitative detection of SARS-CoV-2 antigens in human nasal or throat swabs from individuals who are at risk or suspected of COVID-19 by their healthcare provider during the acute phase of infection. Test results should be considered in conjunction with other diagnostic and clinical information.

PRINCIPLES OF THE TEST

Nucleocapsid proteins in the sample are bound by capture reagents in the test lines as they are transported through the lateral flow strip, and made visible by secondary reagents.

A visible test line confirms the presence of the virus or fragment of the virus, indicating that the subject is experiencing COVID-19 infection.

The appearance of the CONTROL line (marked C) confirms that the test has been performed correctly.

STORAGE

This product is stable at room temperature (2-30°C).

WARNINGS & PRECAUTIONS

- For *in vitro* diagnostic use only.
- Single use. Used tests must not be re-used.
- Do not use after the expiry date printed on the packaging.
- Store at room temperature.
- Dispose of used kit components in clinical waste.
- Do not open pouch until you are ready to use the test. Use within 10 min of opening.

LIMITATIONS OF USE

- The COVID-19 Antigen Test is designed for use by medical professionals or trained personnel who are competent in administrating rapid antigen tests. Sample collection by self-swabbing is acceptable
- For reliable results, follow the instructions
- Test results should be used in conjunction with other clinical and patient information
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results may occur if antigen levels extracted in a specimen are below the sensitivity of the test or sampled inappropriately.

If you have any questions or comments, please contact our helpline on **+44 1234 780020** during UK office hours, or email **info@mologic.co.uk**

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