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PathoCatch™
COVID-19 Ag
LATERAL FLOW TEST DEVICE

Mylab Discovery solutions | ACCELBIO

Version 1.1
20 Nov. 2020

INTENDED USE

PathoCatch™ COVID-19 Antigen Lateral Flow Test Device is a lateral flow immunoassay intended for in vitro qualitative detection of Nucleocapsid protein antigen from SARS-CoV-2 in Nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

ORDER INFORMATION

Pack Size	REF
25 Tests	MPAG25

Testing is limited to laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests or by similarly qualified non-U.S. laboratories and as applicable, Point of Care (POC) testing.

Test results are for the identification of SARS-CoV-2 Nucleocapsid protein antigen which is generally detectable during the acute phase of infection. Though positive results indicate the presence of viral antigens, it is recommended to correlate clinically with patient history and other diagnostic information to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Further, 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. Negative results should be considered in the context of a patient's recent exposures, history; the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary for patient management. The PathoCatch™ COVID-19 Antigen Lateral Flow Test Device is intended for use at Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation. The PathoCatch™ COVID-19 Antigen Lateral Flow Test Device is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronaviruses belong to the genus Betacoronavirus, COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. The saliva-based COVID-19 diagnosis offers an improvement over standard nasal swab methods because people can collect their own samples with ease - simply spit into a sterile tube and mail it to a lab for processing.

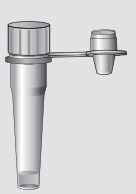
TEST PRINCIPLE

PathoCatch™ COVID-19 Antigen Lateral Flow Test Device is a rapid, two site sandwich immunochromatography assay to detect COVID-19 SARS-CoV-2 Nucleocapsid antigen from nasal swab specimen.
The test assembly consists of highly sensitive and specific monoclonal anti-SARS-CoV-2 Nucleocapsid antibodies immobilized on the Nitrocellulose membrane as test line (T), Goat anti-rabbit IgG as procedural control line (C), Conjugate pad immobilized with anti-SARS-CoV-2 Nucleocapsid specific monoclonal antibodies colloidal gold Conjugate and Rabbit IgG colloidal gold Conjugate, buffered sample pad and absorbent pad .

After addition of the nasal swab sample from the extraction buffer tube to the sample well of the device, the SARS-CoV-2 Nucleocapsid antigen, if present in the sample binds to the colloidal gold conjugated anti-SARS-CoV-2 Nucleocapsid specific monoclonal antibodies to form antigen-antibody complex. As this complex moves in the test window under capillary action, it binds to specific monoclonal anti-SARS-CoV-2 Nucleocapsid antibodies coated on the test region (T) to form a pink-purple coloured test line indicative of positive result for COVID-19 antigen. If there is no test line developed, it is indicative of a negative result for COVID-19 antigen or there is no detectable level of antigen in the sample. The sample and the unconjugated complex moves further to the control region to form a control line (C) of Rabbit IgG Colloidal gold conjugate and Goat anti-rabbit IgG. Appearance of Control line acts as a procedural control to confirm that the sample was adequate and test was correctly performed. Test results are interpreted visually within 20 minutes based on the presence or absence of visually detectable pink-purple coloured test and control line.

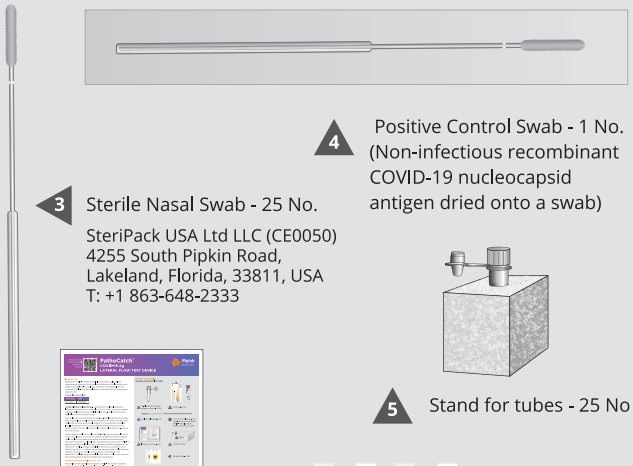
REAGENT AND MATERIAL

Reagents and Materials Provided



1 Pre-filled buffer tubes for antigen extraction - 25 No.

2 Test card - 25 No.



4 Positive Control Swab - 1 No. (Non-infectious recombinant COVID-19 nucleocapsid antigen dried onto a swab)

3 Sterile Nasal Swab - 25 No.
SteriPack USA Ltd LLC (CE0050)
4255 South Pipkin Road,
Lakeland, Florida, 33811, USA
T: +1 863-648-2333

5 Stand for tubes - 25 No

6 Instruction for Use - 1 No.

7 Biohazard Bag - 25 No.

Material Required But Not Provided: Timer, Clock or Stopwatch

WARNING AND PRECAUTION

1. Do not reuse the used test card
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results
3. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases
4. Do not open the sealed pouch unless ready to conduct the assay. Once opened, the cassettes should be used within 3 minutes
5. Do not use expired devices
6. Bring all reagents to room temperature (15°C-30°C) before use
7. Do not use the components in any other type of test kit as a substitute for the components in this kit
8. Do not mix components from different kit lots
9. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19
10. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled

GLOSSARY OF SYMBOL

EC REP	Authorized Representative in the European Community	CE	CE mark European Conformity		Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing		Tests per Kit		Keep away from sunlight
	Store between		Use By or Expiration Date		Do not reuse	CONT	Content of the kit
	Manufacturer	IVD	For in vitro Diagnostic use only		Do Not Use If Damaged		Keep Dry

STORAGE AND STABILITY

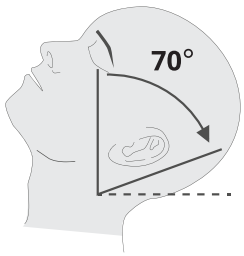
1. Store the PathoCatch'" COVID-19 Ag Card test at 2-30°C. The product is stable up to 24 months from date of manufacturing
2. After aluminum foil bag is unsealed, the test card should be used immediately. Open pack storage of unsealed cassette/ card is not recommended
3. For specimen stability, once the nasal swab specimen is collected in extraction solution, it is stable only up to one hour

SPECIMEN COLLECTION AND PREPARATION

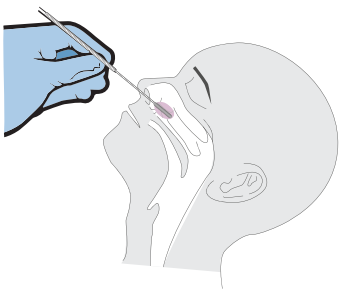
When collecting any type of sample, follow universal collection precautions and guidelines according to your organization. For specimen collection of nasal swabs, follow the Centers for Disease Control and Prevention (CDC) Swab Collection Guidelines or from other academic bodies of repute.

The steps that follow apply to a nasal swab. Please refer to the Limitations section of this Product Insert.

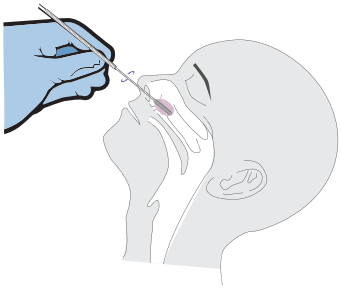
SAMPLING FROM A NASAL SWAB:



1. Tilt patient's head back 70°



2. A swab sample is needed from both nostrils and this is taken using the same swab. While gently rotating the swab, insert swab less than one inch into the first nostril until resistance is met at Turbinates. (Turbinates are the small structures inside the nose).



3. Rotate the swab 10 times against the nasal wall. Remove and repeat this process by using the same swab into the second nostril. Then place the Swab into the Extraction Vial. See instructions for Sample Extraction.

LIMITATION OF THE PROCEDURE

1 This reagent is only used for in vitro diagnosis

2 This reagent is only used for qualitative detection and cannot indicate the level of novel coronavirus antigen in the specimen

3 This reagent is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail

4 Failure to follow the test procedure and interpretation of test results may be adversely affect test performance and produce invalid result

5 A negative result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained

6 A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of COVID-19 infection and should be confirmed by viral culture or an molecular assay or ELISA

7 Positive result, do not rule out co infections with other pathogen

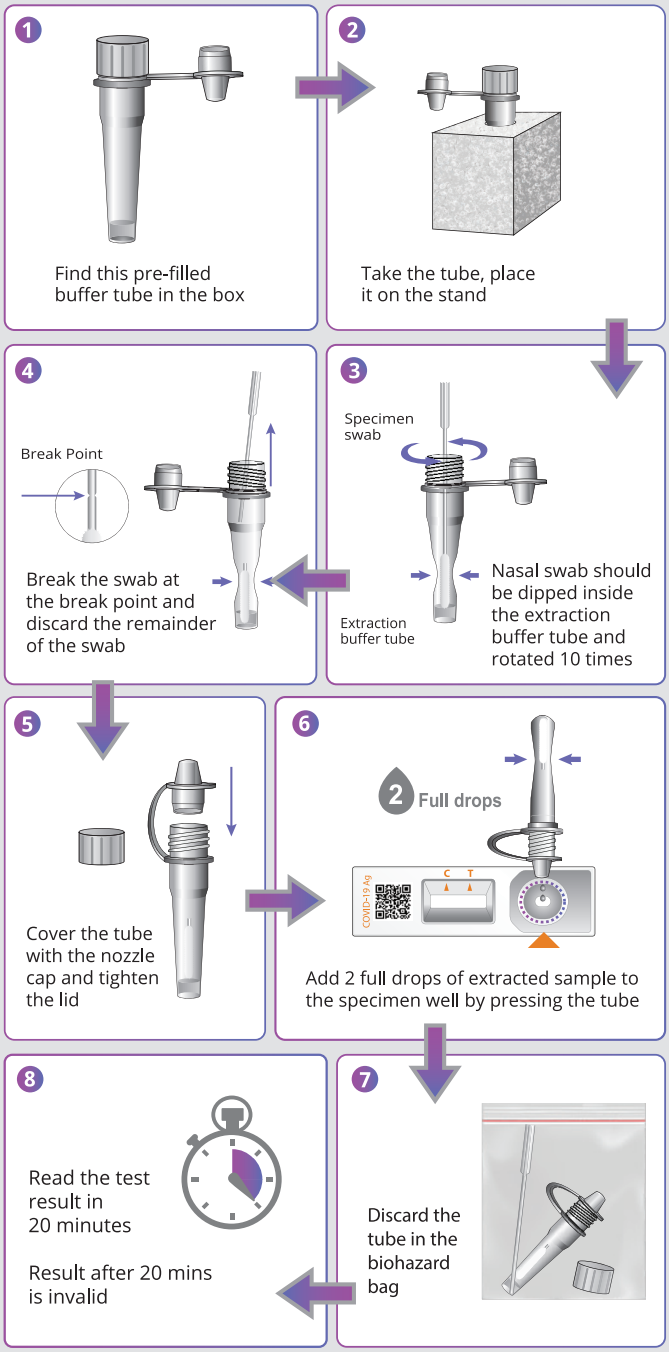
8 For more accuracy of immune status additional follow up testing using other laboratory method is recommended

SAMPLE TEST PROCEDURE - 8 SIMPLE STEPS

Please read the manual and the instrument operation manual carefully before use

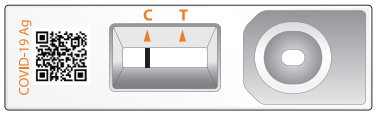
1. Find the Pre-filled buffer tube and remove it out of the box and tap vertically on the horizontal surface, to make sure that the extraction buffer settles at the bottom of the tube
2. Take the tube and place it on the stand provided along with the kit
3. Remove the cap and take patient nasal swab and dip in the pre-filled extraction tube and swirl 10 times ensuring the swab is immersed well in the extraction buffer
4. Find the Break point of the swab and by pressing with your thumb break the swab at the break point and discard the remainder of the swab. Mix well. Please ensure the extracted sample is Mucous Free
5. Cover the tube with nozzle cap and tighten the lid
6. Open the pouch containing the test device. DO NOT leave the test device unused once opened for more than 3 minutes. Add 2 full drops of mucous free of extracted antigen buffer mixture into the sample well of the test device, by pressing the tube, and wait for 15 mins for the results to appear
7. Discard the tube properly as per biohazard disposal rules. **All components of this kit should be discarded as Biohazard waste according to the local regulatory requirements**

8 Read the results within 20 minutes. Strong positive results can be reported within 10-15 minutes. However wait up to 20 minutes to report negative results. Results after 20 minutes are no longer valid.

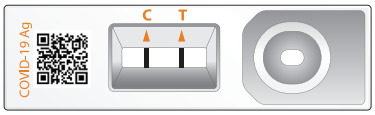


INTERPRETATION OF ASSSAY RESULT

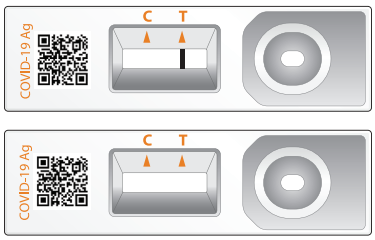
1 NEGATIVE RESULT: If there is only a quality control line C, the detection line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative



2 POSITIVE RESULT: If both the quality control line C and the detection line appear, novel coronavirus antigen has been detected and the result is positive for antigen



3 INVALID: If the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure below) and the test shall be conducted again. Kindly read the results within 20 minutes after addition of 2 full drops of extracted antigen buffer mixture



PERFORMANCE CHARACTERISTICS

Clinical Performance:

The performance of the PathoCatch™ COVID-19 Antigen lateral flow device was established with 554 nasal swabs prospectively collected and enrolled from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. All specimens within a pre-specified date range were selected and then sequentially tested in a blinded fashion. External control testing, using PathoCatch™ COVID-19 Ag Card Positive and Negative Controls, was performed prior to sample testing each day.

The performance of the PathoCatch™ COVID-19 Antigen lateral flow device was compared to results of a nasopharyngeal or oropharyngeal swab stored in 3 mL viral transport media tested with EUA RT-PCR test for detection of SARS-CoV-2.

Table 1: Overall Performance of PathoCatch™ COVID-19 Antigen lateral flow device compared to RT-PCR

PathoCatch™ COVID-19 Ag Test	Comparator EUA RT-PCR test		
	Positive	Negative	Total
Positive	92	-	92
Negative	8	454	462
Total	100	454	554
PPA	92/100 (92%)		
NPA	454/454 (100%)		
OPA	546/554 (98.5%)		
PPV	92/92 (100%)		
NPV	454/462 (98.26%)		

PPA: Positive Percent Agreement = True Positives / True Positives + False Negatives
NPA: Negative Percent Agreement = True Negatives / True Negatives + False Positives.
OPA: Overall Percent Agreement = True Positives + True Negatives / Total Samples
PPV: Positive Predictive Value = True Positives / True Positive + False Positive
NPV: Negative Predictive Value = True Negatives / True Negative + False Negative

Patient Demographics

Patient demographics (age and time elapsed since onset of symptoms) are available for the 554 samples used in the analysis. (Table 2 and 3)

Table 2: Positive results broken down by age of the patient:

Age	PathoCatch™ COVID-19 Antigen Lateral flow card		
	Total	# Positive	Prevalence
< 5 years	0	0	NA
6 to 21 years	116	10	8.6%
22 to 59 years	342	62	18.13%
≥60 years	96	20	20.83%

Table 3: The Positive results broken down by days since symptom onset:

Post symptom onset day (POD)	Cumulative RT-PCR positives	Cumulative PathoCatch™ COVID-19 Ag positives	PositivePercent Agreement (PPA)
0	0	0	NA
1	8	8	100
2	14	14	100
3	30	30	100
4	48	48	100
5	70	66	94.28
6	88	82	93.18
7	100	92	92.00

Further data were analyzed to better understand the correlation of PathoCatch™ COVID-19 Antigen Lateral card test performance to the cycle threshold of RT PCR, estimating the viral titer present in the clinical sample As presented in the Table 4, the positive agreement of the PathoDatect™ COVID-19 Ag Card is higher with samples of a Ct count <34.

Table 4: PathoCatch™ COVID-19 Ag Card Performance against the Comparator Method – by Cycle Threshold Counts

PathoCatch™ COVID-19 Ag Test	Comparator Method	
	Positive (<34 Ct)	Positive (≥34 Ct)
Positive	60	32
Negative	2	6
Total	62	38
Positive Agreement (%)	**96.77**	**84.21**

ANALYTICAL PERFORMANCE

1. Limit of Detection:

The Limit of Detection (LoD) of PathoCatch™ COVID-19 Antigen lateral flow test device was determined using limiting dilutions of heat-inactivated SARS-CoV-2 (bei Resources NR-52286). Negative natural nasal swab specimens were eluted in Phosphate buffer saline (PBS). Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as a diluent. Inactivated SARS-CoV-2 virus is diluted in clinical matrix pool to generate virus dilutions for testing. Contrived nasal swab samples were prepared by absorbing approximately 50 microliters of each virus dilution onto the swab and were tested according to the kit insert.

For initial LOD screening, Tenfold serial dilutions of the heat inactivated virus were made in clinical matrix pool and tested in triplicates. Based on this testing, the concentration chosen for LoD calculation was 3.40 x10^2 TCID50/mL.with nasal swab matrix.

For precise LoD determination, Twofold serial dilutions were made starting from 3.40 x10^2 TCID50/mL till 21.25 TCID50/ml concentration in clinical matrix pool and tested with a total of 20 replicates per concentration with PathoCatch™ COVID-19 Antigen Lateral Flow Test Device.

Analytical sensitivity (LOD) of PathoCatch™ COVID-19 Antigen Lateral Flow Test Device was found to be 85 TCID50/ml at 95% confidence interval with nasal swab specimens.

Concentration TCID50/ml	Number positives/Total	% Hit rate
85	19/20	95

2. Cross reactivity (Analytical specificity) and microbial interference:

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms, Protein Basic Local Alignment Search Tool (BLAST) analysis of antigen sequence from PathoCatch™ COVID-19 Antigen Lateral Flow Test Device were performed against public domain protein sequences with default settings with no or low identity with other organisms.

Further, cross reactivity and potential interference of PathoCatch™ COVID-19 Antigen Lateral Flow Test Device was evaluated by wet testing against normal and pathogenic organisms that may be present in the nasal cavity. Each of the organism, viruses, and yeast were tested in the absence or presence of heat inactivated SARS-CoV-2 virus. No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration of 106 cfu/mL for bacteria and yeast, and 105 pfu/mL for viruses. Wet testing could not be performed for some organism enlisted below due to unavailability of pathogens.

Table 1: Organisms tested for cross reactivity and microbial interference study

Other high priority pathogens from the same virus family	**Wet testing for cross reactivity and microbial interference**	**In silico protein BLAST analysis**
Human coronavirus 229E	✓	✓
Human coronavirus 0C43	✓	✓
Human coronavirus HKU1	✓	✓
Human coronavirus NL63	✓	✓
SARS-coronavirus	✓	✓
MERS-coronavirus	✓	✓
High priority organisms likely in the circulating area		
Adenovirus (e.g. C1 Ad. 71)	X	✓
Human Metapneumovirus (hMPV)	X	✓
Parainfluenza virus 1-4	✓	✓
Influenza A and B	✓	✓
Enterovirus (e.g. EV68)	✓	✓
Respiratory syncytial virus	X	✓
Rhinovirus	X	✓
Chlamydia pneumonia	X	✓
Haemophilus influenza	✓	✓
Legionella pneumophila	X	✓
Mycobacterium tuberculosis	✓	✓
Streptococus pneumonia	✓	✓
Streptococcus pyrogenes	✓	✓
Bordetella pertussis	✓	✓
Mycoplasma pneumonia	✓	✓
Pneumocystis jirovecii (PJP)	X	✓
Pooled human nasal wash - to represent diverse microbial flora in the human respiratory tract	✓	X
Influenza C	X	✓
Parechovirus	X	✓
Candida albicans	X	✓
Corynebacterium diphtheria	X	✓
Legionella non-pneumophila	✓	✓
Bacillus anthracosis (Anthrax)	X	✓
Moraxella cararrhalis	X	✓
Neisseria elongate and miningitidis	X	✓
Pseudomonas aeruginosa	✓	✓
Staphylococcus epidermis	✓	✓
Staphylococcus salivarius	X	✓
Leptospirosis	✓	✓
Chlamydia psittaci	X	✓
Coxiella burneti (Q-Fever)	X	✓
Streptococcus aureus	✓	✓

3. High Dose Hook Effect

No high dose hook effect was observed when tested with highest concentration of 3.40X 10^5 TCID50/ml of inactivated SARS-CoV-2 virus with PathoCatch™ COVID-19 Antigen Lateral Flow device.

4. Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the PathoCatchTM COVID-19 Antigen Lateral Flow device at the concentrations listed below and were found not to affect test performance.

Substance	**Active ingredient**	**Concentration**
Endogenous	Mouth Wash	2% w/v
	Whole blood	1% v/v
OTC Nasal drops	Phenylephrine	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Sore Throat Phenol Spray	Phenol	15% v/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
Antibacterial, Systemic	Tobramycin	0.0004% w/v
Antiviral drug	Zanamivir	0.5% w/v
Antiviral drug	Oseltamivir Phosphate	0.5% w/v

5. Point of Care:

Testing was performed by operators with no laboratory experience and who are representative of the intended users at CLIA waived testing sites. Testing was conducted by five intended users. No training on the use of the test was provided to the operators. One nasal swab was tested directly in the PathoCatch™ Ag Card test according to product instructions and the other swab was eluted in viral transport media (VTM) and sent for EUA RT-PCR as a comparator test. Swabs were tested by operators who were blinded to the RT-PCR test result for PathoCatch™ COVID-19 Antigen Lateral flow test. The performance of PathoCatch™ COVID-19 Ag test was established with 100 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

PathoCatch COVID-19 Ag test by non-laboratory personnel	**Comparator EUA RT-PCR test**		
	Positive	**Negative**	**Total**
Positive	29	0	29
Negative	1	70	71
Total	30	70	100

% Positive Agreement =29/30*100=96.66%

% Negative Agreement= 70/70*100=100%

Ct value in RT-PCR was ≈35 for positive sample missed by PathoCatch™, indicating it may be due to low viral load for Ag test and not due to operator handling.

Mylab Discovery solutions

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Now track every Test Card details with unique QR code

PathoCatch™
COVID-19 Ag LATERAL FLOW TEST DEVICE

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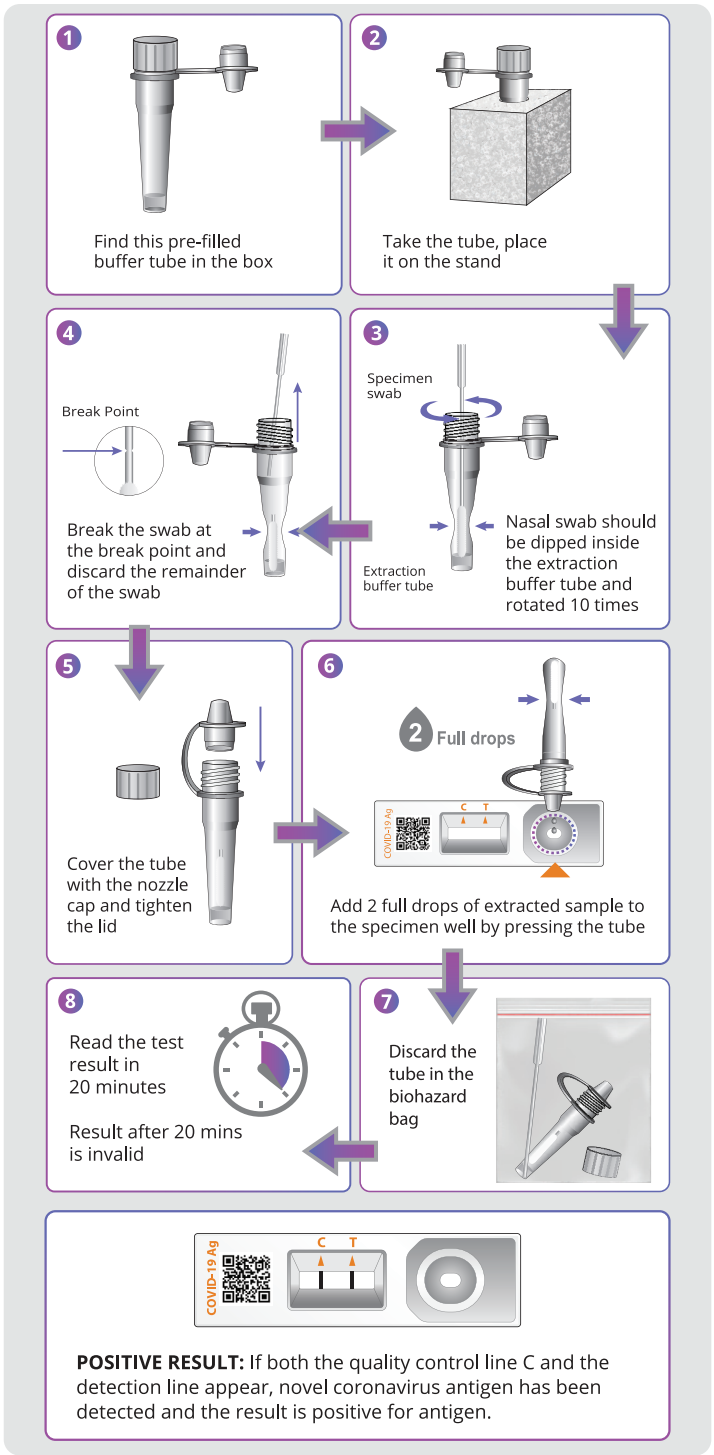
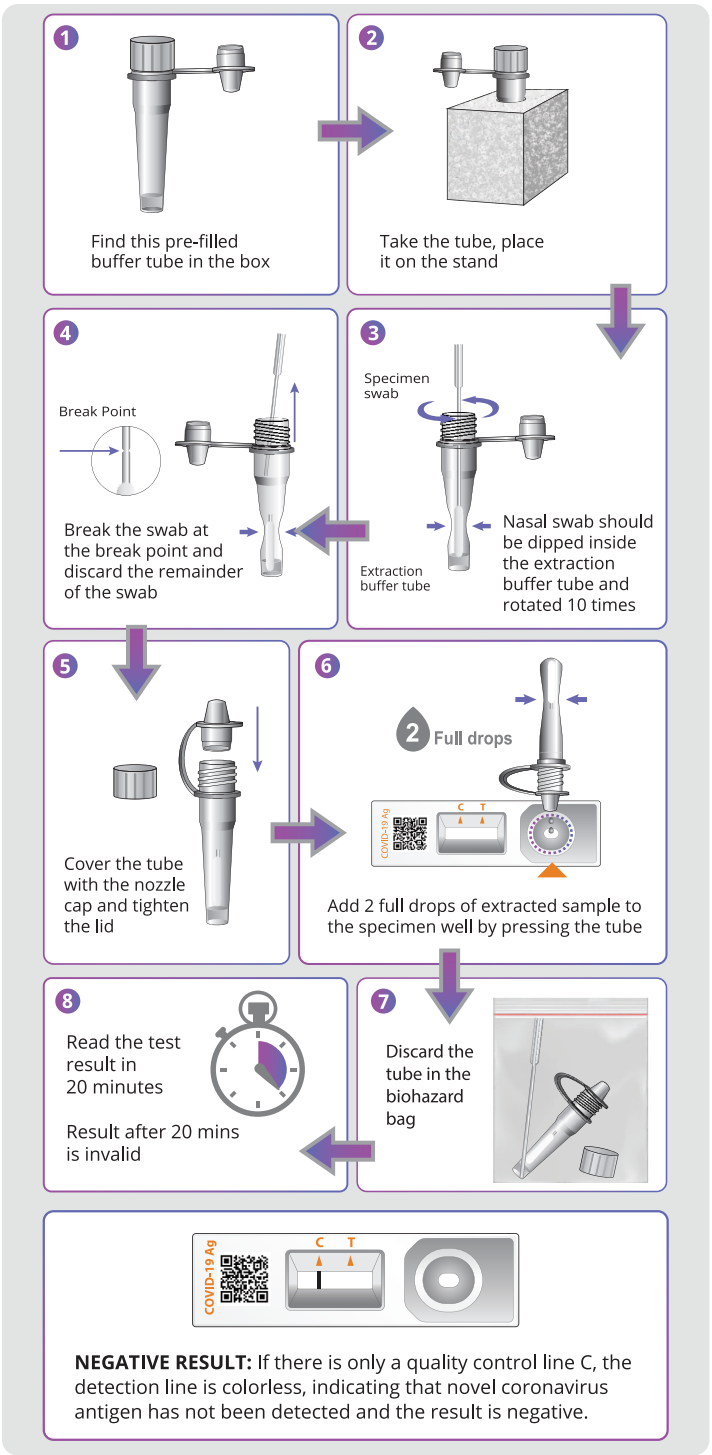
QUALITY CONTROL

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. PathoCatch™ COVID-19 Ag Card kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups or your lab's standard Quality Control procedures.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.





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