OnSite® COVID-19 + Influenza A/B Ag Rapid Test

REF R0188C CE

10108903

Barcode for RTR use only

Instructions for Use

INTENDED USE

The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test is a lateral flow immunoassay for the simultaneous qualitative detection and differentiation of SAR-CoV2, Influenza A, and/or Influenza B viral antigens directly from anterior nasal or nasopharyngeal swab specimens taken by a healthcare provider from individuals who are suspected of a respiratory viral infection, within the first seven days of symptom onset.

The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test can detect SARS-CoV-2, including variants of concern and dominant influenza virus strains A/2009 H1N1, A/H3N2, B/Victoria lineage, B/Yamagata lineages, and others. Performance characteristics may vary against other emerging influenza strains. This test is not intended to detect Influenza C antigens.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary for determination of infection status and patient management decisions. Positive results do not rule out other bacterial or viral infections.

Negative results from patients with symptom onset beyond seven days should be confirmed with a molecular assay. Negative results do not rule out 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, and the presence of clinical signs and symptoms consistent with COVID-19 and/or Influenza A/B.

The product is intended to be used in any laboratory or non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulations. For *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION OF THE TEST

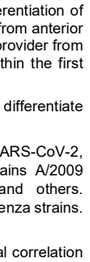
SARS-CoV-2 belongs to the broad family of coronaviruses which are capable of causing COVID-19-related illnesses ranging from the common cold to more severe diseases[1]. Up to November 2022, the WHO has reported over six hundred million confirmed cases of COVID-19 globally, including over six million deaths[2].

Influenza A/B is a contagious respiratory illness caused by influenza A/B viruses that infect the nose, throat, and sometimes the lungs[3-5]. It can cause mild to severe illness, and at times can lead to death.

Both COVID-19 and influenza A/B have similar symptoms with varying degrees ranging from no symptoms (asymptomatic), to severe symptoms[6]. Differentiating these two viral infections with a laboratory rapid test is helpful for the correct treatment[7-9].

The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test detects the presence of antigens from SARS-CoV-2, Influenza A and Influenza B virus within the first seven days of the onset of symptoms. Test results should be interpreted after 15 minutes. Results should not be interpreted after 20 minutes. Minimally skilled personnel can perform the test without the use of cumbersome laboratory equipment.

TEST PRINCIPLE



The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a colored conjugate pad containing anti-SARS-CoV-2, anti-Flu B, and anti-Flu A antibodies conjugated with colloidal gold (antibody conjugates) and 2) a nitrocellulose membrane strip containing 3 test lines (COVID-19 Ag (C-19), Flu B Ag (B) and Flu A Ag (A) lines), and a control line (C line). The C-19 line is pre-coated with anti-SARS-CoV-2 antibody , the B line is pre-coated with anti-Influenza B antibody, and the A line is pre-coated with anti-Influenza A antibody. The C line is pre-coated with control antibody.

The specimen is collected with either a nasopharyngeal or a nasal swab, and the SARS-CoV-2, Influenza B, and Influenza A nucleocapsid antigens are extracted from the swab with extraction buffer.

When applied to the sample well, the antigen extracts will migrate by capillary action across the test strip. SARS-CoV-2 antigen, if present in the sample, will bind to the antibody conjugates. The immunocomplex will be captured on the membrane by the pre-coated anti-SARS-CoV-2 antibodies, forming a colored C-19 line, indicating a COVID-19 positive test result. Absence of the C-19 line indicates a negative COVID-19 result. Influenza B antigen, if present in the sample, will bind to the antibody conjugates. The immunocomplex will be captured on the membrane by the pre-coated anti-Influenza B antibodies, forming a colored B line, indicating an Influenza B positive test result. The absence of the B line suggests a negative Influenza B result. Influenza A antigen, if present in the sample, will bind to the antibody conjugates. The immunocomplex will be captured on the membrane by the pre-coated anti-Influenza A antibodies, forming a colored A line, indicating Influenza A positive test result. The absence of the A line suggests a negative Influenza A result.

The absence of all test lines (C-19, B, and A) suggests a negative result. Each strip test contains an internal control (C line) which should exhibit a colored line regardless of color development on the test lines (C-19, B, and A). If no C line develops, the test result is invalid and the test must be repeated.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette
   b. One desiccant
2. Sealed pouch containing pre-filled extraction tubes
3. Extraction tube nozzles
4. Extraction tube rack
5. Individually sealed pouches containing a sterile swab
6. Instructions for Use

MATERIALS MAY BE REQUIRED BUT NOT PROVIDED

1. Positive control
2. Negative control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock, watch or other timing device
2. Disposable gloves, biohazard disposal container

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use

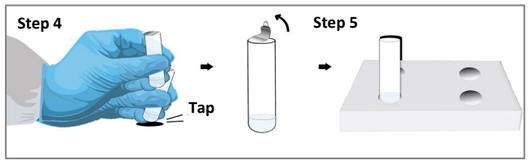
1. Read these Instructions for Use completely before performing the test. Failure to follow these instructions could lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired tests.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after testing.
7. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
8. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
9. Handle negative and positive controls in the same manner as patient specimens.
10. Read test results 15 minutes after specimen is applied to the sample well. Consider any results read after 20 minutes invalid and repeat test.
11. Do not perform the test in a room with strong air flow, i.e., an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze or expose the kit to temperatures above 30°C.

PREPARATION FOR ASSAY PROCEDURE

1. Before running the assay, ensure that the test area is sanitized. Open the kit and ensure that all materials described in "Reagents and Materials Provided" are included and intact, and that the kit is not expired. Obtain a timing device (clock, watch, or timer) and read these Instructions for Use carefully.
2. Wash or sanitize hands thoroughly and put on gloves.
3. Fold/assemble the sample extraction tube rack.
4. Remove one pre-filled extraction tube from the sealed pouch and close the pouch with the unused tubes. Hold the pre-filled extraction tube upright. Before opening the tube, tap the bottom of the tube on a clean, flat surface to ensure that any liquid on the seal moves down into the tube.



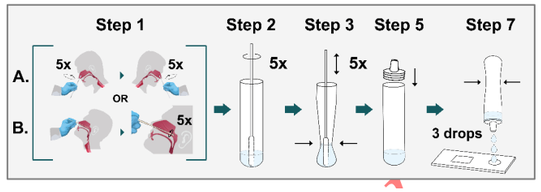
5. Carefully remove the foil seal from the extraction tube and place the open tube in the extraction tube rack provided with the kit.

SAMPLE COLLECTION AND ASSAY PROCEDURE

Consider any materials of human origin as potentially infectious, and handle them with standard biosafety procedures.

1. **Collect Specimens following a procedure for A) Nasal swab specimens, or B) Nasopharyngeal swab specimens.**

   Reference image below for sample collection of each specimen type and assay procedure.



A) <u>Nasal swab specimens</u>

A1. Remove mucus from the patient's nose.

A2. Hold the patient's head in a vertical position and looking slightly downwards (see Figure A).

A3. Open the swab package. Do not touch the swab's absorbent tip. Be sure to open the package on the opposite end of the absorbent tip.

A4. Carefully insert the entire absorbent tip of the swab in one nostril. Do not insert the swab any deeper if you feel strong resistance (no more than 2 cm into the nose). Rotate the swab at least 5 times, ensuring that the absorbent tip of the swab presses against the nasal wall.

A5. Remove swab from nostril and using the same swab, repeat step A4 in the other nostril.

A6. Withdraw the swab from the nasal cavity.

B) <u>Nasopharyngeal swab specimens</u>

B1. Remove mucus from the patient's nose.

B2. Hold the patient's head in a vertical position and looking slightly upwards (see Figure B above).

B3. Open the swab package. Do not touch the swab's absorbent tip. Be sure to open the package on the opposite end of the absorbent tip.

B4. Carefully insert the entire absorbent swab tip into the patient's nostril that presents the most secretion, keeping it near the nose septum floor while gently pushing into the posterior nasopharynx.

B5. Rotate the swab at least 5 times.

B6. Withdraw the swab from the nasal cavity

2. Insert the absorbent tip of the swab into the extraction buffer tube and swirl the swab at least 5 times.
3. Squeeze the tube against the submerged swab several times to transfer the sample into the liquid.
4. Remove the swab while squeezing the tube against the swab. Dispose the swab into a biohazard disposal container.
5. Place the nozzle onto the extraction tube and ensure it is firmly attached.
6. Remove the cassette device from the sealed pouch just prior to testing. Lay the device on a clean, flat surface and label it with the specimen ID/name.
7. Invert and gently squeeze the sample extraction tube to add 3 drops of specimen into the sample well of the test cassette one drop at a time .
8. Set the timing device for 15 minutes.
9. Read the results after 15 minutes.

Note: Results might be visible after a shorter time, however, they should only be interpreted between 15-20 minutes after dispensing the sample material onto the test cassette.

10. Collect all used items (swab, cassette, sample extraction tube, foil seal, nozzle, and used gloves) and discard as biohazardous waste following local laws governing the disposal of devices.

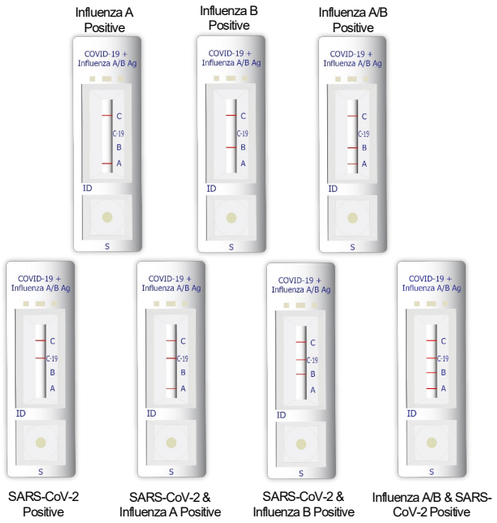
<u>Assay Procedure for VTM specimens</u>

To test specimens stored in VTM, follow "**Preparation for Assay Procedure**" section, then pipet 300µl of the VTM specimen into the extraction tube, pipet up and down 5 times to mix and proceed to step 5 of "**Sample Collection and Assay Procedure**" section above.

INTERPRETATION OF ASSAY RESULTS

1. **NEGATIVE RESULT:** If only the C line develops, the test indicates no detectable Influenza or COVID-19 antigens in the specimen. The result is negative or non-reactive.

2. **POSITIVE RESULTS:** If both the C line and any of the test lines develop, Influenza viral antigens and/or COVID-19 virus antigen is detected in the specimen. The result is positive or reactive. Some specimens might produce a faint band, but every visible test line band indicates a positive result independent of the band intensity.



3. **INVALID RESULTS:** If no C line develops, the assay is invalid for that test, regardless of color development on any of the test lines. The test must be repeated.

QUALITY CONTROL

1. **Internal Control**: This test contains a built-in control feature, the C line. If the C line does not develop after sample application, the result is invalid. Review the entire procedure and repeat the test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to ensure the proper performance of the assay, particularly under the following circumstances:
   a. At regular intervals, following local requirements and regulations.
   b. A new operator uses the kit.
   c. A new lot or a new shipment of test kits is used.
   d. The temperature during storage of the kits falls outside of 2-30°C.
   e. The temperature of the test area falls outside of 15-30°C.
   f. To verify a frequency of positive or negative results higher than expected.
   g. To investigate the cause of repeated invalid results.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance Characteristics

1.1. COVID-19 Ag Clinical performance in nasopharyngeal swab specimens

The clinical performance of the COVID-19 Ag test was evaluated at five clinical sites in Asia and South America, in nasopharyngeal (NP) swabs specimens collected from subjects suspected of COVID-19 and from healthy individuals. Two NP swabs were collected from each subject, one for COVID-19 Ag Test and the other one for testing by commercially available real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2, used as the reference method for this study. The overall performance of the COVID-19 Ag test in this study is shown on the table below:

RT-PCR Test (Reference)	COVID-19 Ag Test Result		
	Positive	Negative	Total
Positive	103	11	114
Negative	0	487	487
Total	103	498	601

Relative Sensitivity: 90.4% (95% CI: 83.4-95.1%); Relative Specificity: 100% (95% CI: 99.3-100%); Overall Agreement: 98.2% (95% CI: 96.8-99.1%)

1.2. COVID-19 Ag Clinical performance in nasal swab specimens

The clinical performance of the COVID-19 Ag test was evaluated at five clinical sites in Europe, Asia and South America, in nasal swab specimens collected from subjects suspected of COVID-19 and from healthy individuals. Two swabs were collected from each subject, one nasal swab for the COVID-19 Ag test and one NP swab for testing by commercially available real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2, used as the reference method for this study. The combined performance of the COVID-19 Ag test in these studies is shown on the table below:

RT-PCR Test (Reference)	COVID-19 Ag Rapid Test Result		
	Positive	Negative	Total
Positive	155	15	170
Negative	2	523	525
Total	157	538	695

Relative Sensitivity: 91.2% (95% CI: 86.0-94.6%); Relative Specificity: 99.6% (95% CI: 98.6-99.9%); Overall Agreement: 97.6% (95% CI: 96.1-98.5%)

1.3. Influenza Ag Clinical performance

A total of 798 respiratory specimens were tested by the Influenza A/B Ag Rapid Test and by Immuno-fluorescent assay (IFA) as the reference assay. The performance of the Influenza A/B Ag Rapid Test in this test is shown on the table below:

	Influenza A/B Ag Rapid Test		
IFA	**Positive**	**Negative**	**Total**
Positive	186	31	217
Negative	35	546	581
Total	221	577	798

Relative Sensitivity: 85.7% (95% CI: 80.4-89.7%), Relative Specificity: 94.0% (95% CI: 91.7-95.6%), Overall Agreement: 91.7% (95% CI: 89.6-93.4%)

A total of 1395 culture specimens were tested by the Influenza A/B Ag Rapid Test. The performance of the Influenza A/B Ag Rapid Test in this test is shown on the table below:

	Influenza A/B Ag Test		
Cell Culture	**Positive**	**Negative**	**Total**
Positive	436	40	476
Negative	48	871	919
Total	484	911	1395

Relative Sensitivity: 91.6% (95% CI: 88.8-93.8%), Relative Specificity: 94.8% (95% CI: 93.1-96.0%), Overall Agreement: 93.7% (95% CI: 92.3-94.9%)

2. Analytical Performance

2.1. Analytical Sensitivity (Limit of Detection, LoD)

The LoD of the *OnSite* COVID-19 + Influenza A/B Ag Rapid Test was determined by evaluating a serial dilution of SARS-Related Coronavirus 2 (SARS-CoV-2), Influenza A and Influenza B viruses. Multiple negative nasal swab specimens were eluted in extraction buffer, then combined and mixed thoroughly to create clinical negative matrix pools for each matrix to be used as the diluent. Virus lysates were diluted in each of these matrices to generate virus dilutions for testing. Each nasal swab was spiked with 50 µL of each virus dilution, extracted with extraction buffer and tested according to the product IFU. The assay LoD was determined nasal swab specimens as the lowest concentration that was detected ≥ 95% of the time in the respective specimen matrix.

The LoD of the *OnSite* COVID-19 + Influenza A/B Ag Rapid Test for each virus in nasal swab matrices was listed below:

Viral Strain	LOD ($TCID_{50}$/mL)	% Positive
SARS-Related Coronavirus 2 (SARS-CoV-2) Culture Fluid (USA-WA1/2020)	6.3×10^{2}	100%
Influenza A/California/7/2009 H1N1 (California/07/09)	7.5×10^{1}	100%
Influenza A/Hong Kong/2671/2019 H3N2 Fluid (HongKong/2671/19)	2.1×10^{3}	100%
Influenza B/Washington/02/2019 Victoria lineage (Washington/02/19)	8.4×10^{2}	100%
Influenza B/Phuket/3073/2013 Yamagata lineage (Phuket/3073/13)	1.48×10^{1}	100%

The LoD of the *OnSite* COVID-19 + Influenza A/B Ag Rapid Test in nasopharyngeal swab matrix is similar to the LoD in nasal swab matrix.

2.2 Strain Reactivity with SARS-CoV-2 and Influenza A/B Viruses

The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test can detect the Alpha (U.K.), Beta (South Africa), Gamma (Brazil), Delta (India), Eta (Nigeria), Iota (USA), Kappa (India), Lambda (Peru), P.2 (Brazil), B.1.620, and all recent omicron variants at similar levels as the original SARS-CoV-2 strain[10].

Strain reactivity of the *OnSite* COVID-19 + Influenza A/B Ag Rapid Test was evaluated for multiple different Influenza strains. Each strain was diluted and tested in triplicate until a point where not all of the replicates were detected as positive. The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test can detect at least 11 Influenza A H1N1, 14 H3N2, H3N1, H5N1, 7 Influenza B Victoria Lineage, 5 Influenza B Yamagata Lineage strains.

3. Analytical Specificity (Cross-Reactivity and Microbial Interference)

The analytical specificity of the *OnSite* COVID-19 + Influenza A/B Ag Rapid Test was evaluated by testing commensal and pathogenic microorganisms that may be present in the nasal cavity. Each of the organisms were tested in triplicate in the absence or presence of 3X LoD SARS-CoV-2 and Influenza A/B inactivated viruses. No cross-reactivity or microbial interference were observed with the following microorganisms when tested at the concentrations presented in the table below:

Potential Cross-Reactant	Concentration	Cross-Reactivity (Yes/No)	Microbial Interference (Yes/No)
Human coronavirus 229E	21.9µg/ml	Yes (3/3 positive)	No (3/3 positive)
Human coronavirus OC43	3.16×10^{6} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Human coronavirus NL63	1.41×10^{5} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
MERS-coronavirus	2.5µg/ml	No (3/3 negative)	No (3/3 positive)
SARS-coronavirus	2.5µg/ml	No (3/3 negative)	No (3/3 positive)
Adenovirus (e.g., C1 Ad. 71)	7×10^{7} NIU/ml	No (3/3 negative)	No (3/3 positive)
Human Metapneumovirus (hMPV)	1.55×10^{4} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus 2	1.6×10^{6} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus 3	1.6×10^{7} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus 4	1.15×10^{6} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Influenza A	12.6µg/ml	No (3/3 negative)	No (3/3 positive)
Influenza B	11.2µg/ml	No (3/3 negative)	No (3/3 positive)
Enterovirus	2.8×10^{6} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Respiratory syncytial virus	2.8×10^{4} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Rhinovirus	2.2×10^{6} PFU/ml	No (3/3 negative)	No (3/3 positive)
Haemophilus influenzae	5.2×10^{7} CFU/ml	No (3/3 negative)	No (3/3 positive)
Streptococcus pneumoniae	2×10^{4} CFU/ml	No (3/3 negative)	No (3/3 positive)
Candida albicans	4.5×10^{7} $TCID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Pooled human nasal wash – *representative of normal respiratory microbial flora*	N/A	No (3/3 negative)	No (3/3 positive)
Bordetella pertussis	3.9×10^{7} CFU/ml	No (3/3 negative)	No (3/3 positive)
Mycoplasma pneumoniae	4.4×10^{7} CFU/ml	No (3/3 negative)	No (3/3 positive)
Chlamydophila pneumoniae	1.4×10^{7} IFU/ml	No (3/3 negative)	No (3/3 positive)
Legionella pneumophila	7.8×10^{6} CFU/ml	No (3/3 negative)	No (3/3 positive)
Staphylococcus aureus	1.38×10^{7} CFU/ml	No (3/3 negative)	No (3/3 positive)
Staphylococcus epidermidis	9.27×10^{6} PFU/ml	No (3/3 negative)	No (3/3 positive)
Influenza C	2.1×10^{6} $CEID_{50}$/ml	No (3/3 negative)	No (3/3 positive)
Mycobacterium tuberculosis	>2×104 CFU/ml	No (3/3 negative)	No (3/3 positive)
Pneumocystis jirovecii (PJP)	3.45×106 CFU/ml	No (3/3 negative)	No (3/3 positive)
Human Coronavirus HKU1	66 µg/ml	No (3/3 negative)	No (3/3 positive)

4. Interfering Substances

The following potentially interfering substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with *OnSite* COVID-19 + Influenza A/B Ag Rapid Test at the concentrations listed in the following table and were found not to affect test performance for detection of both positive and negative specimens:

Interfering Substance	Concentration	Interference (Yes/No)	Interfering Substance	Concentration	nterference (Yes/No)
Whole Blood	7%	No (6/6 correct)	Dextromethorphan	0.11 µg/mL	No (6/6 correct)
Menthol	5.6g/ml	No (6/6 correct)	Mucin protein	17.5 mg/mL	No (6/6 correct)
Saline	15%	No (6/6 correct)	OTC Nasal Drops (Phenylephrine)	15% v/v	No (6/6 correct)
Acetylsalicylic Acid	21 mg/dL	No (6/6 correct)	OTC Nasal Gel (Sodium Chloride)	14%	No (6/6 correct)
Zanamivir	2 mg/mL	No (6/6 correct)	OTC Nasal Spray (Fluconazole)	7%	No (6/6 correct)
Budesonide	44.1 ng/mL	No (6/6 correct)	Throat Lozenge (Benzocaine, Menthol)	1%	No (6/6 correct)
Ribavirin	7 mg/mL	No (6/6 correct)	Antibiotic, Nasal Ointment (Mupirocin)	0.25%	No (6/6 correct)
Oseltamivir	15.4 µg/mL	No (6/6 correct)	Afrin (Oxymetazoline)	15% v/v	No (6/6 correct)
Diphenhydramine	5.4 µg/mL	No (6/6 correct)	CVS Nasal Spray (Cromolyn)	15% v/v	No (6/6 correct)
Homeopathic (Alkalol)	1:10 Dilution	No (6/6 correct)	Zicam	5% v/v	No (6/6 correct)
Fluticasone Propionate	5% v/v	No (6/6 correct)			

5. Hook Effect

No high dose hook effect was observed with the *OnSite* COVID-19 + Influenza A/B Ag Rapid Test up to at least 1000X the LoD of the test, corresponding to 3×10^{7} $TCID_{50}$/mL of inactivated SARS-CoV-2, 1×10^{4} $TCID_{50}$/mL Influenza A or 6.9×10^{5} $TCID_{50}$/mL Influenza B viruses.

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 and Influenza A/B virus antigens in the swab specimens from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may lead to inaccurate results.
2. The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test is limited to the qualitative detection of SARS-CoV-2, Influenza A and Influenza B viral antigens. The intensity of the test line does not have linear correlation with virus titer in the specimen.
3. Sensitivity can differ with various strains of SARS-CoV-2 or Influenza due to differences of antigen expression. Specimens might contain a new or non-identified strain of SARS-CoV-2 or Influenza that expresses varying amounts of antigen.
4. Individuals who have received nasally administered Influenza vaccine might have positive test results for up to three days after vaccination[10,11].
5. A negative or non-reactive result for an individual subject indicates absence of detectable of SARS-CoV-2 antigen, Influenza A viral antigens, and Influenza B viral antigens. However, a negative or non-reactive result does not preclude the possibility of SARS-CoV-2, Influenza A, or Influenza B virus infection.
6. A negative or non-reactive result can occur if the quantity of the SARS-CoV-2 virus (antigen) or Influenza A and B virus present in the specimen is below the detection limit of the assay, or if the virus detected was not present in the swab specimen sampled, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.
7. The *OnSite* COVID-19 + Influenza A/B Ag Rapid Test detects both viable and non-viable SARS-CoV-2, Influenza A, and Influenza B antigens. Test performance depends on antigen load in the sample. A positive test does not rule out the possibility that other pathogens may be present.
8. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
9. Performance of the *OnSite* COVID-19 + Influenza A/B Ag Rapid Test has been validated in specimens stored in multiple viral transport media (VTM). However, specimens stored in PBS or saline solutions should not be tested on the *OnSite* COVID-19 + Influenza A/B Ag Rapid Test.
10. Performance of the test has not been established for monitoring antiviral treatment of SARS-CoV-2 infection or influenza.

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Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ_N	Tests per kit
2°C 30°C	Store between 2-30°C	EC REP	Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

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