BD Kit For Rapid Detection of SARS-CoV-2

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English

REF 256091 BD Kit for Rapid Detection of SARS-CoV-2, 30 Test
REF 256113 BD Kit for Rapid Detection of SARS-CoV-2, 1 Test
REF 256114 BD Kit for Rapid Detection of SARS-CoV-2, 5 Test

INTENDED USE

The BD Kit for Rapid Detection of SARS-CoV-2 is a chromatographic immunoassay intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swabs from individuals who are without symptoms, or with symptoms, who are suspected of SARS-CoV-2 infection by their healthcare provider.

Visually read results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

The BD Kit for Rapid Detection of SARS-CoV-2 is intended for use in point of care settings for home use / self-test, and by healthcare professionals or trained users specifically instructed in the use of the BD Kit for Rapid Detection of SARS-CoV-2 and proper infection control procedures.

SUMMARY AND EXPLANATION OF THE TEST

A novel coronavirus (2019-nCoV) was identified in December 2019[1], which has resulted in hundreds of millions of confirmed human infections worldwide. Cases of severe illness and deaths have been reported. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

The median incubation time is estimated to be approximately 5 days[2] with symptoms estimated to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, and shortness of breath.

PRINCIPLES OF THE PROCEDURE

When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to detector particles in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by lines of antibodies bound on the membrane.

REAGENTS

The following components are included in the BD Kit for Rapid Detection of SARS-CoV-2.

Materials Provided:

KIT COMPONENT	QUANTITY			DESCRIPTION
	256091	256113	256114	
BD Kit for Rapid Detection of SARS-CoV-2 System Test Devices	30 single use test devices	1 single use test device	5 single use test devices	Foil pouched test device containing one reactive strip. Each strip has one line of murine anti-SARS coronavirus monoclonal antibody on the test line, and one of biotin coupled to bovine protein on the positive control line. Murine and Leporine anti-SARS coronavirus and anti-biotin monoclonal antibodies conjugated to detector reagents are bound in the sample delivery area.
Extraction Reagent	30 single use reaction tubes, each with 325 µL extraction reagent and having an integral dispensing tip	1 single use reaction tube, with 325 µL extraction reagent and having an integral dispensing tip	5 single use reaction tubes, each with 325 µL extraction reagent and having an integral dispensing tip	Detergent solution with less than 0.1% sodium azide (preservative).
Specimen sampling swabs	30 sterile, single use specimen sampling swabs	1 sterile, single use specimen sampling swab	5 sterile, single use specimen sampling swabs	For sample collection and transfer.

Materials Provided (continued):

KIT COMPONENT	QUANTITY			DESCRIPTION
	256091	256113	256114	
SARS-CoV-2 (+) Control Swab	1 each – individually wrapped for single use	None	None	Non-infectious, recombinant viral protein antigen with less than 0.1% sodium azide.
SARS-CoV-2 (–) Control Swab	1 each – individually wrapped for single use	None	None	Buffer with less than 0.1% sodium azide.
Assay documentation	1 each - Instructions for use 1 each - Quick reference instruction card 1 each - Nasal sampling instructions	1 each - Instructions for use	1 each - Instructions for use	

Materials Required But Not Provided:

- Timer
- Tube rack for specimens
- Any necessary personal protective equipment

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use. Do not reuse the test device or kit components.
2. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
3. Do not use this kit beyond the expiration date printed on the outside carton.
4. Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.
5. Do not mix components from different kits or from other BD diagnostic assays, even if they look similar.
6. Kit components, other than the swabs used for specimen collection, should not make contact with the patient.
7. Proper specimen collection, handling, and processing are critical to the performance of this test.
8. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
9. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.
10. The SARS-CoV-2 positive control swabs have been prepared from recombinant viral proteins and do not contain infectious material.
11. Dispose of used BD Kit for Rapid Detection of SARS-CoV-2 test devices and reagents as biohazardous waste in accordance with federal, state, and local requirements.
12. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. If there is contact with skin, wash immediately with plenty of water. Contact with acids produces very toxic gas.
13. BD Kit for Rapid Detection of SARS-CoV-2 test devices used in a laminar flow hood or in areas with high air flow should be covered during test development to ensure proper sample flow.
14. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at bd.com.

STORAGE

Kits must be stored at 2–30 °C.

SPECIMEN COLLECTION AND HANDLING

Specimen Collection and Preparation

Acceptable specimens for testing with this kit include nasal swab specimens obtained by the dual nares collection method. It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after 5 days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/ or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Nasal Swab Specimen Collection

NOTE: The BD Kit for Rapid Detection of SARS-CoV-2 includes swabs for nasal specimen collection. When collecting a nasal swab sample, use the nasal swab supplied in the kit.

1. Insert swab into one nostril of the patient. The 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 that both mucus and cells are collected.
2. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
3. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the BD Kit for Rapid Detection of SARS-CoV-2.

DO'S AND DON'TS OF SPECIMEN COLLECTION

- Use only swabs provided with the kit.
- Do test sample immediately and always within 1 hour of collection.

For laboratory support for COVID-19 in the EU/EEA, visit https://www.ecdc.europa.eu/en/novel-coronavirus/laboratory-support.

Outside the United States, refer to applicable guidelines from other national or local authorities.

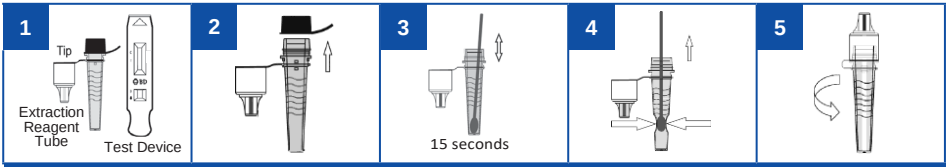
TEST PROCEDURE

Reagents, specimens and devices must be at room temperature (15–30 °C) for testing.

Getting ready to test

Once the nasal swab has been collected from the nostrils, the swab must be processed within 1 hour.

Procedural steps for Nasal Swabs or control swabs:



1
- Remove one extraction reagent tube/tip and one BD Kit for Rapid Detection of SARS-CoV-2 test device from its foil pouch immediately before testing.
- Label one test device and one extraction reagent tube for each specimen or control to be tested.
- Place the labeled extraction reagent tube(s) in a rack in the designated area of the workspace.

2 Remove and discard the cap from the extraction reagent tube.

3 Insert the swab into the tube and plunge the swab up and down in the fluid for a minimum of 15 seconds, taking care not to splash contents out of the tube.

4 Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

5 Press the attached tip firmly onto the extraction reagent tube containing the processed sample (threading or twisting is not required). Mix thoroughly by swirling or flicking the bottom of the tube.

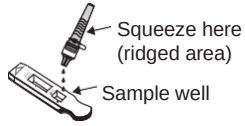
Once the swab has been processed in the extraction reagent and the tube has been capped, the sample must be added to the test device within 30 minutes.

TEST EXECUTION

6 **Adding the specimen to the test device**

- Invert the extraction reagent tube and hold it vertically (approximately 1 inch above the sample well).
- Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.

NOTE: Squeezing the tube too close to the tip may cause leakage.



7 **Timing development**

- Allow the test to develop for **15 minutes**.

Caution: incorrect results may occur if development time is less than 15 minutes. Some lines may appear on the device sooner.

- If running test under laminar flow hood, cover test device to avoid inconsistent flow.

INTERPRETATION OF RESULTS

When the test is ready, elevate the device, if necessary, to a position where the device reading window is optimally positioned for user visualization. Slowly tilt the device back and forth to remove unnecessary glare.

Examine the device reading window for the visual presence of lines in the Control (C), Test (T) and Non-specific (N) regions.

Examples of Valid Test Results are listed below:

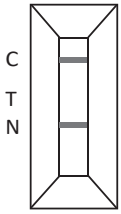
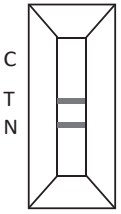
Negative		Positive	
 Control Line Only	Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.	 Control Line and Test Line	Positive for the detection of SARS-CoV-2 antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Record result. Properly dispose of test device. Do not re-read test devices.

Invalid test results: Invalid tests should be repeated

There are six possible invalid test results

The test is invalid due to the presence of a Non-specific line or absence of a Control line.
The test must be repeated. If the result is still invalid, the specimen cannot be interpreted.

Invalid	Invalid	Invalid	Invalid	Invalid	Invalid
					
Test line only	Control line and Non-specific line	Test line and Non-specific line	Non-specific line only	No lines	All 3 lines

QUALITY CONTROL

Each BD Kit for Rapid Detection of SARS-CoV-2 test device contains both positive and negative internal/procedural controls:

- The internal positive Control line (C) validates the immunological integrity of the device, proper reagent function, and assures correct test procedure.
- The N line (Non-specific line) functions as a background line looking for possible assay interferants. If visible, the result is invalid.

EXTERNAL POSITIVE AND NEGATIVE CONTROLS

Positive and Negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test reagents perform as expected. Prepare kit control swabs and test using the same procedure as used for patient specimens.

BD recommends controls be run once for:

- each new kit lot,
- each new operator,
- as required by internal quality control procedures and in accordance with local and national regulations or accreditation requirements.

If the kit controls do not perform as expected, do not report patient results. Contact your local BD representative.

LIMITATIONS OF THE PROCEDURE

- Users should test specimens as quickly as possible after specimen collection, within 1 hour after specimen collection and within 30 minutes of placing the swab into the extraction reagent.
- Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.
- This BD Kit for Rapid Detection of SARS-CoV-2 is only intended for nasal swab specimens that are collected and tested directly (i.e., swabs that have NOT been placed in transport media). The kit includes a pre-diluted processing reagent in a ready to use "unitized" tube. This kit IS NOT INTENDED for testing liquid samples such as wash or aspirate samples or swabs in transport media as results can be compromised by over dilution.
- Results from the BD Kit for Rapid Detection of SARS-CoV-2 test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.
- Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab specimens only and are only intended to be used with the other contents of this kit. The BD Kit for Rapid Detection of SARS-CoV-2 can detect both viable and non-viable SARS-CoV-2 material.
- The BD Kit for Rapid Detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
- This device has been evaluated for use with human specimen material only.
- The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern.
- The validity of the BD Kit for Rapid Detection of SARS-CoV-2 test has not been proven for identification/ confirmation of tissue culture isolates and should not be used in this capacity.

CLINICAL PERFORMANCE

The performance of the BD Kit for Rapid Detection of SARS-CoV-2 has been demonstrated in two studies. The first study is evaluated performance in symptomatic individuals and the second study assessed performance in asymptomatic individuals.

Study 1

In the symptomatic study, clinical performance of a visually-read assay was established with 319 direct nasal swabs prospectively collected and enrolled from individual symptomatic patients who were suspected of COVID-19 (within 5 days of onset of two or more self-reported symptoms). [a] Eligible subjects were 18 years or older and samples were collected by qualified personnel from 21 geographically diverse areas across the United States. Nasal swabs were collected following the dual nares method and handled as described in the collection device instructions for use.

Specimens were frozen within 30 minutes of collection. All specimens within a pre-specified date range were selected and sequentially tested in a blind fashion. The BD Kit for Rapid Detection of SARS-CoV-2 was analyzed by visually reading the test device. The participants were blinded to the comparator result and recorded their observations manually. After every 50 specimens, a different participant performed the visual interpretation. Overall, there were seven different

participants reading the devices. The performance of the BD Kit for Rapid Detection of SARS-CoV-2 was compared to results of a nasopharyngeal swab stored in 3 mL viral transport media tested with an Emergency Use Authorized molecular (RT-PCR) test for detection of SARS-CoV-2.

[a] Symptoms included: new loss of taste or smell, fever, shortness of breath or difficulty breathing, diarrhea, GI upset, headache, extreme tiredness, fatigue, weakness, dry cough, sore throat, runny or stuffy nose, nasal congestion, muscle aches, body aches, chills, repeated shaking with chills.

Table 1: Summary of the Performance of the BD Kit System for Rapid Detection of SARS-CoV-2 Compared to RT-PCR for Nasal Swabs in Symptomatic Individuals.

	Reference PCR Results		
BD Visual Results	POS	NEG	Total
POS	51	1	52
NEG	5	262	267
Total	56	263	319

PPA: 91.1% (C.I. 80.7%–96.1%)
NPA: 99.6% (C.I. 97.9%–99.9%)
OPA: 98.1% (C.I. 96.0%–99.1%)
PPV: 98.1% (C.I. 90.7%–99.9%)
NPV: 98.1% (C.I. 96.0%–99.4%)

Study 2

In the asymptomatic study, performance was established with 370 direct nasal swabs prospectively collected and enrolled from individual asymptomatic patients who were receiving testing for COVID-19. Eligible subjects were all ages and samples were collected by qualified personnel from 3 geographically diverse outpatient clinics in the United States. Nasal swabs were collected following the dual nares method and handled as described in the collection device instructions for use. Specimens were stored frozen within 30 minutes of collection and stored until tested. All specimens within a pre-specified date range were selected and then sequentially tested in a blinded fashion. The BD Kit for Rapid Detection of SARS-CoV-2 was analyzed by visually reading the test device. Each device was read visually by a participant. The participant was blind to the comparator results. Overall, there were five different participants reading the devices. The performance of the BD Kit for Rapid Detection of SARS-CoV-2 was compared to results of a nasal swab stored in 3 mL viral transport media tested with an Emergency Use Authorized molecular (RT-PCR) test for detection of SARS-CoV-2. Using the cycle threshold (Ct) from the comparator assay, performance is presented overall and by Ct≤33 to demonstrate that positive agreement of the assay is higher with samples below this threshold. A lower Ct value corresponds to higher virus concentrations, therefore Ct value can be a surrogate for the amount of virus present in the sample. A Ct threshold of Ct≤33 was chosen due to evidence suggesting that patients with Ct value >30 are no longer contagious.[3,4,5]

Table 2: Summary of the Performance of the BD Kit for Rapid Detection of SARS-CoV-2 Compared to RT-PCR for Nasal Swabs in Asymptomatic Individuals.

	Reference PCR Results		
BD Visual Results	POS	NEG	Total
POS	13	2	15
NEG	7	348	355
Total	20	350	370

OPA: 97.6% (C.I. 95.4%–98.7%)
PPV: 86.7% (C.I. 64.8%–98.5%)
NPV: 98.0% (C.I. 96.7%–99.1%)

Table 3: Summary of the Performance of the BD Kit for Rapid Detection of SARS-CoV-2 Compared to RT-PCR for Nasal Swabs in Asymptomatic Individuals Categorized by Ct cutoffs.

Overall PPA	Ct≤33 PPA	Overall NPA
65.0% (C.I. 43.3%–81.9%)	72.2% (C.I. 49.1%–87.5%)	99.4% (C.I. 97.9%–99.8%)

EXPLANATION OF TERMS:
C.I. : Confidence Interval
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 Positives + False Positives)
NPV: Negative Predictive Value = True Negatives / (True Negatives + False Negatives)

ANALYTICAL PERFORMANCE

The BD Kit for Rapid Detection of SARS-CoV-2 test device is produced by an identical process as the BD Veritor™ System for Rapid Detection of SARS-CoV-2, however the devices are interpreted differently. The BD Kit for Rapid Detection of SARS-CoV-2 is interpreted visually whereas the BD Veritor™ System for Rapid Detection of SARS-CoV-2 is interpreted by the BD Veritor™ Plus Analyzer system. Because the devices are functionally the same, the analytical validation data generated for the validation of BD Veritor™ System for Rapid Detection of SARS-CoV-2 also applies to the BD Kit for Rapid Detection of SARS-CoV-2 visual read assay.

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

The LOD for the BD Veritor™ System for Rapid Detection of SARS-CoV-2 was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The material was supplied at a concentration of 2.8×10^5 $TCID_{50}$/mL. In this study, designed to estimate the LOD of the assay when using a direct nasal swab, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 50 µL samples were added to swabs and then tested in the BD Veritor™ assay using the procedure appropriate for patient nasal swab specimens. A concentration was chosen between the last dilution to give three positive results and the first to give three negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

Starting Material Concentration	Estimated LOD	No. Positive/Total	% Positive
2.8×10^5 $TCID_{50}$/mL	1.4×10^2 $TCID_{50}$/mL	19/20	95%

Limit of detection of the visual read was established in two studies. One with two experienced operators and one with eleven inexperienced operators. The inexperienced users had varying education, age, gender and healthcare backgrounds, however, none had experience with the BD Veritor™ System or any BD lateral flow assay. Serial dilutions of gamma irradiated virus were prepared in nasal fluid. The samples were randomized and read by the BD Veritor™ Plus Analyzer at 15 minutes and then read visually by different operators using blinded samples. In both analytical studies, the limit of detection of the visual read was determined to be one 2-fold dilution higher than the BD Veritor™ Plus Analyzer with an acceptance criteria of ≥95% detection. These studies showed that the instruments can consistently detect slightly fainter lines than a human.

CROSS-REACTIVITY (ANALYTICAL SPECIFICITY)

Cross-reactivity of the BD Veritor™ System for Rapid Detection of SARS-CoV-2 was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the BD Veritor™ System for Rapid Detection of SARS-CoV-2. Each organism and virus was tested in triplicate. The final concentration of each organism is documented in the following table. This data was determined using the instrumented BD Veritor™ System for Rapid Detection of SARS-CoV-2 assay.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E (heat inactivated)	1.0×10^5 U/mL	No
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No
Adenovirus	1.0×10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	5.2×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4	1.6×10^4 $TCID_{50}$/mL	No
Influenza A	2.5×10^5 $TCID_{50}$/mL	No
Influenza B	2.9×10^5 $TCID_{50}$/mL	No
Enterovirus	4.0×10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	4.0×10^5 $TCID_{50}$/mL	No
Rhinovirus	1.1×10^5 PFU/mL	No
SARS-coronavirus	4.5×10^5 PFU/mL	No
MERS-coronavirus	1.5×10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	1.4×10^6 CFU/mL	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
Streptococcus pyogenes	1.6×10^6 CFU/mL	No
Candida albicans	1.8×10^6 CFU/mL	No
Pooled human nasal wash	100%	No
Bordetella pertussis	1.4×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No
Chlamydia pneumoniae	1.0×10^6 IFU/mL	No
egionella pneumophila	1.0×10^6 CFU/mL	No

This data was determined using the instrumented BD Veritor™ System for Rapid Detection of SARS-CoV-2 assay.

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For *P. jirovecii* one area of sequence similarity shows 45.4% homology across 9% of the sequence, making cross-reactivity in the BD Veritor™ sandwich immunoassay highly unlikely.
- No protein sequence homology was found between SARS-CoV-2 and *M. tuberculosis*, and thus homology-based cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 revealed that the only potential for homology is with the HKU1 nucleocapsid phosphoprotein. Homology is relatively low, at 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.

ENDOGENOUS INTERFERING SUBSTANCES

Various substances were evaluated with the BD Veritor™ System for Rapid Detection of SARS-CoV-2. The substances tested included whole blood 4%, mucin and various medications. No interference was noted with the BD Veritor™ System for Rapid Detection of SARS-CoV-2 assay for any of the substances tested.

Substance	Concentration Tested	Interference (Yes/No)
Afrin Nasal Spray (Oxymetazoline)	5% v/v	No
Flonase (Fluticasone)	5% v/v	No
Nasacort (Triamcinolone)	5% v/v	No
Neo-Synephrine (Phenylephrine hydrochloride)	5% v/v	No
Oseltamivir	2.2 µg/mL	No
Mucin protein	2.5 mg/mL	No
Rhinocort (Budesonide)	5% v/v	No
Saline nasal spray	15% v/v	No
Zanamivir	282 ng/mL	No
Zicam Cold Remedy (Galphimia glauca, Luffa operculata, Sabadilla)	5% v/v	No
Whole blood	4% v/v	No
Cepacol (Menthol/Benzocaine)	1.5 mg/mL	No
Ricola (menthol)	1.5 mg/mL	No
Tobramycin	4 µg/mL	No
Sucrets (Dyclonine/Menthol)	1.5 mg/mL	No
NeilMed Naso Gel	5% v/v	No
Zicam nasal spray (Oxymetazoline)	10% v/v	No
Alkalol nasal wash	10% v/v	No
Fisherman's Friend (menthol)	1.5 mg/mL	No
Chloraseptic (Phenol Spray)	15% v/v	No
Mupirocin	10 mg/mL	No

Additionally, the following were tested for interference in a negative and a 3x LOD sample. No interference was noted at the levels tested.

Substance	Concentration Tested	Interference (Yes/No)
Afrin Nasal Spray (Oxymetazoline)	15% v/v	No
Neo-Synephrine (Phenylephrine hydrochloride)	15% v/v	No
Oseltamivir	2.2 µg/mL	No
Mucin protein	5 mg/mL	No
Mupirocin	10 mg/mL	No
Rheumatoid Factor	12.5 IU/mL	No

Note: Based on *in vitro* testing, false positive results cannot be ruled out in patients with rheumatoid factor higher than 12.5 IU/mL in nasal fluid, although it is unclear if such concentrations are clinically relevant.

This data was determined using the instrumented BD Veritor™ System for Rapid Detection of SARS-CoV-2 assay.

Additionally, the following substances were tested and the results interpreted visually. No interference was noted.

Substance	Concentration Tested	Interference (Yes/No)
Whole blood	4% v/v	No
Mucin protein	2.5 mg/mL	No

MICROBIAL INTERFERENCE

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 assay was evaluated with various organisms at the concentrations indicated below. No interference was noted.

Potential Microbial Interferent	Concentration Tested	Interference (Yes/No)
Human coronavirus 229E	1.0×10^5 U/mL	No
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No
Adenovirus	1.0×10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	5.2×10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4a	1.5×10^4 $TCID_{50}$/mL	No
Influenza A	2.5×10^5 $TCID_{50}$/mL	No
Influenza B	2.9×10^5 $TCID_{50}$/mL	No
Enterovirus D68	4.0×10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	4.0×10^5 $TCID_{50}$/mL	No
Rhinovirus 3	1.1×10^5 PFU/mL	No
SARS-coronavirus	4.5×10^5 PFU/mL	No
MERS-coronavirus	1.5×10^5 $TCID_{50}$/mL	No
Haemophilus influenzae	1.4×10^6 CFU/mL	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
Streptococcus pyogenes	1.6×10^6 CFU/mL	No
Bordetella pertussis	1.4×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No
Chlamydia pneumoniae	1.0×10^6 IFU/mL	No
Legionella pneumophila	1.0×10^6 CFU/mL	No
Pooled human nasal wash	N/A	No
Candida albicans	1.8×10^6 CFU/mL	No

This data was determined using the instrumented BD Veritor™ System for Rapid Detection of SARS-CoV-2 assay.

REPRODUCIBILITY

Another study was designed to assess the capability of users to test seeded swab samples across the dynamic range of the assay with eleven (11) users, over two (2) days, using dilution preparations in four (4) separate sessions with a single lot of devices. The following table shows the performance.

Sample	Session No. 1		Session No. 2		Session No. 3		Session No. 4		Total	
	% Positive	95% C.I.	% Positive	95% C.I.	% Positive	95% C.I.	% Positive	95% C.I.	% Positive	95% C.I.
2x LOD	100% (15/15)	(79.6%, 100%)	100% (10/10)	(72.3%, 100%)	100% (15/15)	(79.6%, 100%)	100% (15/15)	(79.6%, 100%)	100% (55/55)	(93.5%, 100%)
1x LOD	100% (15/15)	(79.6%, 100%)	100% (10/10)	(72.3%, 100%)	100% (15/15)	(79.6%, 100%)	100% (15/15)	(79.6%, 100%)	100% (55/55)	(93.5%, 100%)
0.5x LOD	100% (15/15)	(79.6%, 100%)	70% (7/10)	(39.7%, 89.2%)	93.3% (14/15)	(70.2%, 98.8%)	86.7% (13/15)	(62.1%, 96.3%)	89.1% (49/55)	(78.2%, 94.9%)
0.25x LOD	33.3% (5/15)	(15.2%, 58.3%)	20% (2/10)	(5.7%, 51.0%)	33.3% (5/15)	(15.2%, 58.3%)	20% (3/15)	(7.1%, 45.2%)	27.3% (15/55)	(17.3%, 40.2%)
0.125x LOD	0% (0/15)	(0%, 20.4%)	0% (0/10)	(0%, 27.8%)	6.7% (1/15)	(1.2%, 29.8%)	0% (0/15)	(0%, 20.4%)	1.8% (1/55)	(0.3%, 9.6%)
Negative Nasal Fluid	0% (0/15)	(0%, 20.4%)	0% (0/10)	(0%, 27.8%)	0% (0/15)	(0%, 20.4%)	0% (0/15)	(0%, 20.4%)	0% (0/55)	(0%, 6.5%)

HIGH DOSE HOOK EFFECT

No high dose hook effect was observed up to 2.8 x 10^5 $TCID_{50}$/mL of gamma-inactivated SARS-CoV-2 with the BD Veritor™ System for Rapid Detection of SARS-CoV-2 test.

TECHNICAL SUPPORT

Outside the United States, contact your local BD representative.

REFERENCES

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html. Accessed March 30, 2020.
2. https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm
3. CDC. Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance). (2020).
4. CDC. Duration of Isolation and Precautions for Adults with COVID-19. (2020).
5. Bullard, et al. Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples. CID. 2020; Nov 15;71 (10); DOI:10.1093/cid/ciaa638

CHANGE HISTORY

Revision	Date	Change Summary
01	2021-08	Initial release for Taiwan.

SYMBOLS GLOSSARY	
LOT	Batch code
	Biological risks
REF	Catalogue number
	Caution
	Contains sufficient for <*n*> tests
	Positive control
	Negative control
	Date of manufacture
	Do not re-use
	Fragile, handle with care
IVD	*In vitro* diagnostic medical device
	Manufacturer
	Recyclable
	Temperature limit
	This way up
	Use-by date

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