

# FREND™ COVID-19 Ag+FLU A&B

Qualitative assay for COVID-19 Nucleocapsid protein,  
Influenza A&B Nucleoprotein

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**REF** FRCGFL 020

**IVD** For *in vitro* diagnostic use only

## Intended use

The FREND™ COVID-19 Ag+FLU A&B is an *in vitro* diagnostic medical device based on fluorescence immunoassay (FIA) for use with the FREND™ System. It is designed for the qualitative detection of the nucleocapsid protein of SARS-CoV-2 and nucleoprotein of Influenza A and B strains directly from nasopharyngeal swab specimens from individuals suspected with novel coronavirus disease 2019 (COVID-19) or/and flu by their healthcare provider.

## Principle of the assay

FREND™ COVID-19 Ag+FLU A&B is a single-use fluorescence immunoassay (FIA) kit that can detect the presence of the nucleocapsid protein of SARS-CoV-2 and nucleoprotein of Influenza A&B in nasopharyngeal swab specimen via sandwich immunoassay. The lysis buffer extracts virus from the swab specimen and releases viral proteins. Within FREND™ COVID-19 Ag+FLU A&B cartridge, the released target proteins are captured and detected by antibodies conjugated to fluorescent micro-particles. The FREND™ System analyzes fluorescence intensity of control zone for validity of the test zone for the presence of the nucleoproteins and displays the result on the screen after about 4 minutes of process.

## Material provided

Q'ty	Contents	Catalogue number
20	Test cartridges	FRCGFL 020
20	Lysis tubes	
20	Filter dropper with a specimen cup	
20	Disposable pipette tip	
20	Disposable sterile nasopharyngeal swabs*	
01	Influenza A&B Positive control swab	
01	COVID-19 Ag Positive control swab	
01	Negative control swab	
01	Code chip	
01	Package insert	

## Product description manufactured by other companies\*

**Product name:** Disposable sterile nasopharyngeal swab (Sterile flocked swab)

**Model name:** NFS-1

**Manufacturer:** Noble Bioscience Inc.

**Certificate:** CE marked (Class IIa) under the supervision of Notified Body 2292

**EC REP:** S.B Pharma GmbH (Address: Max-Planck Str. 39a D-50858, Köln, Germany / Tel. +49-(0)2234-988-1521 / Fax. +49(0)-2234-988-1523)

**Description:** Disposable sterile nasopharyngeal swab is a sterile flocked swab, it is intended to collect specimens in the nasal cavity of patients being suspected of any disease. This is a single-use device and sterilized by gamma irradiation sterilization process.

## Warning and Precautions

- The FREND™ COVID-19 Ag+FLU A&B cartridges are intended for *in vitro* diagnostic use only.
- The FREND™ COVID-19 Ag+FLU A&B cartridges are only to be used on the NanoEntek FREND™ System.
- The FREND™ COVID-19 Ag+FLU A&B cartridges and Lysis tubes are disposable, single use devices. Do not reuse them under any circumstances.
- Allow sealed cartridges and Lysis tubes to come to room temperature for 15-30 minutes prior to use.
- Cartridges and Lysis tubes should not be frozen.
- Assure the humidity in the laboratory is in the 10-80% range when tests are run.
- Avoid cross-contamination between samples by using a new pipette tip for each new specimen.
- Avoid high humidity, direct sunlight or heat when storing cartridges and Lysis tubes.
- Inaccurate results are possible if the sample used is contaminated in any way.
- Inadequate pipetting or inappropriate use of the fixed volume pipette may occur insufficient or excessive volume of lysed specimen into the cartridge which may affect test results.
- Discard and do not use any damaged or dropped cartridges.
- Do not use the cartridge after the expiration date on the pouch.
- Do not use the cartridge if the pouch is damaged or the seal is broken.
- Do not use Lysis tube if leakage is found.
- Perform testing as specified in the package insert and the user manual.
- Inadequate or inappropriate sample collection, storage, and transport may bring false test results.
- Use only the provided swab for specimen collection.
- Keep the cartridge sealed in the pouch until ready to use.
- Use the cartridge immediately after opening the pouch.
- For professional use only.
- Use Universal Precautions when handling all specimens and controls. Wear disposable gloves when handling the cartridges and the samples.
- Wash hands thoroughly and often after handling reagent cartridges or samples.
- Do not ingest the silica gel packet found in the cartridge pouch.
- Do not bend cartridges.

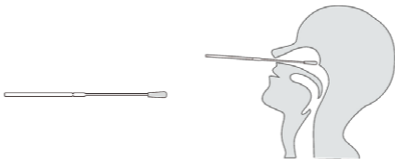
## Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at refrigerator temperature storage (2-8 °C). Reagent stability has been demonstrated for twelve months from the date of manufacture. The expiration date is clearly indicated on the product box and the cartridges.

## Specimen collection and handling

### Nasopharyngeal swab

- (1) Tilt patients' head back 70°.
- (2) Open nasopharyngeal swab in the FREND™ COVID-19 Ag+FLU A&B kit.
- (3) Carefully insert flexible shaft through nares parallel to palate (not upwards) until resistance is met, or distance is equivalent to half the distance from the patient's ear to their nostril.
- (4) Gently rub and roll the swab several times.
- (5) Leave the swab in place for several seconds to absorb secretions.
- (6) Slowly remove the swab as rotating it.



## Procedure

### Code chip installation

A lot-specific Code chip is supplied with each kit of FREND™ COVID-19 Ag+FLU A&B. When using a new lot of reagent, the Code chip of the same lot must be installed in the FREND™ System. Please refer to the FREND™ System User manual for more detailed instructions relative to the Code chip installation. Abbreviated instructions are as follows:

- (1) Insert the FREND™ System electrical cord into an appropriate outlet.
- (2) Insert the Code chip into the Code chip slot at the rear of the system following the arrows.
- (3) Press the 'Setup' button on the 'Main' screen.
- (4) Press the 'Code chip' button on the 'Setup' screen.
- (5) The information embedded on the FREND™ COVID-19 Ag+FLU A&B Code chip is automatically saved on the FREND™ System.
- (6) When the Code chip installation is completed, press the 'OK' button to go back to the 'Setup' screen.
- (7) Press the 'Item' button on the 'Setup' screen.
- (8) Click the FREND™ COVID-19 Ag+FLU A&B cartridge and check the installed lot number and the installation date of the Code chip.
- (9) Press the 'Home' button to go to the 'Main' screen to begin running external quality control and specimen swabs.

### Specimen processing

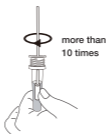
Allow the sealed pouches containing the FREND™ COVID-19 Ag+FLU A&B cartridges and lysis tubes to come to room temperature for 15-30 minutes prior to use. Collected specimens are used immediately and do not store.

## Assay procedure



### STEP 01.

Put the swab from which the specimen was collected into the lysis tube.



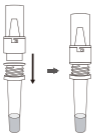
### STEP 02.

Stir the swab up and down more than 10 times to dissolve its content in the lysis buffer.



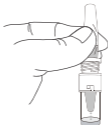
### STEP 03.

Remove liquid from the swab as much as you can, and dispose the used swab in bio-hazardous waste.



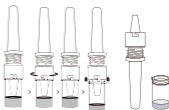
### STEP 04.

Gently push the filter dropper with a specimen cup against the lysis tube and close it tight.



### STEP 05.

Invert the lysis tube and gently squeeze the lysis tube until all the specimen solution inside the lysis tube is dropped and collected in the specimen cup.



### STEP 06.

Separate the specimen cup that is tight with lysis tube and the filter dropper by rotating counterclockwise. Take off the lysis tube from the specimen cup. Dispose the lysis tube in biohazard waste and leave the specimen cup for the next step.



### STEP 07.

Take 35µL of a sample from the specimen cup using a pipette.



### STEP 08.

Load the sample into the cartridge inlet.



### STEP 09.

Insert the cartridge into the FRENDS™ System.

- (1) Take out one lysis tube and one filter dropper and remove the cap of the tube by rotation.
- (2) Put the swab from which the specimen was collected into the lysis tube following the procedure according to “Specimen collection and sampling”.
- (3) Stir the swab up and down more than 10 times to dissolve its content in the lysis buffer.
- (4) Remove the swab riding the sides of the tube wall to remove liquid absorbed in the swab.
- (5) Discard the used swab in biohazard waste.
- (6) Gently push the filter dropper with a specimen cup against the lysis tube and close it tight.

**⚠ Note : Do not rotate and remove the specimen cup attached on the dropper. It is required to be attached for the following procedures.**

- (7) Invert the lysis tube and gently squeeze the lysis tube until all the specimen solution inside the lysis tube dropped and collected in the specimen cup.
- (8) Separate the specimen cup that is tight with lysis tube and the filter dropper by rotating counterclockwise. Take off the lysis tube from the specimen cup. Dispose the lysis tube in biohazard waste and leave the specimen cup for the next step.
- (9) Take 35  $\mu$ L of a sample from the specimen cup using a pipette.
- (10) Load the sample into the cartridge inlet.
- (11) Press the ‘Test’ button on the ‘Main’ screen of the FRENDS™ System.
- (12) The system moves to the Patient ID screen automatically.
- (13) Type the Patient ID and press the ‘Enter’ button to begin the test.
- (14) Insert the cartridge into the cartridge slot using the cartridge arrows as a guide.

**⚠ Caution: Please check the direction of the cartridge before insertion and assure the insertion is complete.**

**⚠ Caution: Please insert the cartridge into the FRENDS™ System after loading the sample into the cartridge.**

- (15) When the reaction in the cartridge is complete, the FREND™ System will automatically begin the reading.
- (16) After the reaction ends, cartridge will be ejected and the result will be displayed and saved.
- ⚠ Caution: Do not remove power from the FREND™ System while a cartridge is in the reading chamber. This may cause a system error.**
- (17) If the FREND™ System is connected to the printer (optional), press 'Print' button and the result will be printed out.
- (18) For more detailed instructions, please refer to the 'FREND™ System User manual'.

## Quality Control

Control swabs are intended to be used as quality control samples that represent influenza A&B positive, SARS-CoV-2 positive and negative control swab samples. These controls can be used to validate the FRENDS™ COVID-19 Ag + FLU A&B reagents and the FRENDS™ System.

The control swabs can be run to:

- Train the operator
- Demonstrate the integrity of the kit when the lot has changed or the new shipment has made.
- Conform to the regulations or the requirements by Local, State and Federal implementation.

Each box of FRENDS™ COVID-19 Ag + FLU A&B contains three control swabs as below,

- 1x Influenza A&B positive control swab
- 1x COVID-19 Ag positive control swab
- 1x Negative control swab


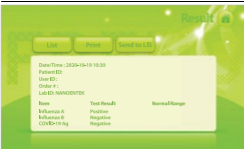
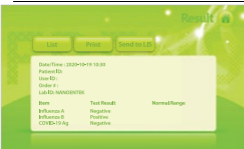
The control swabs in this kit should be tested using the “Assay procedure” described in this package insert. The Influenza A&B positive control swab contains both influenza A and influenza B antigen, and COVID-19 Ag positive control swab contains SARS-CoV-2 antigen. Negative control swab is the matrix-only which is used for base of both influenza and COVID-19 Ag positive control swab except it does not contain relative antigens.

The following test results should be shown the same using the indicated control swab to pass the QC test.

Influenza A&B positive control swab		COVID-19 Ag positive control swab		Negative control swab	
Influenza A	“Positive”	Influenza A	“Negative”	Influenza A	“Negative”
Influenza B	“Positive”	Influenza B	“Negative”	Influenza B	“Negative”
COVID-19 Ag	“Negative”	COVID-19 Ag	“Positive”	COVID-19 Ag	“Negative”

Do not perform patient tests or report patient test results if the QC fails after the repeat.

## Display and Interpretation of results

Displayed result	Description												
 <p>The screenshot shows a green-themed interface with a 'Result' header. At the top are buttons for 'List', 'Print', and 'Send to LIS'. Below is a patient information box with fields for Date/Time, Patient ID, User ID, Order #, and Lab ID. A table displays the test results:</p> <table border="1"><thead><tr><th>Item</th><th>Text Result</th><th>Normal Range</th></tr></thead><tbody><tr><td>Influenza A</td><td>Negative</td><td></td></tr><tr><td>Influenza B</td><td>Negative</td><td></td></tr><tr><td>COVID-19 Ag</td><td>Negative</td><td></td></tr></tbody></table>	Item	Text Result	Normal Range	Influenza A	Negative		Influenza B	Negative		COVID-19 Ag	Negative		<p>Influenza A : "Negative" Influenza B : "Negative" COVID-19 Ag : "Negative" → Negative result on the presence of SARS-CoV-2 nucleocapsid protein and the presence of Influenza nucleoproteins.</p> <p><b>Note :</b> <i>Negative result does not rule out false negative. Negative results from patients with symptoms should be treated as presumptive and confirmation with a molecular assay may be performed.</i></p>
Item	Text Result	Normal Range											
Influenza A	Negative												
Influenza B	Negative												
COVID-19 Ag	Negative												
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Item	Text Result	Normal Range											
Influenza A	Positive												
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Item	Text Result	Normal Range											
Influenza A	Negative												
Influenza B	Positive												
COVID-19 Ag	Negative												

Result

List Print Send to LIS

Date/Time : 2020-10-10 10:33  
 PatientID :  
 UserID :  
 Order # :  
 LabID: MANDENTEX

Item	Test Result	Normal Range
Influenza A	Negative	
Influenza B	Negative	
COVID-19 Ag	Positive	

Influenza A : “Negative”  
 Influenza B : “Negative”  
 COVID-19 Ag : “Positive”  
 → Positive result on the presence of nucleocapsid protein from SARS-CoV-2.

**Note** : A positive result does not rule out co-infections with other pathogens.

Result

List Print Send to LIS

Date/Time : 2020-10-10 10:33  
 PatientID :  
 UserID :  
 Order # :  
 LabID: MANDENTEX

Item	Test Result	Normal Range
Influenza A	Positive	
Influenza B	Negative	
COVID-19 Ag	Positive	

Influenza A : “Positive”  
 Influenza B : “Negative”  
 COVID-19 Ag : “Positive”  
 → Positive results on the presence of nucleoprotein from Influenza A strain and nucleocapsid protein from SARS-CoV-2.

**Note** : A positive result does not rule out co-infections with other pathogens.  
 Co-infection with Influenza A or/and B or/and SARS-CoV-2 is rare but possible. Therefore dual or triple positive should be confirmed with higher method.

## Performance evaluation

### Limit of Detection

The Limit of Detection (LoD) was determined using limiting dilutions of each virus for each item. To reflect the procedure of using swabs directly to collect specimen, the virus was serially diluted in phosphate buffer, spiked on the swab, dried and used following the procedures as instructed in the package insert.

## (1) Influenza A

Total 42 strains of Influenza A were purchased from National Institute for Biological Standards and Control (NIBSC) and prepared as described above.

No.	NIBSC Code	Strain	LoD	Unit
1	19/306	A/Victoria/2454/2019 (IVR-207) (H1N1)	2.71	ng/mL
2	19/310	A/Hong Kong/2671/2019 (IVR-208) (H3N2)	5.25	ngHA/mL
3	19/312	A/Guangdong-Maonan/SWL1536/2019 (CNIC-1909) (H1N1)	215.6	ngHA/mL
4	20/108	A/HongKong/2671/2019 (NIB-121)(H3N2)	105.85	ngHA/mL
5	01/614	A/New Caledonia/20/99	65	ngHA/mL
6	15/238	A/New Caledonia/71/2014 (NYMCX-257A) (Egg derived antigen)	3.84	ngHA/mL
7	14/200	A/Puerto Rico/8/34 (H1N1)	3.2	ngHA/mL
8	07/102	A/Solomon Islands/3/2006 (H1N1)(IVR-145)	5.7	ngHA/mL
9	12/112	A/Victoria/210/2009 (H3N2) (NYMCX-187)	23.04	ngHA/mL
10	12/114	A/Victoria/361/2011 (H3N2) (IVR-165)	64.78	ngHA/mL
11	09/310	A/Wisconsin/15/09 (H3N2) (NYMCX-183)	61.82	ngHA/mL
12	16/238	A/Anhui/1/2013 (NIBRG-268) (H7N9)	6.08	ngHA/mL
13	07/290	A/Anhui/1/05 (H5N1) IBCDC-RG-6	5.45	ngHA/mL
14	79/560	A/Brazil/11/78	25.6	ngHA/mL
15	80/517	A/Bangkok/1/79	5.5	ngHA/mL
16	83/537	A/Philippines/2/82	9.98	ngHA/mL
17	86/576	A/Mississippi/1/85	1.58	ngHA/mL
18	03/220	A/Wyoming/03/03	2.75	ngHA/mL
19	04/264	A/New York/55/2004 (H3N2) (NYMC X-157)	25.3	ngHA/mL
20	17/154	A/Michigan/45/2015 (NYMC X-275)	2208	ngHA/mL
21	19/104	A/Kansas/14/2017 (NYMC X-327) (H3N2)	8.63	ngHA/mL
22	88/654	A/England/427/88	19.6	ngHA/mL
23	90/500	A/Shanghai/16/89	11.01	ngHA/mL
24	94/516	A/Shangdong/9/93	9.5	ngHA/mL
25	18/190	A/Brisbane/01/2018 (NYMC X-311)	81.32	ngHA/mL
26	18/238	A/Brisbane/02/2018 (IVR-190) (H1N1)	15.17	ngHA/mL
27	16/292	A/Singapore/GP1908/2015 (IVR-180)	40	ngHA/mL
28	18/110	A/Singapore/INFIMH-16-0019/2016 (IVR-186)	170.64	ngHA/mL
29	99/714	A/Singapore/1/57 (H2N2)	3.69	ngHA/mL
30	18/196	A/Guangdong/17SF003/2016. NIBRG-375 (H7N9)	12.27	ngHA/mL
31	19/212	A/South Australia/34/2019 (IVR-197) (H3N2)	70.52	ngHA/mL
32	15/104	A/South Australia/55/2014 Cell derived	24.76	ngHA/mL
33	19/204	A/Newcastle/82/2018 (H3N2) (cell derived)	10.74	ngHA/mL
34	14/254	A/Switzerland/9715293/2013 (NIB88)	275.28	ngHA/mL
35	13/112	A/Texas/50/2012 (NYMC X-223)	4.74	ngHA/mL
36	78/560	A/Texas/1/77	19.5	ngHA/mL
37	92/530	A/Texas/36/91	4.59	ngHA/mL
38	99/614	A/Sydney/5/97	1195.6	ngHA/mL
39	09/184	A/Vietnam/1194/2004 (H5N1) NIBRG-14	6.7	ngHA/mL
40	13/164	A/California/7/2009 (H1N1pdm)(NYMC X-179A)	1767	ngHA/mL
41	16/286	A/Hong Kong/4801/2014 (H3N2) (2016-2017)	427.2	ngHA/mL
42	08/100	A/Brisbane/59/2007 (IVR-148) (H1N1)	20.25	ngHA/mL

## (2) Influenza B

Total 14 strains of Influenza B were purchased from National Institute for Biological Standards and Control (NIBSC) and prepared as described above.

NO.	NIBSC Code	Strain	LoD	Unit
1	08/140	B/Florida/4/2006	4.5	ngHA/mL
2	08/184	B/Malaysia/2506/2004	3200	ngHA/mL
3	14/146	B/Brisbane/60/2008 (NYMC BX-35)(Cell Derived)	34.0	ngHA/mL
4	14/274	B/Brisbane/9/2014 (Egg Derived)	2310	ngHA/mL
5	15/100	B/Utah/9/2014 (Cell Derived)	0.4	ngHA/mL
6	16/118	B/Brisbane/60/2008 (NYMC BX-35) (Egg Derived)	2816	ngHA/mL
7	16/158	B/Phuket/3073/2013	5136	ngHA/mL
8	18/100	B/Maryland/15/2016	684.4	ngHA/mL
9	18/104	B/Maryland/15/2016 (NYMC BX-69A)	690	ngHA/mL
10	19/208	B/Victoria/705/2018 (BVR-11) (B Victoria Lineage)	434.5	ngHA/mL
11	19/210	B/Darwin/7/2019 (B Victoria Lineage) (Cell Derived)	1.23	ng/mL
12	19/238	B/Washington/02/2019 (B Victoria Lineage)	349.6	ng/mL
13	19/308	B/Singapore/INFTT-16-0610/2016 (B Yamagata lineage) (cell derived)	861.4	ngHA/mL
14	94/500	B/Panama/45/90	11.3	ngHA/mL

## (3) COVID-19 Ag

Heat-inactivated SARS-CoV-2, USA-WA1/2020 isolate from ZeptoMetrix was prepared as described above.

Strain	LoD (Limit of Detection)
Heat inactivated SARS-CoV-2	$1.62 \times 10^4$ TCID <sub>50</sub> /mL

## Interference

In the FRENDS™ COVID-19 Ag+FLU A&B test, the potential chemicals as a drug or biological products that may be found in the upper respiratory tract were selected and it was confirmed that the following interfering agents did not interfere the assay on the stated concentration.

NO.	Substances	Concentration	Unit
1	Whole Blood	4	% (w/v)
2	Mucin from bovine submaxillary gland	1	µg/mL
3	4-Acetamidophenol	1	mg/mL
4	Acetylsalicylic acid	1	mg/mL
5	Albuterol	0.083	mg/mL
6	Amantadine Hydrochloride	900	ng/mL
7	Afrin	50	µg/mL
8	Beclometasone	500	ng/mL
9	Budesonide	500	ng/mL
10	Benzocaine	1.5	mg/mL
11	Chlorpheniramine maleate	5	mg/mL
12	CVS Nasal Drops	1	mg/mL
13	CVS Nasal Spray	1	mg/mL
14	Dexamethasone	2.5	mg/mL
15	Diphenhydramine HCl	5	mg/mL
16	Fexofenadine	500	ng/mL
17	Fluticasone	500	ng/mL
18	guaifene sin	5	mg/mL
19	Ibuprofen	500.3	µg/mL
20	L-ascorbic acid	29.9	µg/mL
21	Loratidine	100	ng/mL
22	Mometasone	500	ng/mL
23	Mupirocin	1	mg/mL
24	Osetamivir Phosphate	500	ng/mL
25	Pseudoephedrine HCl	2	mg/mL
26	Tobramycin	500	ng/mL
27	Triamcinolone	500	ng/mL
28	Zanamivir	1	mg/mL
29	Galphimia glauca	10	mg/mL
30	Histaminum hydrochloricum	10	mg/mL
31	Flunisolide	250	µg/mL
32	Sodium Chloride with Preservatives	0.9	% (w/v)
33	Phosphate buffer (pH7.4)	50	mM

## Cross-reactivity

Potential virus or the bacteria that may show similar symptoms as COVID-19 or Influenza were selected and evaluated at the concentration as indicated did not show cross-reactivity in the FRENDS™ COVID-19 Ag+FLU A&B test.

NO.	Substances(Virus/Bacteria)	Concentration	Unit
1	Human adenovirus B (Adenovirus type 3)	3.00 X 10 <sup>5</sup>	PFU/mL
2	Human adenovirus B (Adenovirus type 11)	2.20 X 10 <sup>6</sup>	PFU/mL
3	Human adenovirus C (Adenovirus type 1)	7.00 X 10 <sup>6</sup>	PFU/mL
4	Human adenovirus C (Adenovirus type 5)	2.00 X 10 <sup>8</sup>	PFU/mL
5	Human adenovirus E (Adenovirus type 4)	4.00 X 10 <sup>6</sup>	PFU/mL
6	Human enterovirus A (Enterovirus Type 71)	1.00 X 10 <sup>5</sup>	PFU/mL
7	Human enterovirus B (Coxsackievirus B5)	2.50 X 10 <sup>9</sup>	PFU/mL
8	Human enterovirus D (Enterovirus Type 70)	4.40 X 10 <sup>7</sup>	PFU/mL
9	Human Rhinovirus A, Human Rhinovirus 7	8.00 X 10 <sup>4</sup>	PFU/mL
10	Human Rhinovirus A, Human Rhinovirus 8	1.30 X 10 <sup>6</sup>	PFU/mL
11	Human Rhinovirus B, Human Rhinovirus 14	6.00 X 10 <sup>4</sup>	PFU/mL
12	Human Rhinovirus B, Human Rhinovirus 42	5.50 X 10 <sup>3</sup>	PFU/mL
13	Measles virus	7.00 X 10 <sup>3</sup>	PFU/mL
14	Parainfluenza virus 1	1.85 X 10 <sup>5</sup>	PFU/mL
15	Parainfluenza virus 2	1.00 X 10 <sup>7</sup>	PFU/mL
16	Parainfluenza virus 3	8.00 X 10 <sup>5</sup>	PFU/mL
17	Parainfluenza virus 4a	4.50 X 10 <sup>4</sup>	PFU/mL
18	Parainfluenza virus 4b	2.60 X 10 <sup>5</sup>	PFU/mL
19	Human Respiratory syncytial virus A	4.00 X 10 <sup>6</sup>	PFU/mL
20	Human Respiratory syncytial virus B	1.20 X 10 <sup>7</sup>	PFU/mL
21	Human Respiratory syncytial virus A2	1.40X 10 <sup>7</sup>	PFU/mL
22	Human Influenza A H1N1	1.55 X 10 <sup>5</sup>	PFU/mL
23	Human Influenza A H3N2 (A/Aichi/2/1968)	2.50 X 10 <sup>6</sup>	PFU/mL
24	Human Influenza A H3N2 (A/Brisbane/09/2006)	1.00 X 10 <sup>5</sup>	PFU/mL
25	Human Influenza B virus	6.00 X 10 <sup>5</sup>	PFU/mL
26	Streptococcus pneumoniae (Klein) Chester 262[CIP 104340]	1 X 10 <sup>6</sup>	CFU/mL
27	Mycoplasma pneumoniae Somerson et al.	1 X 10 <sup>6</sup>	CFU/mL
28	Legionella pneumophila subsp. pneumophila Brenner et al. Philadelphia-1	1 X 10 <sup>6</sup>	CFU/mL
29	Human coronavirus (229E)	2.09 X 10 <sup>5</sup>	TCID <sub>50</sub> /mL
30	Human corona virus Betacoronavirus (OC43)	5.25 X 10 <sup>5</sup>	TCID <sub>50</sub> /mL
31	Human corona virus alphacoronavirus (NL63)	7.05 X 10 <sup>4</sup>	TCID <sub>50</sub> /mL
32	MERS-CoV (heat-inactivated)	1.78 X 10 <sup>5</sup>	TCID <sub>50</sub> /mL
33	SARS-CoV-2 (Heat inactivated)	7.55 X 10 <sup>5</sup>	TCID <sub>50</sub> /mL
34	Haemophilus influenzae	1 X 10 <sup>6</sup>	CFU/mL
35	Streptococcus pyogenes Rosenbach	1 X 10 <sup>6</sup>	CFU/mL
36	Candida albicans (Robin) Berkhout	1 X 10 <sup>6</sup>	CFU/mL
37	Pooled human nasal wash - representative of normal respiratory microbial flora	50	%(v/v)
38	Bordetella pertussis (Bergey et al.) Moreno-Lopez	1 X 10 <sup>6</sup>	CFU/mL
39	Chlamydia pneumoniae	1 X 10 <sup>6</sup>	CFU/mL
40	Pneumocystis carinii DeLanoe and DeLanoe (Pneumocystis jirovecii (PJP))	1 X 10 <sup>6</sup>	CFU/mL
41	Streptococcus equi subsp. equi Sand and Jensen	1 X 10 <sup>6</sup>	CFU/mL
42	Phosphate buffer (pH7.4)	50	mM

## **Precision**

As a result of the repeatability and reproducibility test for FRENDS™ COVID-19 Ag+FLU A&B, all negative samples were negative, and all positive samples were positive, which met the criteria.

## **Clinical performance**

The total of 338 clinical specimens were tested with the FRENDS™ COVID-19 Ag+FLU A&B and Real-time reverse transcription PCR. Positive Percent Agreement (PPA), Negative Percent Agreement (NPA), Positive Predictive Value (PPV), Negative Predictive Value (NPV) and prevalence were calculated.

### (1) Influenza A

FRENDS™ COVID-19 Ag + FLU A&B		RT-PCR		Total	(%)		95% CI (%)	
		Positive	Negative				Lower Limit	Upper Limit
Influenza A	Positive	38	1	39	PPA	100	88.57	100.0
	Negative	0	299	299	NPA	99.67	97.86	99.98
Total		38	300	338	PPV	97.44	84.92	99.87
					NPV	100.0	98.42	100.0
					Prevalence	11.24	8.17	15.22

### (2) Influenza B

FRENDS™ COVID-19 Ag + FLU A&B		RT-PCR		Total	(%)		95% CI (%)	
		Positive	Negative				Lower Limit	Upper Limit
Influenza B	Positive	39	4	43	PPA	97.50	85.27	99.87
	Negative	1	294	295	NPA	98.66	96.37	99.57
Total		40	298	338	PPV	90.70	76.95	96.98
					NPV	99.66	97.83	99.98
					Prevalence	11.83	8.68	15.88

### (3) COVID-19 Ag

FRENDS™ COVID-19 Ag + FLU A&B		RT-PCR		Total	(%)		95% CI (%)	
		Positive	Negative				Lower Limit	Upper Limit
COVID-19 Ag	Positive	43	1	44	PPA	95.56	83.64	99.23
	Negative	2	292	294	NPA	99.66	97.81	99.98
Total		45	293	338	PPV	97.73	86.49	99.88
					NPV	99.32	97.30	99.88
					Prevalence	13.31	9.97	17.51

## Glossary of Symbols



Caution, warning,  
Consult accompanying documents

**REF**

Catalogue number/Reference number



[www.nanocentek.com/eifu.php](http://www.nanocentek.com/eifu.php)

Consult Instructions for Use  
An electronic instructions for use (eIFU) indicator (website address) may accompany the symbol when used to indicate an instruction to consult an eIFU.

**LOT**

Lot number/Batch number



Use by  
YYYY-MM-DD or YYYY-MM



Manufacturer

**EC REP**

Authorized representative in the European Community



CE marking

**IVD**

*In vitro* diagnostic medical device



Temperature limitation



Contains sufficient for <n> tests



Do not reuse



Do not use if package is damaged

**Rx Only**

For prescription use only  
CAUTION: Federal (U.S.) law restricts this device to sale by or on order of a physician.

**US Corporation**

US Corporation

**Patient ID**

Patient ID

**Result**

Result



Sample Drop

Sample Drop

## Kit Contents



Cartridge



Lysis tube



Filter dropper with a specimen cup



Disposable pipette tip



Disposable sterile nasopharyngeal swab



COVID-19 Ag Positive control swab



Influenza A&B Positive control swab



Negative control swab



Code chip



Package insert



**NanoEntek**

e-mail : [ivdst@nanoentek.com](mailto:ivdst@nanoentek.com)

website : [www.nanoentek.com](http://www.nanoentek.com)



**NanoEntek, Inc.**

851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea

Tel : +82-2-6220-7940 / Fax : +82-2-6220-7999

**US Corporation**

**NanoEntek America, Inc.**

220 Bear Hill Road, Suite 102, Waltham, MA 02451, USA

Tel : +1-781-472-2558 / Fax : +1-781-790-5649

**EC REP MT Promedt Consulting GmbH**

Ernst-Heckel-Straße 7, 66386 St. Ingbert Germany