NanoEntek

CE IVD

FREND™ COVID-19 Ag+FLU A&B

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

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 pecimen.
- 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.

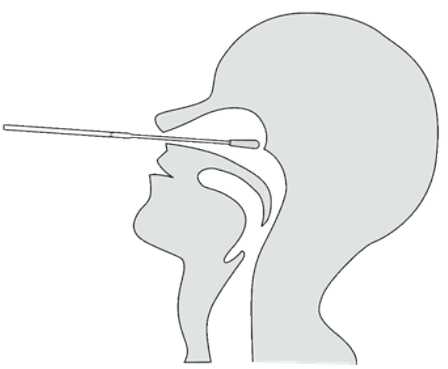
Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at refrigerator temperature storage (2-8℃). 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.

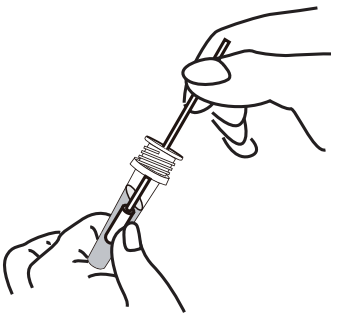
(8) Click the FREND™ COVID-19 Ag+FLU A&B cartridge and check the installed lot number and the installation date of the Code chip.

(9) Press the ’Home’ button to go to the ‘Main’ screen to begin running external quality control and specimen swabs.

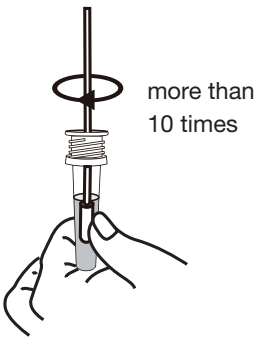
Specimen processing

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 not stored.

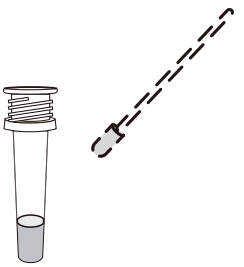
Assay procedure



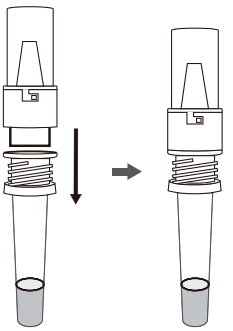
STEP 01.
Put the swab from which the specimen was collected into the lysis tube.



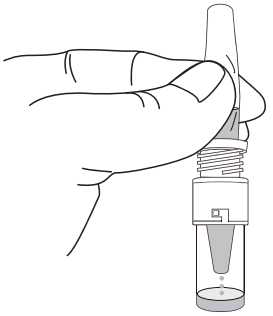
STEP 02.
Stir the swab up and down more than 10 times to dissolve its content in the lysis buffer.



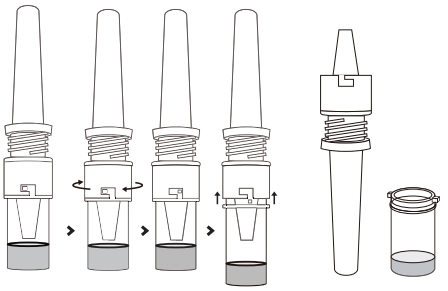
STEP 03.
Remove liquid from the swab as much as you can, and dispose the used swab in bio-hazardous waste.



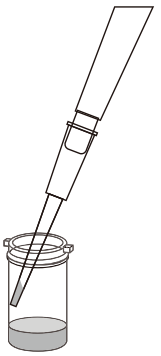
STEP 04.
Gently push the filter dropper with a specimen cup against the lysis tube and close it tight.



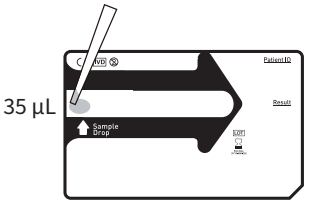
STEP 05.
Invert the lysis tube and gently squeeze the lysis tube until all the specimen solution inside the lysis tube dropped and collected in the specimen cup.



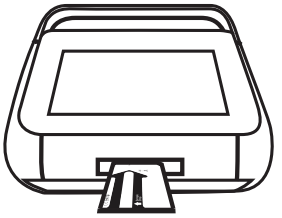
STEP 06.
Separate the specimen cup that is tight with lysis tube and the filter dropper by rotating counterclockwise. Take off the lysis tube from the specimen cup. Dispose the lysis tube in biohazard waste and leave the specimen cup for the next step.



STEP 07.
Take 35 µL 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 FREND™ 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 handling”.

(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 μL 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 FREND™ 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 FREND™ 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'.

Display and Interpretation of results

Displayed result	Description
	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. ***Note :*** *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.*
	Influenza A : “Positive” Influenza B : “Negative” COVID-19 Ag : “Negative” → Positive result on the presence of nucleoprotein from Influenza A strain. ***Note :*** *A positive result does not rule out co-infections with other pathogens.*
	Influenza A : “Negative” Influenza B : “Positive” COVID-19 Ag : “Negative” → Positive result on the presence of nucleoprotein from Influenza B strain. ***Note :*** *A positive result does not rule out co-infections with other pathogens.*

	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.*
	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.*

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.

N0.	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	158	ngHA/mL
18	03/220	A/Wyoming/03/03	275	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 (NYMCBX-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	1.62×10^2 $TCID_{50}$/mL

Interference

In the FREND™ 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	Beclomethasone	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	Oseltamivir 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 FREND™ COVID-19 Ag+FLU A&B test.

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

Precision

As a result of the repeatability and reproducibility test for FREND™ 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 FREND™ 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

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

(2) Influenza B

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

(3) COVID-19 Ag

FREND™ COVID-19 Ag + FLU A&B		RT-PCR		Total	(%)		95% CI (%)	
							Lower Limit	Upper Limit
		Positive	Negative		PPA	95.56	83.64	99.23
COVID-19 Ag	Positive	43	1	44	NPA	99.66	97.81	99.98
	Negative	2	292	294	PPV	97.73	86.49	99.88
Total		45	293	338	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
LOT	Lot number/Batch number
	Use by YYYY-MM-DD or YYYY-MM
	Manufacturer
EC REP	Authorized representative in the European Community
CE	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
	For prescription use only
	Irritant

NanoEntek

ivdst@nanoentek.com
www.nanoentek.com

Manufactured by
NanoEntek, Inc.
851-14 Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea
Tel.:+82-2-6220-7942, Fax.:+82-2-6220-7999

EC REP **MT Promedt Consulting GmbH**
Altenhofstrasse 80, 66386 St. Ingbert, Germany

Revised on 2020.11.30