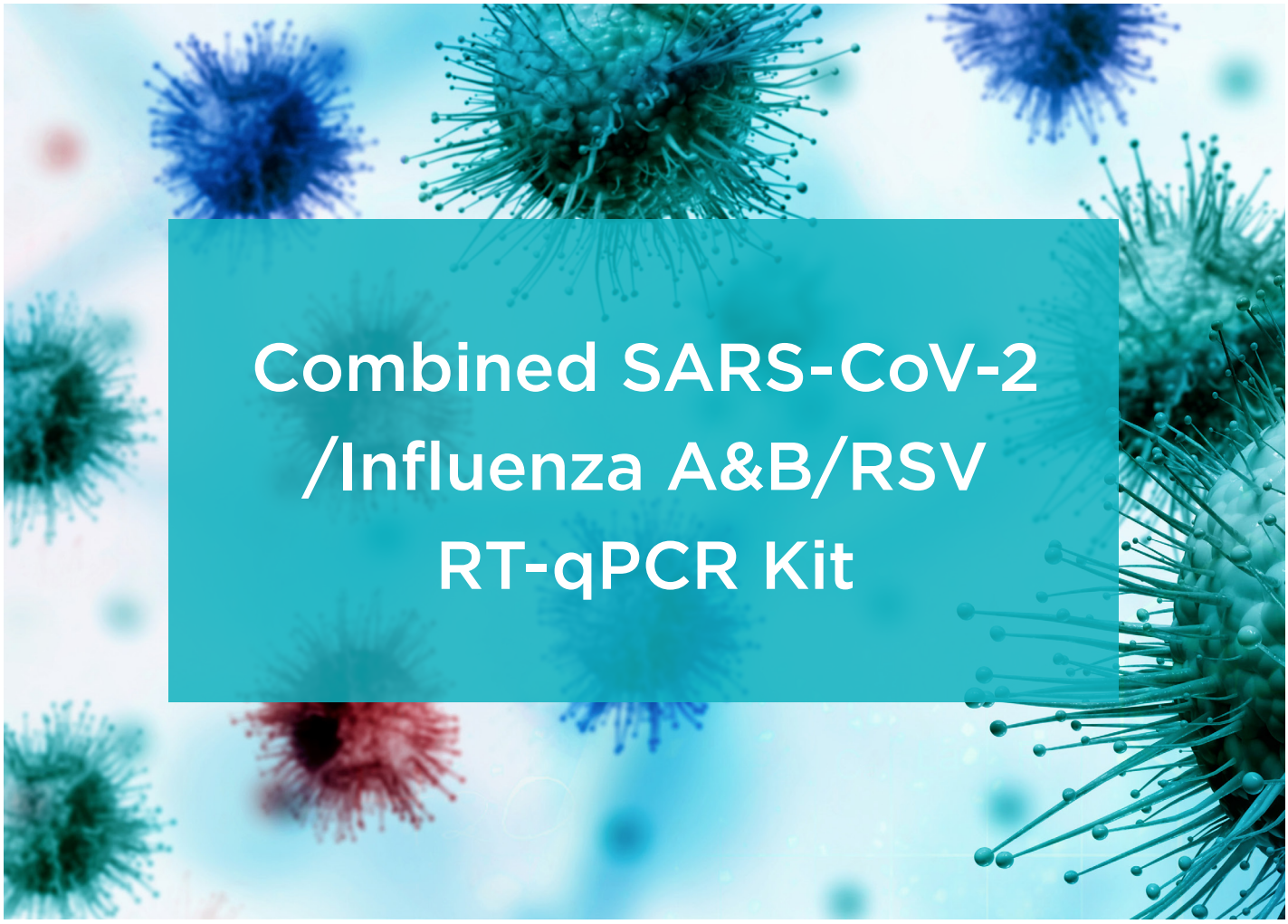
NIPD GENETICS



Combined SARS-CoV-2 /Influenza A&B/RSV RT-qPCR Kit

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Version History

Version Number	Section and Designation
2020-10-31	Release Section

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Trademarks and Disclaimers

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Symbols


Reagents/sample


Manufacturer


1.5mL Tube


Keep dry


Telephone number


Expiration date


Consult Instructions For Use (IFU)


Email address

Contains sufficient for N tests


Temperature limits

Lot number

Item number

Material consists of polypropylene and can be recycled with plastic (PMD)

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Definitions

NTC	No (Negative) Template Control
PTC	Positive Template Control
qPCR	Quantitative PCR
RT-qPCR	Real-time quantitative PCR
cDNA	Complementary DNA
WHO	World Health Organization
CDC	Centers for Disease Control and Prevention
UTM	Universal Transport Medium
VTM	Virus Transport Medium
GLP	Good Laboratory Practice
RSV	Respiratory Syncytial Viruses

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Intended Use

For research use only. Not intended for diagnostic procedures. According to the MEDDEV. 2.14/2 rev.1 IVD Directive, the NIPD Genetics Combined SARS-CoV-2/ Influenza A&B/RSV RT-qPCR Kit falls under the RUO product category to be used for better identification and quantification of individual chemical substances or ligands in biological specimens. The RUO product is not sold by the manufacturers with an intended use within the definition of an IVD as defined by the IVD Directive in Article 12(b). They may more appropriately fall under the category of products for general laboratory use. They may be used as an element in a homebrew diagnostic testing plan to determine the possibility of their potential future use as IVDs.

Purpose, Scope And Users

SARS-CoV-2 was initially named as 2019 novel coronavirus (2019-nCoV) and was identified by Chinese authorities after a pneumonia outbreak took place in December 2019 in Wuhan, Hubei Province, China. The WHO declared an international health emergency on January 31, 2020. The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) recommend random testing for the asymptomatic population and testing for anyone who exhibits symptoms from specimens collected from the upper respiratory tract and/or lower respiratory specimens for the identification of SARS-CoV-2 and other respiratory viruses, such as Influenza and RSV. RT-qPCR is the gold-standard method for identifying active infections.

The NIPD Genetics Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit is a multiplex real-time RT-qPCR assay for the direct qualitative detection of RNA from 4 viruses: the novel coronavirus (SARS-CoV-2), influenza A, influenza B, and respiratory syncytial virus A/B (RSV A/B) from human respiratory samples collected via the nasopharyngeal and/or oropharyngeal swab method. The validation was performed on real-time PCR instrument QIAquant 96 5plex (230 V) Real-Time PCR Detection System. This test can distinguish between influenza A and B subtypes but does not differentiate between RSV A and B. RNA is isolated from respiratory specimens, reverse transcribed and amplified using RT-qPCR and detected with four different fluorescent dye probes, allowing multiplexing and co-detection per sample reaction.

Rationale

Diagnosis of the aforementioned viruses can be challenging due to the symptoms similarity. However, discriminatory, and early diagnosis is important for disease management and treatment, therefore, real-time PCR assay can be a sensitive and reliable method for detecting SARS-CoV-2, influenza A/B and RSV viruses. This assay is used for research purposes only, and NIPD Genetics takes no responsibility for the outcome of patient treatment if the results are being used to guide medical treatment from healthcare professionals.

Quality Control And Validity Of Results

The Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit contains positive (PTC) and negative (NTC) template controls to be able to control PCR amplification. Both controls must be included in each run for appropriate QC, results interpretation and for the results to be considered valid.

Introduction

Coronaviruses are single-stranded, positive-sense, non-segmented RNA viruses that belong to the ***Coronaviridae*** family. They are the largest known RNA viruses with genomes ranging between 27–31.5 kb. There are six coronavirus species known to cause human diseases 229E, OC43, NL63, HKU1, MERS-CoV and SARS-CoV. SARS-CoV-2, named as a 2019 novel coronavirus (2019-nCoV) is responsible for the current pandemic affecting millions of people worldwide. The virus is transmitted from human-to-human through respiratory droplets via direct or indirect contact. Symptoms of SARS-CoV-2 may appear from 2 to 14 days after exposure to the virus and the most common symptoms are fever, dry cough, fatigue. Less common symptoms include aches and pains, nasal congestion, sore throat, diarrhea, loss of smell (anosmia) or loss of taste (ageusia) etc. The strongest and most consistent evidence for increased risk comes from patients with BMI greater than 30 kg/m^2, diabetes mellitus type 2 and with underlying lung and heart conditions, who are more likely to develop severe complications and require ICU admission and oxygen support.

Influenza viruses are negative-sense viruses that belong to the ***Orthomyxoviridae*** family. The most common influenza viruses that infect humans are influenza A and B. Most common symptoms include fever, cough, sore throat, nasal congestion, and discharge that can lead to more serious complications of pneumonia. Age and underlying lung medical conditions (e.g. COPD, IPF, asthma, smokers) increase the risk of developing complications.

Human respiratory syncytial viruses (RSV) are non-segmented, negative, single-stranded linear RNA genome viruses that belong to the ***Paramyxoviridae*** family. RSV causes respiratory infections in humans, including bronchitis, pneumonia, and chronic obstructive pulmonary infections. Common symptoms include nasal discharge, low-grade fever, cough, sore throat, headache, and wheezing.

All aforementioned viruses, are transmitted among humans in three ways: (1) by direct contact with infected individuals; (2) by contact with contaminated objects (such as toys, doorknobs); and (3) by inhalation of virus-laden aerosols.

Product Description

The Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit is designed for the detection and differentiation of SARS-CoV-2, influenza A and B (flu A/B) and human respiratory syncytial virus A/B (RSV A/B) in respiratory specimens. The assay is a real-time one-step reverse transcription polymerase chain reaction (RT-qPCR) test that uses fluorescent dye probes specific for the viruses. This test can distinguish between influenza A and B but cannot distinguish between RSV A and B. RNA isolated from the respiratory specimens is reverse transcribed into complementary DNA (cDNA) and then amplified by polymerase chain reaction (PCR). Primers and probes were selected from a conserved region of the N gene (N) for the detection of SARS-CoV-2, a conserved region of the matrix (M1) gene for the detection of influenza A, a conserved region of the non-structural 2 gene (NS2) for influenza B and a conserved region of the N gene for RSV A/B. During DNA amplification, DNA polymerase cleaves the probe bounded to the complementary DNA sequence causing the quencher dye to detach from the reporter producing a fluorescent signal. This process is repeated with each cycle resulting to an analogous increase in fluorescence intensity. Therefore, the fluorescence is proportional to the quantity of target RNA as it is measured on qPCR instrument in real-time for every cycle.

General Guidelines

Transport And Storage Conditions

The reagents are shipped and stored at -20°C until the expiration date, as stated on the label. To minimize freeze and thaw cycles and preserve the integrity of the PTC, we recommend aliquoting and storing at -20°C. All components must be kept away from sunlight.

Training Requirements

Testing for presence of viral RNA should be performed in an equipped laboratory with staff trained to carry out the relevant technical procedures according to the Occupational Safety and Health Administration (OSHA) Laboratory standards. Refer to the World Health Organization Interim guidance on laboratory biosafety[1] and the Centers for Disease Control and Prevention (CDC) guidelines for Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with SARS-CoV-2[2].

Precautions And Recommendations

- The procedures in this handbook must be followed as described. Any deviations may result in assay failure or cause erroneous results and interpretation.
- GLP is required to ensure the performance of the kit, with care required to prevent contamination of the kit components. Components thought to have become contaminated should be discarded as standard laboratory waste in a sealed pouch or zip-lock plastic bag.
- Specimen samples must be collected, transported, and stored according to appropriate laboratory guidelines. For details, refer to the CDC guidelines[3] for "Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19".
- Samples should be processed within 4 hours post collection. Samples that will be processed after the 4-hour window post-collection need to be stored between 2-8°C for up to 72 hours.
- Thaw reagents at room temperature prior to use and keep reagents on ice.
- Shelf-life of reagents is 6 months when properly stored.
- Do not use reagents past the expiration date. After the expiration date the quality guarantee is no longer valid.
- Do not mix reagents from different kits and/or lots and/or another supplier.
- Wear personal protective equipment (PPE), such as disposable gloves, goggles, and mask during collection and sample processing.
- Handle all specimens as if infectious using GLP and the Occupational Safety and Health Administration (OSHA) Laboratory standard (29 CFR 1910.1450).
- Perform all manipulations of potential live virus samples within a class II (or higher) biological safety cabinet.
- Dispose of waste in compliance with local, state, and federal regulations.

- Regular decontamination of commonly used equipment is recommended, especially micropipettes and work surfaces with at least 70% (v/v) ethanol. If you are working with RNA, to prevent degradation, it is recommended for the processing area benches to be wiped with RNase AWAY ® or 10% freshly prepared Bleach.
- Please consult the safety data sheet (SDS) before using this kit, which is available on request.
- Consult each Real-Time qPCR instrument's reference manual for additional warnings, precautions, procedures, and data analysis.

[1] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications (13 May 2020)

[2] https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Flab-biosafety-guidelines.html

[3] https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

Test Procedure

NIPD Genetics Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit has been validated on nasopharyngeal and oropharyngeal specimens collected with synthetic fiber swabs and placed immediately into a sterile transport tube containing of Universal transport medium (UTM) or Viral Transport Media (VTM) or PBS.

Specimen Collection And Storage

- Nasopharyngeal and/or oropharyngeal specimens should be collected using only swabs with a synthetic tip, and an aluminum or plastic shaft and placed in sterile tube containing of viral transport medium or PBS.
- Follow specimen collection device manufacturer instructions for proper collection methods.
- Samples shall be processed within 4 hours after collection. Samples that will not be processed within 4 hours after collection will be stored at 2-8°C for up to 72 hours after collection.

Extraction Kits

NIPD Genetics Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit has been tested using the following extraction systems:

- Quick-DNA/RNA™ Viral MagBead (Cat. No. R2141, Zymo Research)
- Magno-Virus (K-2-16/1000, Sacace Biotechnologies)
- MagMAX Viral/Pathogen Nucleic Acid Isolation Kit (A48310, ThermoFisher Scientific)
- TANBead OptiPure Viral Auto Plate (96 test) (Cat. No.:301009 - 665A46, TAN Bead)

Real-Time PCR Instruments

NIPD Genetics Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit has been tested on the following equipment:

- QIAquant 96 5plex (230 V)

Required Equipment And Consumables (Not Provided)

The following list includes the materials that are required for use but not included in Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit:

- Real-Time qPCR instrument
- RNA extraction reagents
- Specimen collection and transport system: Sterile synthetic fiber nasopharyngeal and/or oropharyngeal swabs, Universal Viral Transport Tube, Viral Transport Media (VTM)
- Laboratory freezers: - 30°C to - 10°C and/or ≤ –70°C
- Centrifuge for 1.5 mL tubes and PCR-well strips or 96-well plates
- Vortex instrument
- Micropipettes (2-20 µL, 20-200 µL)
- Filter tips
- PPE

Compatibility With Common Real-Time PCR Equipment

The Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit is compatible with the following extraction platforms and real-time PCR instruments. Please consult the instrument's manual for use and parameter settings.

Agilent Technologies	AriaMx/AriaDx Real-Time PCR System Mx3000P™ Real Time PCR System Mx3005P™ Real Time PCR System
Applied Biosystems	7500 Fast & 7500 Real-Time PCR System QuantStudio™ 5 Fast/QuantStudio™ 5 Real-Time PCR System QuantStudio™ 6 Flex 96-well Fast
Bio-Rad	CFX96TM Real-Time PCR Detection System CFX384TM Real-Time PCR Detection System iCycler iQTM Real-Time PCR Detection System iCycler iQTM5 Real-Time PCR Detection System
Qiagen	Rotor-Gene® Q
Abbott	Abbott m2000 RealTime System

Table 1

Consumables

Kit Components

Kit size: 96 Reactions

Lid color	Component	Description	Quantity x Volume
Black	RT-qPCR Mix	DNA Polymerase, dNTPs, and all required buffer components	1 vial x 960µl
Blue	Reverse Transcriptase	Reverse Transcriptase & RNase Inhibitor	1 vial x 96µl
Green	Primer Mix	Primers complementary to specific regions for influenza A, influenza B, RSV A/B, and SARS-CoV-2	1 vial x 87µl
Yellow	Probe Mix	Fluorescent dye probes complementary to specific regions of influenza A, influenza B, RSV A/B and SARS-CoV-2	1 vial x 87µl
Red	Positive Template Control (PTC)	Mix of non-infectious cDNA from four viruses	1 vial x 480µl
Natural	Nuclease-free water (NTC)	RNAse/DNAse-free water	1 vial x 692µl

Table 2

Technical Procedure

1. Collect nasopharyngeal and/or oropharyngeal swabs in VTM or UTM and extract RNA using desired extraction and purification method as per manufacturer's instructions.
2. Thaw reaction components at room temperature, then place on ice. After thawing, briefly mix each component by inversion, pipetting or gentle vortexing.
3. Determine the total volume for the appropriated number of reactions, plus 5% extra and prepare assay mix of all components except RNA template. Mix thoroughly, but gently, by pipetting or vortexing.
4. Collect assay mix to the bottom of the tube by brief centrifugation.

Reaction Mix Component	1X Reaction (µl)
RT-qPCR Mix	10
Reverse Transcriptase	1
Primer Mix	0.9
Probe Mix	0.9
Nuclease-free water	2.2
Template RNA	5
Total reaction volume	**20**

Table 3

5. Aliquot assay mix into qPCR tubes or plate. For best results, ensure you use calibrated micropipettes and minimize bubbles during transfer.
6. Add RNA samples to qPCR tubes or plate. Seal tubes with flat, optically transparent caps or transparent film. If you are using film, properly seal plate edges and corners to prevent artifacts caused by evaporation.
7. Spin tubes or plate briefly for 1 minute at 2,500–3,000 rpm to remove bubbles and collect liquid at the bottom.
8. Program real-time instrument with indicated thermocycling protocol (Table 4). Fluorogenic data are collected during the annealing/extension step: FAM for influenza A, HEX for influenza B, ROX for RSV, Cy5 for SARS-CoV-2.

Cycles	Step	Time	Temperature
1	Reverse Transcription	10 min	55°C
1	Initial Denaturation	1 min	95°C
40	Denaturation	10 sec	95°C
	Annealing/Extension (Data Collection)	15 sec	55°C

Table 4

Results Interpretation

The analysis of the controls and clinical samples is done by the software of the PCR instrumentation according to manufacturer´s instructions. It is recommended to set the threshold values for each channel independently. Use the PTC amplification curve (Fig.1) as a starting point during the run validation to ensure that thresholds fall within the linear phase of the fluorescence curve and above any background signal. The threshold value for different instruments may vary due to different signal intensities. Interpretation of clinical samples should only be performed after the PTC and NTC have been determined to be valid. In cases where one or more controls fail the acceptance criteria, they are reported as 'Invalid' and retesting is required.

For a valid RT-qPCR run the following specified value conditions must be met as Table 5. If the specified values are not met, check the following before repeating the test:

- Expiration date of the reagents used
- Functionality of the devices used
- Correct test procedure

Controls	Influenza A (FAM)	Influenza B (HEX)	RSV (ROX)	SARS-CoV-2 (Cy5)	Test Interpretation
NTC	NA	NA	NA	NA	Valid
PTC	Ct ≤35	Ct ≤35	Ct ≤35	Ct ≤35	Valid

Table 5

Influenza A (FAM)	Influenza B (HEX)	RSV (ROX)	SARS-CoV-2 (Cy5)	Result
+	-	-	-	Positive for Influenza A
-	+	-	-	Positive for Influenza B
-	-	+	-	Positive for RSV
-	-	-	+	Positive for SARS-CoV-2
+	+	-	-	Positive for Influenza A and Influenza B
+	-	+	-	Positive for Influenza A and RSV
+	-	-	+	Positive for Influenza A and SARS-CoV-2
+	+	+	-	Positive for Influenza A and B, and RSV
+	+	-	+	Positive for Influenza A and B, and SARS-CoV-2
+	-	+	+	Positive for Influenza A, RSV and SARS-CoV-2
-	+	+	-	Positive for Influenza B and RSV
-	+	-	+	Positive for Influenza B and SARS-CoV-2
-	-	+	+	Positive for RSV and SARS-CoV-2
-	-	-	-	Negative for all viruses

Table 6

Assessment of clinical sample test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If one or more controls are not valid, the patient results cannot be interpreted. For interpretation of patient sample results, use Table 6.

Positive Result

When all controls exhibit the expected results and one or more of the viral targets (influenza A, influenza B, RSV and/or SARS-CoV-2) crosses the threshold line before 37 cycles then the specimen is considered positive for those virus(es). Multiple viruses may be detected in a single specimen.

Negative Result

When all controls exhibit the expected results, a specimen is considered negative if all viral targets' cycle threshold curves (influenza A, influenza B, RSV and/or SARS-CoV-2) do not cross the threshold line before 40 cycles (< 40 cycles).

Invalid Result

When all controls exhibit the expected results and curves cross the threshold line after 37 Ct for influenza A, influenza B, RSV and/or SARS-CoV-2, then the result is invalid. Repeat RT-qPCR testing of viral RNA and/or re-extract and repeat RT-qPCR. If the specimen remains invalid upon retest, collection of a new specimen and subsequent testing should be considered.

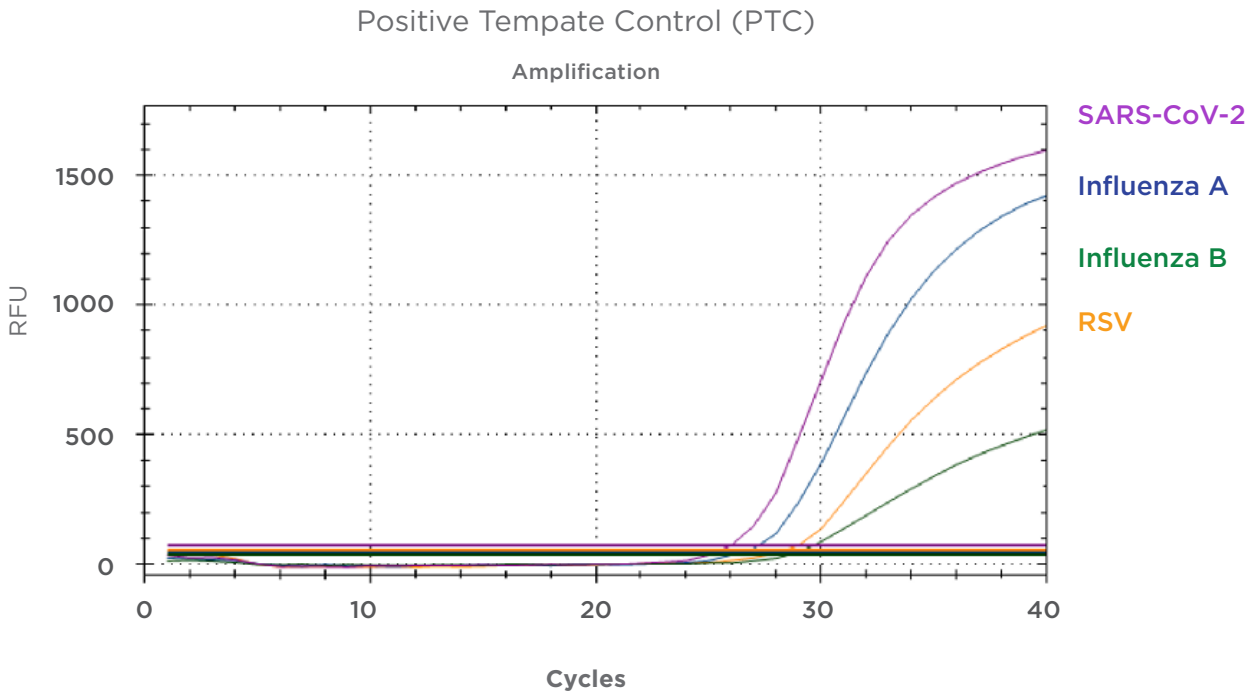

Figure 1: Positive Template Control (PTC). All targets show amplification as per expectation.

Limitations Of The Procedure

- This test is intended only for human respiratory samples.
- A false negative result may occur if a specimen is improperly collected, transported, or handled. False negative results may also occur if amplification inhibitors are present or if inadequate numbers of viral genome copies are present in the specimen.
- Positive and negative predictive values are highly dependent on prevalence. Negative predictive value is lower during peak activity when prevalence of disease is high. Positive predictive value is lower during periods of low influenza, RSV or SARS-CoV-2 activity when prevalence is moderate to low.
- The performance of the assay has not been established in individuals who received nasally administered influenza vaccine. Individuals who received nasally administered influenza A vaccine may have positive influenza A test results for up to three days after vaccination[4].
- Mutations or polymorphisms in the primer or probe binding sites can interfere with the detection of new or unknown virus variants and can lead to false negative results.
- Extremely low concentrations of the target sequences can be detected even when found under the limit of detection (LoD). This is termed as a false positive.
- A positive test result does not necessarily indicate the presence of viable virus. A positive result indicates that the target genes are present.
- An interference study evaluating the effect of common cold medications was not performed.
- The performance of this test has not been established for monitoring treatment of influenza A, influenza B, RSV, or SARS-CoV-2 infection.
- This test cannot rule out diseases caused by other pathogens.

[4] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm

Performance Characteristics

Analytical Sensitivity

Analytical sensitivity of the Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit was tested using RNA purified from complete genomes of influenza A virus, influenza B, RSV A, RSV B and a SARS-CoV-2 viruses to determine the lowest detectable concentration and the limit of detection (LoD). The estimated LoD was defined as the lowest concentration in which each target demonstrated 100% positivity.

The Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit has a LoD[5] for each virus at:

- 10 c/µl copies/reaction for SARS-CoV-2
- 1.95 c/µl copies/reaction for influenza A
- 15.63 c/µl copies/reaction for influenza B
- 7.81 c/µl copies/reaction for RSV

[5] Measured as genome copies/µl

Analytical Specificity

The specificity of the Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit was confirmed by using a panel of genomic material representing the most common respiratory pathogens. No cross-reactivity was detected between any of the following microorganisms listed in Table 7.

Bocavirus
Bordetella bronchiseptica
Bordetella holmesii
Bordetella parapertussis
Bordetella pertussis
Chlamydia caviae
Chlamydia psittaci genotype A and C
Chlamydophila pneumoniae CM-1
Human coronavirus 229E, OC43, NL63 and HKU1
MERS Coronavirus
Haemophilus influenzae (MinnA strain)
Legionella bozemanii
Legionella dumoffii
Legionella longbeachae
Legionella micdadei
Legionella pneumophila
Human metapneumovirus A and B

Table 7

Clinical Evaluation

Clinical performance of the NIPD Genetics Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit was evaluated with human upper respiratory specimens. A total of 57 positive samples (29 SARS-CoV-2 positive, 23 influenza A positive, 3 influenza B positive, 2 RSV) and 50 negative samples were correctly classified showing 100% agreement with FDA-authorized CDC 2019-nCOV, Influenza A & B, RSV-Real-Time RT-PCR Diagnostic Panels. All positive samples were uniquely positive for the single virus as seen in Table 8.

Clinical Specimen Panel

	Influenza A	Influenza B	RSV	SARS-CoV-2	Negative
Influenza A Positive	23/23	0/23	0/23	0/23	0/23
Influenza B Positive	0/3	3/3	0/3	0/3	0/3
RSV Positive	0/2	0/2	2/2	0/2	0/2
SARS-CoV-2 Positive	0/29	0/29	0/29	29/29	0/29
Negative	0/50	0/50	0/50	0/50	50/50
Total	**23**	**3**	**2**	**29**	**50**

Table 8

Appendix Data

Sample (n)	SARS-CoV-2 (n=29)	Influenza A (n=23)	Influenza B (n=3)	RSV (n=2)
1	33.0	NA	NA	NA
2	31.7	NA	NA	NA
3	29.3	NA	NA	NA
4	24.6	NA	NA	NA
5	30.3	NA	NA	NA
6	21.0	NA	NA	NA
7	32.8	NA	NA	NA
8	32.5	NA	NA	NA
9	31.3	NA	NA	NA
10	31.9	NA	NA	NA
11	22.2	NA	NA	NA
12	18.2	NA	NA	NA
13	31.7	NA	NA	NA
14	23.7	NA	NA	NA
15	30.9	NA	NA	NA
16	31.2	NA	NA	NA
17	30.4	NA	NA	NA
18	32.3	NA	NA	NA
19	22.1	NA	NA	NA
20	19.7	NA	NA	NA
21	35.3	NA	NA	NA
22	30.0	NA	NA	NA
23	30.0	NA	NA	NA
24	34.4	NA	NA	NA
25	34.7	NA	NA	NA
26	32.6	NA	NA	NA
27	32.5	NA	NA	NA
28	30.4	NA	NA	NA
29	29.5	NA	NA	NA

30	NA	25.2	NA	NA
31	NA	35.5	NA	NA
32	NA	22.1	NA	NA
33	NA	28.1	NA	NA
34	NA	22.4	NA	NA
35	NA	19.3	NA	NA
36	NA	22.7	NA	NA
37	NA	18.9	NA	NA
38	NA	21.4	NA	NA
39	NA	28.3	NA	NA
40	NA	24.1	NA	NA
41	NA	24.3	NA	NA
42	NA	24.3	NA	NA
43	NA	24.5	NA	NA
44	NA	25.5	NA	NA
45	NA	24.6	NA	NA
46	NA	33.1	NA	NA
47	NA	23.3	NA	NA
48	NA	23.5	NA	NA
49	NA	24.5	NA	NA
50	NA	27.6	NA	NA
51	NA	27.0	NA	NA
52	NA	31.7	NA	NA
53	NA	NA	24.1	NA
54	NA	NA	22.0	NA
55	NA	NA	16.8	NA
56	NA	NA	NA	30.8
57	NA	NA	NA	20.4
58-107	NA	NA	NA	NA

Table 9: Ct values for the clinical samples (n=107) tested for the clinical evaluation study of the NIPD Genetics Combined SARS-CoV-2/Influenza A&B/RSV RT-qPCR Kit. The spread of Ct values is seen in table 9.