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Advancing Non-Invasive Healthcare

VirPath Respiratory Multiplex qRT- PCR

Instructions For Use (IFU) v2.0

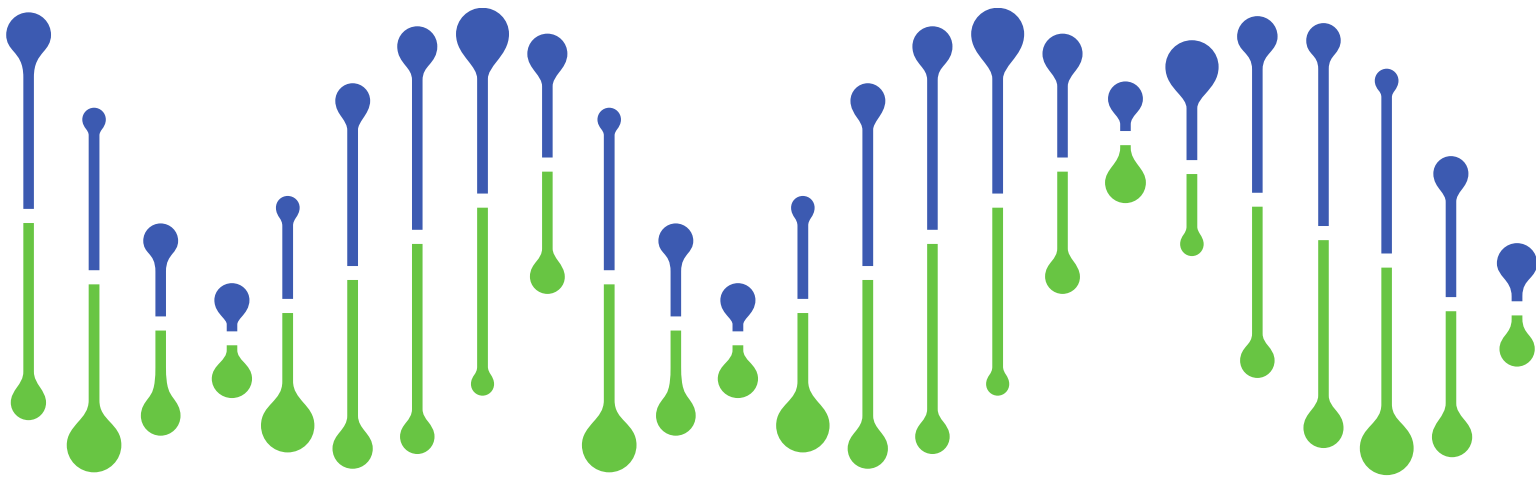
Made in the UK. Nonacus Ltd, Birmingham Research Park, Vincent Drive, Birmingham, B15 2SQ UK.

-20°C Store at -20°C

REF C3COV195

CE

IVD For in vitro diagnostic use



Intended use

The VirPath respiratory multiplex qRT-PCR kit is a qualitative reverse transcription real-time polymerase chain reaction (qRT-PCR) assay intended to be used for the detection of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), Influenza viruses types A and B (Flu A/B) and Respiratory Syncytial virus types A and B. The kit is compatible with genomic RNA extracted from biological samples derived from lower or upper respiratory tract specimens (e.g.nasopharyngeal or oropharyngeal swabs, etc.) collected from individuals that are asymptomatic or symptomatic. The inhibitor tolerant qRT-PCR mix provided in the kit is a one-step solution designed for amplification of the SARS-CoV-2, Flu A/B and RSV A/B RNA targets.

Included in the kit is a multiplex of primer / probe assays which target the nucleocapsid gene (assay N2) and the polymerase gene (assay ORF-1) of Sars-CoV-2; the matrix protein gene (assay M) for Flu A and the non-structural 2 gene (assay NS2) for Flu B; the nucleocapsid gene (assay N) for RSV A and RSV B; and the RPP30 gene (assay RP) used as internal RNA extraction control. Two plasmid controls are included in the kit to confirm functionality of the assays and the qRT-PCR reaction: positive plasmid control 1 (PPC-1) contains plasmids for targets N2, M, N (RSV A) and RP; and positive plasmid control 2 (PPC-2) contains plasmids for targets ORF-1, NS2, N (RSV B) and RP. The kit contains a full process control (FPC) containing Flu A, Flu B, RSV B, SARS-CoV-2 purified, intact viral particles that have been chemically modified to render them non-infectious and refrigerator stable.

Performance has been verified using the BioRad CFX96, controlled by the CFX software. The assay should be compatible with other equivalent real-time PCR cyclers but validation should be performed prior to use.

The VirPath respiratory multiplex qRT-PCR kit is intended for use by trained laboratory technicians who are proficient in performing molecular based tests.

Kit contents

Reagent	Volume (96 rxns)	Storage
VirPath qRT-PCR Master Mix	**1 x 575 µl**	**- 20°C**
Respiratory Multiplex primer / probe mix	**1 x 290 µl**	**- 20°C**
Positive Plasmid Control 1 (PPC-1)	**1 x 200 µl**	**- 20°C**
Positive Plasmid Control 2 (PPC-2)	**1 x 200 µl**	**- 20°C**
Full Process Control (FPC)	**1x 500 µl**	**+4°C***

* see storage and handling details below.

Required equipment

- Class II Biological safety cabinet
- Single and/or multichannel pipettes (10, 100, 200, 1000 µl)
- PCR-clean filtered tips
- 1.5 / 2 ml cold block (or access to ice)
- 96 well cold block (or access to ice)
- qPCR Instrument (4 colour - FAM/HEX/CY5/ROX)
- 96 white-well plate and optical seal compatible with qPCR instrument
- 96 well plate compatible vortexer
- 96 well plate compatible minifuge or centrifuge

Additional user supplied consumables

- Molecular biology grade water

Storage and handling

Upon receipt, store all reagents at -20°C, apart from the FPC. This should be placed and stored at 4°C upon arrival.

Thaw the VirPath qRT-PCR Master Mix on ice and keep on ice at all times. Thaw the Respiratory Multiplex Primers / Probes mix at room temperature in the dark and then keep on ice throughout the qRT-PCR setup preparation. Thaw the Plasmid Positive Controls (PPC-1 and PPC-2) at room temperature and then keep on ice throughout the qRT-PCR setup preparation. The Full Process Control (FPC) should be vortexed for 5 seconds prior to use. After thawing, ensure that all reagents are mixed briefly by vortexing and then spun down. Avoid repeated freeze / thawing whenever possible.

Real-Time PCR systems

This product VirPath SARS-CoV-2 multiplex qRT-PCR kit has been validated for use with the following real-time PCR systems and associated software:

Real-Time PCR sytems	Model	Control Software (Version)
CFX96 Touch™ Real-Time PCR Detection System	1855195 (CFX96)	CFX Maestro Software

This assay should be compatible with other equivalent real-time PCR systems but should be validated prior to use.

RNA extraction kits

The VirPath Respiratory Multiplex qRT-PCR kit should be compatible with most RNA or total nucleic acid extraction products or systems which deliver clean nucleic acid isolation (ie free of PCR inhibitors), but should be validated prior to use.

Warning and precautions

This product should be handled only by trained laboratory technicians who are proficient in performing molecular based tests and it should be used in accordance with the principles of good laboratory practice.

Avoid contact with eyes, skin and clothing. Avoid inhalation and ingestion. A copy of the MSDS is available upon request.

Limitations of use

- The procedures in this IFU must be followed as described. Any deviations may result in assay failure or cause erroneous results.
- Good laboratory practice is required to ensure the performance of the kit, with care required to prevent contamination of the kit components. Components should be monitored for contamination and any components thought to have become contaminated should be discarded in accordance with local waste disposal regulations.
- Interpretation of results must account for the possibility of false negative and false positive results.
- False negative results may be caused by:
    - Unsuitable collection, handling and/or storage of samples.
    - Failure to follow procedures in this handbook.
- False positive results may be caused by:

  - Unsuitable handling of samples containing high concentration of SARS-CoV-2, Flu A/B and RSV A/B viral RNA or positive control template.
  - Unsuitable handling of amplified product.
- All results should be interpreted by a health care professional in the context of patient medical history and clinical symptoms.
- This test cannot rule out diseases caused by other pathogens.
- A negative result for any PCR test does not conclusively rule out the possibility of infection.

Handling of controls

Each plasmid provided in both Positive Plasmid Controls (PPC-1 and PPC-2) is provided at a concentration of 200 copies/µl. When thawed for the first time, it is recommended to aliquot out the entire amount of both controls in single use aliquots in order to minimize freeze / thaw cycles. For each qRT-PCR run, 5 µl of each control are used (ie 5 µl per reaction = 1000 copies per reaction).

When used for the first time, it is recommended to aliquot the Full Process Control (FPC) in single use aliquots of 100 µl each. The aliquots should be stored at +4°C until used. Add 100 µl of FPC to a single well of the sample plate containing clinical samples and top up the volume with molecular biology grate water (if required by the extraction kit used) to reach the required volume.

qRT-PCR setup procedure

Table 1 outlines the required volumes of sample / control and reagents needed to set up the qRT-PCR reaction. Each qRT-PCR run should include the No Template Control (NTC) (ie molecular biology grade water); both Positive Plasmid Controls PPC-1 and PPC-2; and the Full Process Control (FPC). Note that the NTC, PPC-1 and PPC-2 should be included at the qRT-PCR plate setup stage, while the FPC should be added to the sample plate prior to RNA/NA extraction. All procedures should be carried out in a sterile environment, ideally a Class II biosafety cabinet. Thaw reagents as described above and setup the reaction on ice (or cold block) as per the volumes in table 1..

Reagent	Volume
VirPath qRT-PCR Master Mix	**5 µL**
Respiratory Multiplex primer / probe mix	**2.5 µL**
Template	**5 µL**
Water	**7.5 µL**
Total	**20 µL**

Table 1. qRT-PCR reaction mix setup volumes for a single reaction. When preparing a mix for multiple reactions, include a 5% overage for each reagent.

NOTE: the volume of water and template can be adjusted to include more template in the reaction mix as required.

After setting up the qRT-PCR plate, ensure that the reaction mixtures inside the wells are properly mixed by vortexing the plate and then spinning it down. qRT-PCR Plates should be kept chilled at all times during the procedure and must be loaded onto the qRT-PCR immediately after setting up the reaction.

qRT-PCR setup and cycling conditions

Set up the qPCR instrument using manufacturers guidelines and inputting the cycling conditions described in Table 2. Where possible, choose the Quantitation by Comparative Ct (ΔΔCt) method with TaqMan or "Other" reagents (do not add a melt curve option). For qPCR instruments with "FAST" blocks, select the Standard ramp speed. Select the FAM filter for the N2 and ORF-1 target2; the HEX / VIC filter for the M and NS2 targets; the Cy5 / Atto647 filter for the RP target; and the Texas Red / ROX for the N (RSV A/B) targets. If possible, select NFQ-MGB as quencher; or alternatively leave this field empty. Do not select a dye as quencher (such as TAMRA). Set reaction volume to 20 µl.

Step	Cycles	Temperature	Time
1	1	50 °C	10 min
2	1	95 °C	2 min
3	45	95 °C	5 s
4		58 °C	30 s

Table 2. qRT-PCR Program cycling conditions

NOTE: Fluorescence acquisition is performed at step 4.

qRT-PCR data analysis and interpretation

Please note data analysis may vary between qPCR machines and thresholds must be determined empirically by the end user or laboratory, if not utilising the Biorad CFX96 or CFX384 instruments. We recommend setting the baseline start cycle at 5 and the end cycle at 15; and the threshold at 200 RFU (or equivalent ΔCt values if using alternative instruments).

Ct values that fall below the 38 cycles threshold are considered positive signals. Refer to Table 3 below for interpretation of results from control and patient samples.

Sample	N2 / ORF-1 Result (FAM)	M / NS2 Result (HEX / VIC)	N Result (Texas Red / ROX)	RP Result (Cy5 / Atto647)
Positive Plasmid Control 1 (PPC-1)	+	+	+	+
Positive Plasmid Control 1 (PPC-2)	+	+	+	+
Full Process Control (FPC)	+	+	+	-
No Template Control (NTC)	-	-	-	-
SARS-CoV-2 Positive Patient Sample	+	-	-	+
	+	-	-	-
Flu A/B Positive Patient Sample	-	+	-	+
	-	+	-	-
RSV A/B Positive Patient Sample	-	-	+	+
	-	-	+	-
Negative patient sample	-	-	-	+
Failed patient sample	-	-	-	-

Table 3. Interpretation of results for control and patient samples.

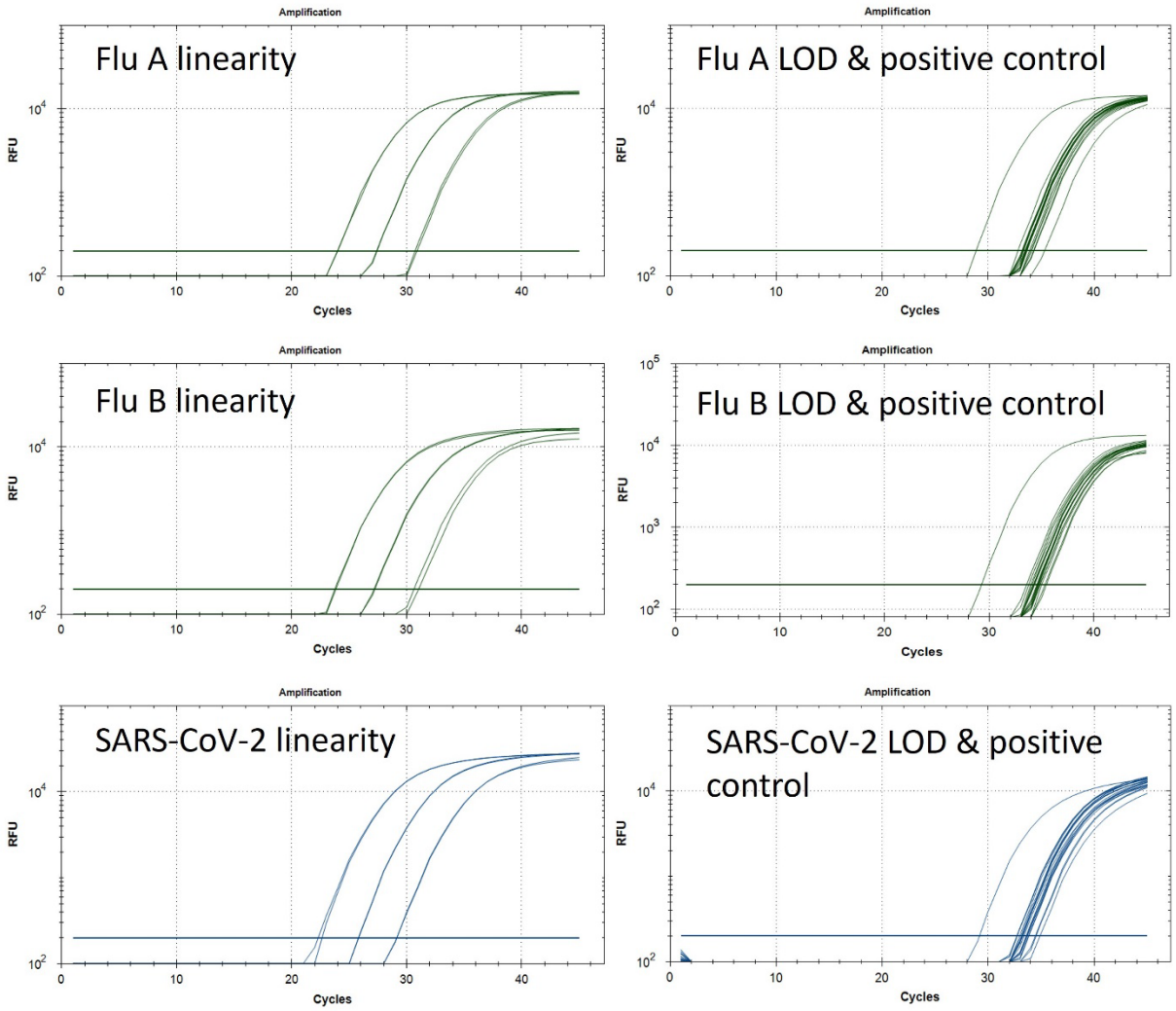
Kit specification and performance summary

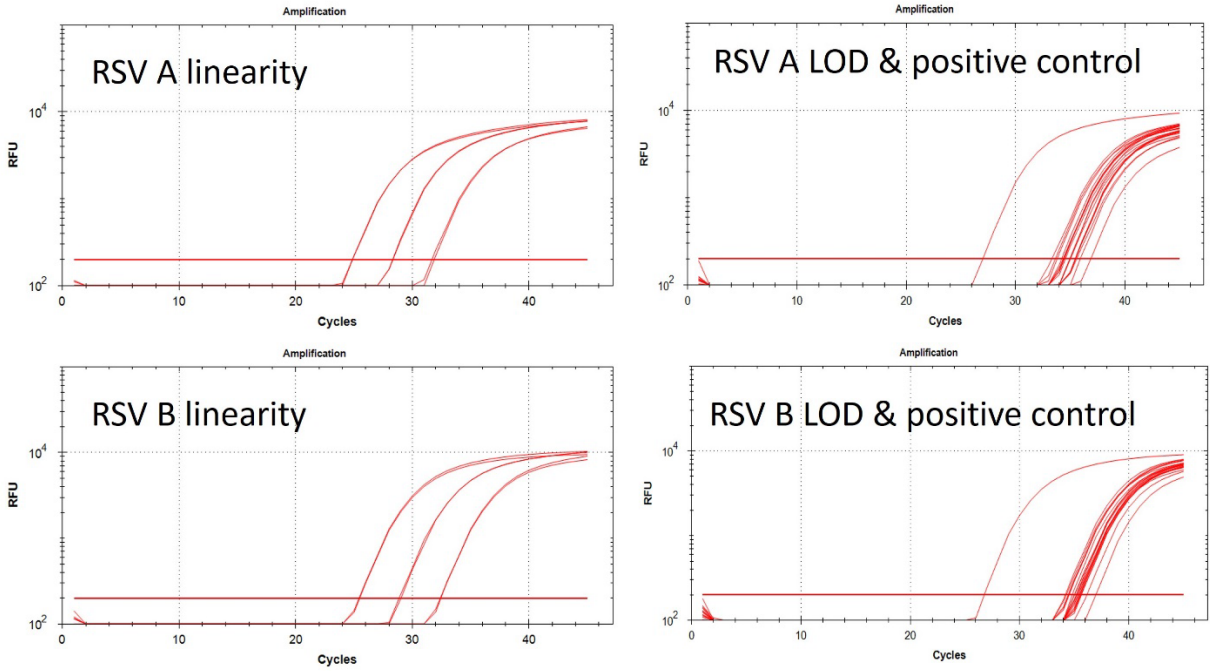
Application	Qualitative PCR test for detection of SARS-CoV-2, Flu A/B, RSV A/B
Type of detection	Ribonucleic acid (RNA) of SARS-CoV-2, Flu A/B, RSV A/B
Sample type	Upper respiratory tract specimens (nasopharyngeal fluids, nasal swab)
qRT-PCR Limit of Detection (95% positivity over 20 replicates).	SARS-CoV-2 (5 copies/rxn), RSV A/RSV B/Flu B (10 copies/rxn), Flu A (20 copies/rxn).
Analytical specificity	100%

qRT-PCR Linearity and Limit of Detection (LOD) Testing

The limit of detection (LOD) was determined by conducting a linearity study through which the minimum copies of viral template RNA that can be detected in a single qRT-PCR reaction were determined. The limit of detection is a copy number providing 95% positivity rate (out of a total of 20 replicates).
Synthetic RNA reference standards for SARS-CoV-2 (Twist Bioscience, cat# 104043), RSV A (Vircell, cat# MBC041), RSV B (Vircell, cat# MBC083), Flu A (ATCC, cat# VR-1884DQ) and Flu B (ATCC, cat# VR-101DQ) were used in a serial dilution experiment following the standard protocol outlined in this IFU for the VirPath Respiratory Multiplex qRT-PCR kit (Figure 1 and Table 4, 5, 6).

Figure 1. Images on the left (linearity): amplification plots for reactions containing 10000, 1000 and 100 copies of synthetic RNA control in duplicate. Images on the right (limit of detection): amplification plots for reactions containing the limit of detection for the synthetic RNA control; 20 replicates were utilised with a 95% detection rate and the positive plasmid control (PPC1 and PPC2) included in the kit was also included for comparison purposes (can be seen as amplification curve showing Ct value <30 in the individual plots). All samples were processed using the VirPath respiratory multiplex kit and run on a BioRad CFX96 qPCR instrument.





Total copies	Assay Flu A		Total copies	Assay Flu B	
	Replicates positive	Average Ct		Replicates positive	Average Ct
10000	2/2	24.00	10000	2/2	23.74
1000	2/2	27.31	1000	2/2	27.15
100	2/2	30.76	100	2/2	30.79
20 (LOD experiment	20/20	33.60 (32.73-35.24)	10 (LOD experiment)	20/20	34.49 (33.48-35.37)

Table 4. qRT-PCR reaction replicates and Ct value summary data for serial dilution of synthetic Flu RNA controls containing 10000, 1000, 100 and LOD copies, processed using the VirPath respiratory multiplex qRT-PCR kit and run on a BioRad CFX96 qPCR instrument. Negative samples do not amplify over 45 cycles.

Total copies	Assay RSV A		Total copies	Assay RSV B	
	Replicates positive	Average Ct		Replicates positive	Average Ct
10000	2/2	24.82	10000	2/2	25.37
1000	2/2	28.45	1000	2/2	28.92
100	2/2	31.72	100	2/2	32.325
10 (LOD experiment	20/20	34.78 (33.28-36.85)	10 (LOD experiment	20/20	35.14 (34.14-36.97)

Table 5. qRT-PCR reaction replicates and Ct value summary data for serial dilution of synthetic RSV RNA controls containing 10000, 1000, 100 and LOD copies, processed using the VirPath respiratory multiplex qRT-PCR kit and run on a BioRad CFX96 qPCR instrument. Negative samples do not amplify over 45 cycles.

Total copies	Assay SARS-CoV-2	
	Replicates positive	Average Ct
10000	2/2	22.38
1000	2/2	25.78
100	2/2	29.10
5 (LOD experiment)	20/20	33.41 (32.61-34.83)

Table 6. qRT-PCR reaction replicates and Ct value summary data for serial dilution of synthetic SARS-CoV-2 RNA controls containing 10000, 1000, 100 and LOD copies, processed using the VirPath respiratory multiplex qRT-PCR kit and run on a BioRad CFX96 qPCR instrument. Negative samples do not amplify over 45 cycles.

Inter-assay and Intra-assay Precision

Inter-assay and intra-assay precision was assessed by creating two pools of synthetic RNA controls by serial dilution. Pool 1 contained SARS-CoV-2 (Twist Bioscience, cat# 104043), Flu A (ATCC, cat# VR-1884DQ) and RSV A (ATCC, cat# VR-26DQ). Pool 2 contained Flu B (ATCC, cat# VR-101DQ) and RSV B (ATCC, cat# VR-1580DQ). Pool 1 and 2 were replicated 10 times across 3 separate plates on 3 separate days and run on the same BioRad CFX96 qPCR instrument. Table 7 below summarises the variability observed across the replicates.

	Flu A Ct	Flu B Ct	RSV A Ct	RSV B Ct	SARS-CoV-2 Ct
Plate 1 Run 1 - 10 replicates	Pool 1	Pool 2	Pool 1	Pool 2	Pool 1
Average	28.78	28.44	29.63	28.57	30.39
Standard Deviation	0.17	0.10	0.22	0.11	0.22
Coefficient of Variation %	0.59	0.36	0.74	0.38	0.71
Plate 2 Run 2- 10 replicates	Pool 1	Pool 2	Pool 1	Pool 2	Pool 1
Average	28.55	28.52	29.50	28.64	30.48
Standard Deviation	0.14	0.09	0.13	0.20	0.23
Coefficient of Variation %	0.48	0.31	0.44	0.70	0.76
Plate 3 Run 3- 10 replicates	Pool 1	Pool 2	Pool 1	Pool 2	Pool 1
Average	28.97	28.79	29.69	29.05	31.29
Standard Deviation	0.13	0.13	0.20	0.05	0.32
Coefficient of Variation %	0.46	0.44	0.70	0.18	1.03
Combined Inter-assay	Pool 1	Pool 2	Pool 1	Pool 2	Pool 1
Average	28.77	28.58	29.61	28.75	30.72
Standard deviation	0.21	0.18	0.10	0.26	0.5
Coefficient of Variation %	0.73	0.63	0.33	0.91	1.61

Table 7. Inter-assay and intra-assay precision for the VirPath Respiratory Multiplex qRT-PCR kit

Cross-Reactivity

The assays included in the VirPath respiratory multiplex qRT-PCR assay were tested for cross-reactivity with common human viruses. Clinical samples at high copy number were utilised (table 8) as well as contrieved Zeptometrix controls (table 9) to ensure that false positives did not occur via the presence of common high titre viruses in the sample. The respiratory panel 2.1 Zeptometrix control (Catalog# NATRPC2.1-BIO) was utilised and is qualitative. Respiratory panel 2.1 contains 2 controls. Respiratory panel 1 (Control 1) contains 12 viruses including Flu A and SARS-CoV-2 (the other viruses are listed in table 9 below). Respiratory panel 2 (Control 2) contains 11 viruses including Flu A, Flu B and RSV A (the other viruses are listed in table 9 below). (+) = present in the control and (-) = not present in the control.

Sample Type	Isolate	Copies	Status (all channels)
Nasopharyngeal Aspirate	Human Parainfluenza 1	1344282	Negative
Nasopharyngeal Aspirate	Human Parainfluenza 2	4933460	Negative
Sputum	Human Parainfluenza 3	495923	Negative
Swab from throat	Human Parainfluenza 4	38475	Negative
Swab from throat	Human Adenovirus	1276396	Negative
Swab from throat	Human Bocavirus	362566	Negative
Nasopharyngeal Aspirate	Human Coronavirus HKU-1	686222	Negative
Broncho-Alveolar Lavage	Human Coronavirus CORV OC43	613059	Negative
Nasopharyngeal Aspirate	Human Coronavirus CORV 229E	11737	Negative
Swab from throat	Human Coronavirus CORV NL63	49295	Negative
Swab from throat	Human alphaherpesvirus 3 (HHV-3)	836477	Negative
Nasopharyngeal Aspirate	Human Metapneumovirus A	189779	Negative
Nasopharyngeal Aspirate	Human Metapneumovirus B	123231	Negative
Nasopharyngeal Aspirate	Human Rhinovirus	153576	Negative
Nasopharyngeal Aspirate	Human Parechovirus	5978	Negative
Swab from nose	Human Enterovirus	69105	Negative

Table 8. Clinical samples utilised to test the cross-reactivity and the outcome upon analysis with the VirPath respiratory multiplex qRT-PCR assay.

Zeptometrix Isolate	Zeptometrix RP2.1 Control expected status	Flu A status (HEX)	Flu B status (HEX)	RSV A status (TexRd)	RSV B status (TexRd)	SARS-CoV-2 status (FAM)	RNase P status
Adenovirus Type 1	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
Adenovirus Type 3	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
Adenovirus Type 31	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
C. pneumoniae	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
Influenza A 2009 H1N1pdm	Control 1 (+), Control 2 (-)	Pos	N/A	Neg	Neg	N/A	Neg
Influenza A H3N2	Control 1 (+), Control 2 (-)	Pos	N/A	Neg	Neg	N/A	Neg
Metapneumovirus 8	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
M. pneumoniae	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
Parainfluenza Type 1	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
Parainfluenza Type 4	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
Rhinovirus 1A	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	N/A	Neg
SARS-CoV-2	Control 1 (+), Control 2 (-)	N/A	N/A	Neg	Neg	Pos	Neg
B. parapertussis	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
B. pertussis	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
Coronavirus 229E	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
Coronavirus HKU-1	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
Coronavirus NL63	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
Coronavirus OC43	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
Influenza AH1	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
Influenza B	Control 1 (-), Control 2 (+)	N/A	Pos	N/A	N/A	Neg	Neg
Parainfluenza Type 2	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
Parainfluenza Type 3	Control 1 (-), Control 2 (+)	N/A	N/A	N/A	N/A	Neg	Neg
RSV A	Control 1 (-), Control 2 (+)	N/A	N/A	Pos	N/A	Neg	Neg

Table 9. Zeptometrix controls utilised to determine the cross-reactivity and the outcome upon analysis the VirPath respiratory multiplex qRT-PCR assay.

In-Silico Cross-Reactivity

Specificity for the target species was analysed by comparing probe and primer sequences against the NCBI nucleotide collection database for possible matches to non-target species. Blast v2.13.0+ was used against the NCBI nucleotide collection database with default short sequence parameters, excluding host organism taxon ID and reporting any results with greater than 0.05 E-value and 90% sequence alignment length against target sequence. No off-target regions were found in any other organism for a primer pair or primer and probe set. This indicates that there is little homology between primer/probe sequences and non-target organisms in the public data and the selected primers and probes are unlikely to generate a false positive result on any organisms with a published genome sequence.

Clinical Verification

A clinical study was undertaken to evaluate the performance of the VirPath Respiratory Multiplex kit against validated clinical tests. For the evaluation of Flu A, Flu B, RSV A and RSV B assays, 137 swab samples were tested:

- 22 positive for Flu A only
- 21 positive for Flu B only
- 23 positive for RSV A only
- 23 positive for RSV B only
- 48 negative

Flu and RSV samples were diagnosed using the CE-IVD Ausdiagnostics Respiratory viruses panel (ref 20602) on the High-Plex 24 system (ref 9150) at an ISO15189 accredited laboratory. Surplus RNA was utilised which was extracted at Nottingham hospital in 2018 using the bioMeriux™ Nuclisens™ easyMAG™ (Lyra™) system.

For the evaluation of the SARS-CoV-2 assays, 173 swab samples were tested:

- 65 positives
- 108 negatives

SARS-CoV-2 samples were diagnosed using the CE-IVD Nonacus VirPath SARS-CoV-2 Multiplex qRT-PCR kit at an ISO15189 accredit laboratory.

The sensitivity and specificity rates for individual and combined targets are detailed in the tables below (table 10, 11, 12 and 13).

VirPath Respiratory multiplex	Comparator test (Ausdiagnostics)	
	Positive (Flu A/B)	**Negative (Flu A/B)**
Positive (Flu A/B)	**43**	**1**
Negative (Flu A/B)	**0**	**94**
Sensitivity %	**100.00**	
Specificity %	**98.95**	

Table 10. Clinical performance of the Flu assay in the VirPath respiratory multiplex qRT-PCR kit.

VirPath Respiratory multiplex	Comparator test (Ausdiagnostics)	
	Positive (RSV A/B)	Negative (RSV A/B)
Positive (RSV A/B)	46	0
Negative (RSV A/B)	0	91
Sensitivity %	100.00	
Specificity %	100.00	

Table 11. Clinical performance of the RSV assay in the VirPath respiratory multiplex qRT-PCR kit.

VirPath Respiratory multiplex	Comparator test (VirPath SARS-CoV-2)	
	Positive (SARS-CoV-2)	Negative (SARS-CoV-2)
Positive (SARS-CoV-2)	65	1
Negative (SARS-CoV-2)	0	108
Sensitivity %	100.00	
Specificity %	99.08	

Table 12. Clinical performance of the SARS-CoV-2 assay in the VirPath respiratory multiplex qRT-PCR kit.

Test	Positive Clinic	Negative Clinic
Positive VirPath Respiratory	**154**	**2**
Negative VirPath Respiratory	**0**	**154**
Sensitivity %	**100**	
Specificity %	**98.72**	

Table 13. Overall clinical performance of the VirPath respiratory multiplex qRT-PCR kit.

Interfering Substances

The following 12 interfering substances were tested at the concentrations detailed in table 14 to determine the effect on the qRT-PCR efficiency and the clinical outcome. No negative impact was observed on qRT-PCR efficiency or outcome.

Substance	Type	Conc.(v/v % or mg/ml	Effect
Blood	Biological	2.50%	No impact
Nasal Spray	Nasal spray	15.00%	No impact
NasalCort	Nasal corticosteroids	5.00%	No impact
OralB	Toothpaste	0.06%	No impact
Listerine	Mouth wash	5.00%	No impact
Chlorasept	Chloraseptic	5.00%	No impact
Mucin	Mucin	2.5	No impact
Lozenges	Throat lozenges	5	No impact
Aciclovir	Anti-viral drugs	3.3	No impact
Bactroban	Antibiotic nasal ointment	5	No impact
Amoxicillin	Antibacterial, systemic	4	No impact
OralJel	Oral anaesthetic	5	No impact

Table 14. List of interfering substances tested at defined concentrations and observed impact.

Technical support

For technical support please contact our dedicated support team on:

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