PHOENIXDX® COFLUENZA 4-PLEX IVD

for diagnostic use

qualitative RT-PCR-based detection of Influenza A, Influenza B & SARS-CoV-2

INSTRUCTIONS FOR USE

50 Tests

REF **PCCSKU15265**

v 1.0

CE IVD

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qualityaustria SYSTEM CERTIFIED ISO 9001:2015 No.21918/0 EN ISO 13485:2016 No.00322/0

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1) INTENDED USE

PHOENIXDX® COFLUENZA 4-PLEX IVD is a real-time RT-PCR-based diagnostic test for the *in vitro* qualitative detection of Influenza A, Influenza B and SARS-CoV-2 in respiratory specimens and sera.

PHOENIXDX® COFLUENZA 4-PLEX IVD detects Influenza A, Influenza B and SARS-CoV-2 RNA in nasopharyngeal and oropharyngeal swab samples during infection. Positive results indicate the presence of Influenza A, Influenza B or SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information must be considered to determine the actual patient infection status. Positive results do not exclude bacterial infection or co-infection with other viruses.

Negative results do not exclude an infection with Influenza A, Influenza B or SARS-CoV-2 and must not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The use of **PHOENIXDX® COFLUENZA 4-PLEX IVD** is intended for use by clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.

2) PHOENIXDX® DETECTION SYSTEM

PHOENIXDX® COFLUENZA 4-PLEX IVD is a real-time RT-PCR-based detection and discrimination system for Influenza A, Influenza B and SARS-CoV-2.

PHOENIXDX® COFLUENZA 4-PLEX IVD detects the presence of highly specific gene sequences of Influenza A, Influenza B, SARS-CoV-2 and one sequence specific for human RNA serving as a human extraction control (**HEC**). Additionally, a non-infectious target positive control (**TPC**) for all viral targets is included. The positive control is used to confirm functionality of the assays and overall PCR performance, the human extraction control is to evaluate the quality of the RNA isolation and overall RNA quality of the sample independently from the viral assays in a different detection channel.

2.1) QPCR-BASED DETECTION

The first step in the detection of Influenza A, Influenza B and SARS-CoV-2 is the conversion of viral RNA into cDNA. Afterwards, the viral target sequences and the **HEC** are simultaneously amplified in one reaction with amplification monitored in real time through the use of fluorescently labelled probes: upon incorporation into the newly amplified DNA strands, the fluorophore is released and an increase in fluorescence signal can be observed.

With **PHOENIXDX® COFLUENZA 4-PLEX IVD**, discrimination between the viral targets is achieved through the use of three different fluorophores that are detected in three different channels: FAM™ for Influenza A, HEX/VIC for Influenza B and ROX for SARS-CoV-2. The **HEC** is detected in the Cy5 channel.

Due to the intrinsic mutation rate of viruses, it is possible that mutations in the target sequence occur and accumulate over time. This can lead to false-negative results with a PCR-based detection approach.

Samples tested positive for any of the viruses should always be confirmed through complementary methods and additional analysis in an independent laboratory.

PHOENIXDX® COFLUENZA 4-PLEX IVD is compatible with every qPCR cycler with calibrated FAM™, HEX/VIC, ROX and CY5 channel.

2.2) MATERIALS PROVIDED

QUANTITY AND VOLUME	COMPONENT
1 x 50 µl	PhoenixDx® **RT Enzyme Mix**
1 x 750 µl	PhoenixDx® **Cofluenza 4-Plex Mix**
1 x 200 µl	PhoenixDx® **Cofluenza TPC**

2.3) ADDITIONAL MATERIALS REQUIRED

- Suitable means & equipment for nucleic acid extraction (see chapter 3.4)
- Real-time PCR detection system equipped for FAM™, HEX/VIC, ROX and Cy5 detection
- Adjustable pipettes & fitting filtered pipette tips
- Nuclease-free water
- Appropriate PSA & workspaces for working with potentially infectious samples
- Surface decontaminants such as DNAZap™ (Life Technologies), DNA Away™ (Fisher Scientific), RNAse Away™ (Fisher Scientific), 10% bleach (1:10 dilution of commercial 5.25-6.0% sodium hypochlorite)
- Nuclease-free tubes / strips / plates to prepare dilutions, mastermixes etc.
- Nuclease-free tubes / strips / plates corresponding to the PCR device
- Suitable storage options for reagents and specimen (4°C, -20°C, -70°C)

2.4) STORAGE

- Store all components at -20°C and avoid repeated freeze and thaw cycles (≤ 3 freeze/thaw cycles; prepare aliquots if required).
- Protect the PhoenixDx® **Cofluenza 4-Plex Mix** from light as prolonged exposure can diminish the performance of the fluorophores.
- If the kit components have been damaged during transport, contact Procomcure Biotech. Do not use as performance may be compromised.
- Keep reagents separate from sample material to avoid contamination.
- Do not use after the designated expiry date.

3) Considerations before Starting

3.1) Biosafety

- Wear appropriate personal protective equipment (e.g. gowns, powder-free gloves, eye protection) when working with clinical specimens.
- Specimen processing should be performed in a certified class II biological safety cabinet following biosafety level 2 or higher guidelines.
- For more information, refer to:
    - Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (SARS-COV-2) https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
    - Biosafety in Microbiological and Biomedical Laboratories 5th edition available at http://www.cdc.gov/biosafety/publications/.
- The use of **PhoenixDx® Cofluenza 4-Plex IVD** and data evaluation is restricted to trained laboratory personnel only.
- Good laboratory practice is essential for optimal performance of this assay. Special care must be taken avoid contamination of the components of the kit. All reagents must be closely monitored for impurities and contamination. Discard suspicious reagents according to local guidelines and regulations.

3.2) Specimens

Only use appropriate specimens for testing, such as:

- Respiratory specimens including nasopharyngeal / oropharyngeal aspirates or washes, nasopharyngeal / oropharyngeal swabs, bronchoalveolar lavage, tracheal aspirates and sputum.
- Swab specimens should be collected only on swabs with a synthetic tip (such as polyester or Dacron®) with aluminum or plastic shafts. Swabs with calcium alginate or cotton tips with wooden shafts are not recommended as they may contain substances that inactivate some viruses and inhibit PCR testing and should only be used if dacron or rayon swabs are not available.

3.3) Specimens - Handling and Storage

- Specimens can be stored at 4°C for up to 72 hours after collection.
- If a delay in extraction is expected, store specimens at -70°C or lower.
- Clinical specimens must be considered potentially infectious and treated accordingly.

⚠ Do not vortex specimens as this will fragment the RNA and lead to failure of the **PhoenixDx® Cofluenza 4-Plex IVD** assays.

Do not use specimens if

- they were not kept at 2-4°C (≤ 4 days) or frozen at -70°C or below.
- they are insufficiently labelled or lack documentation.
- they are not suitable for this purpose (see above for suitable sample material).
- the specimen volume is insufficient.

3.4) Sample Preparation / Nucleic Acid Extraction

- The performance of RT-PCR assays strongly depends on the amount and quality of sample template RNA. It is strongly recommended to qualify and validate RNA extraction procedures for recovery and purity before testing specimens.
- Suitable nucleic acid extraction systems successfully used in combination with **PhoenixDx® Detection Kits** include: Quick-RNA Viral Kits (Zymo Research), bioMérieux NucliSens® systems, QIAamp® Viral RNA Mini Kit, QIAamp® MinElute Virus Spin Kit or RNeasy® Mini Kit (QIAGEN), EZ1 DSP Virus Kit (QIAGEN), Roche MagNA Pure Compact RNA Isolation Kit, Roche MagNA Pure Compact Nucleic Acid Isolation Kit.
- Only extract the number of specimens that will be tested in a single day.
- Do not freeze/thaw extracts more than once before testing as each freeze/thaw cycle will decrease the RNA quality. For optimal results, use directly and do not freeze and thaw before use.
- Extracted nucleic acids should be stored at -70°C or lower and (if re-testing is expected) stored in aliquots.

3.5) Reaction Setup

1) Make sure that all necessary equipment and devices are suitable, calibrated and functional before starting the experiments.
2) Decontaminate equipment and workspace and prepare everything needed for the following experiment to keep the workflow short and repeatable.
3) Switch on the PCR detection system and program it to avoid delays after setting up the reactions.
4) Thaw all components of **PhoenixDx® Cofluenza 4-Plex IVD** on ice and mix gently but thoroughly to ensure even distribution of components. Collect liquid at the bottom of the tube with a quick spin.
5) Set up your **Mastermix Plate**:

    a. Always prepare control reactions with nuclease-free dH_2O instead of sample material **(NTC)** to detect contamination in your reagents.
    b. When using the provided target positive control **(TPC)**, use **4 µl / reaction**.
    c. > 2 replicates / sample are strongly recommended.
    d. Prepare enough mastermix for all planned reactions. It is recommended to prepare mastermix for 2 additional reactions to compensate for pipetting inaccuracies.
    e. Distribute the mastermix to your strips/plate.

Component	Volume
PhoenixDx® RT Enzyme Mix	1 µl
PhoenixDx® Cofluenza 4-Plex Mix	15 µl
isolated sample RNA / TPC / NTC	4 µl / 4 µl / 4 µl dH_2O

6) Transfer the Mastermix Plate to a separate workspace to add the sample material. Preparing reagents and final reaction setup in separate workspaces helps to avoid contamination of equipment and reagents with sample material.

   a. Prepare negative reactions first and seal them before handling positive samples. It is recommended to only bring potentially positive sample material and the included target positive control to the workspace once the NTC is prepared and sealed.
   b. Add your samples to the Mastermix Plate. An example setup is given in **Fig 2).**
   c. Keep reactions on ice until transferring them to the PCR device.

7) Transfer the reactions to the PCR device, then cycle according to these guidelines:

Step	Cycles	Temperature	Duration
Reverse Transcription	1	50°C	5 minutes
Initial Denaturation	1	95°C	5 minutes
Amplification	38	95°C	5 seconds
		60°C[1]	30 seconds

[1] Enable Data Collection for **FAM™** (Influenza A), **HEX/VIC** (Influenza B), **ROX** (SARS-CoV-2) and **Cy5** (**HEC**). Do not set **ROX** as passive reference since the channel is used for detection.

Once the run is finished, do not open the reaction tubes to avoid contamination and discard according to local guidelines and regulations. Do not autoclave as this may contaminate laboratory equipment with amplicons.

4) Analysis

- **dH_2O controls (NTC) must not give a Ct value for any assay**. If they do, the reaction was contaminated with sample RNA / cDNA. Decontaminate equipment and workspace and repeat the reactions. Also, check for device-derived artifacts or falsely placed threshold. **If a contamination persists, use fresh reagents**.

- **All reactions containing RNA isolate must give positive Ct values for the HEC assay when working with samples of human origin. The Ct values are expected around 20-32.** Failure to amplify the negative human extraction control indicates a flawed RNA extraction or loss of RNA isolate due to RNAse contamination. Late Ct values for the **HEC** may indicate a low RNA quality / amount in the extract.

- **For a sample to be considered positive for Influenza A, the FAM™ channel must give a positive Ct value.** Amplification of the HEC in **Cy5 channel** is expected around Ct 20-35. Should the **HEC** fail to amplify, the sample must still be considered positive. This outcome is possible when having an unusually high virus titer, or the sample was not of human origin, but cell culture derived or analysis of surface contamination.

- **For a sample to be considered positive for Influenza B, the HEX/VIC channel must give a positive Ct value.** Amplification of the HEC in **Cy5 channel** is expected around Ct 20-35. Should the **HEC** fail to amplify, the sample must still be considered positive. This outcome is possible when having an unusually high virus titer, or the sample was not of human origin, but cell culture derived or analysis of surface contamination.

- **For a sample to be considered positive for SARS-CoV-2, the ROX channel must give a positive Ct value.** Amplification of the HEC in **Cy5 channel** is expected around Ct 20-35. Should the **HEC** fail to amplify, the sample must still be considered positive. This outcome is possible when having an unusually high virus titer, or the sample was not of human origin, but cell culture derived or analysis of surface contamination.

- **Samples with positive Ct values for the HEC and positive Ct values in more than one of the other three detection channels imply multiple infections.**

- **If no amplification signal in neither the FAM™, HEX/VIC, ROX or Cy5 channel is observed for any assay, PCR was inhibited.** Check reaction setup and device settings and repeat the RNA extraction if necessary. Results are invalid and cannot be interpreted.

- **When using the TPC, a positive Ct in the FAM™, HEX/VIC, ROX and Cy5 channel must be observed. The Ct values for the TPC should be < 35 cycles.** If the Ct value does not correspond to the expected value or not all assays are tested positive, PCR was compromised. Check the reaction setup and PCR device settings and repeat the reactions. Repeated freeze and thaw cycles of the TPC can compromise its quality resulting in late Ct values.

⚠ **Always analyze your sample reactions independently of the TPC reactions**. The TPC is an artificial control construct resulting in a significantly higher signal strength than actual samples. This will lead to a distorted picture when analyzed together with actual samples.
For analysis, the **threshold must be set only for the wells containing sample material** not including wells with TPC reactions. If amplification in sample reactions seems to have failed, check if the TPC reactions are displayed simultaneously.

Table 1 Interpretation of amplification results with PHOENIXDX® COFLUENZA 4-PLEX IVD

FAM™	HEX/VIC	ROX	Cy5	Result
/	/	/	+	The sample does not contain **Influenza A**, **B** or **SARS-CoV-2 RNA**. The control was amplified successfully. The sample is considered **negative for all three viruses.**
/	/	/	/	No amplification in any channel indicates flawed RNA isolation, sample degradation or PCR inhibition. Results cannot be interpreted.
+	/	/	+	The sample is positive for **Influenza A**.
/	+	/	+	The sample is positive for **Influenza B**.
/	/	+	+	The sample is positive for **SARS-CoV-2**.
Positive Ct value in >1 channel			+	The results imply multiple infections. Confirm results with suitable complementary methods.
+	+	+	+	Expected result for the **TPC**.

5) LIMITATIONS

- For reliable results, it is essential to adhere to the guidelines given in this manual. Changes in reaction setup or cycling protocol may lead to failed experiments.
- Depending on the sample matrix, inhibitors may be present in the isolated RNA and disable reverse transcription and / or PCR amplification. If this is the case, another sample type or isolation method may be beneficial.
- Spontaneous mutations within the target sequences may result in failure to detect the target sequence.
- Results must always be interpreted in consideration of all other data gathered from a sample. Interpretation must be performed by personnel trained and experienced with this kind of experiment.
- For safety reasons, specimen collection, transport, storage and processing procedures must be performed by trained personnel only.
- This assay must not be used on specimens directly. Appropriate nucleic acid extraction methods have to be conducted prior to using this assay.
- Reliable results depend strongly on proper sample collection, storage and handling procedures.

6) QUALITY CONTROL

In accordance with Procomcure Biotech GmbH's EN ISO 13485-certified Quality Management System, each lot of **PHOENIXDX® COFLUENZA 4-PLEX IVD** is tested against predetermined specifications to ensure consistent product quality.

7) NON-CLINICAL PERFORMANCE EVALUATION

7.1) ANALYTICAL SPECIFICITY - *IN SILICO* ANALYSIS

The *in silico* analysis for possible cross-reactions with the organisms listed in **Table 2** was performed by mapping primers used with **PHOENIXDX® COFLUENZA 4-PLEX IVD** to the sequences downloaded from NCBI. If any primer sets were mapped to a sequence on opposite strands with short distance in between, potential amplifications were flagged. No potential cross reactivity is expected based on the *in silico* analysis.

7.2) ANALYTICAL SPECIFICITY – *IN VITRO* ANALYSIS

PHOENIXDX® COFLUENZA 4-PLEX IVD was tested for specificity against a set of 60 different controls (e.g. viral, bacterial and human) including one artificial SARS-CoV-2 genome and one SARS-CoV-2 isolate. The experiments were performed according to the protocols and instructions given in this manual.

Table 2 List of organisms used for in vitro specificity testing for SARS-CoV-2 detection.

TARGET	RESULT	TARGET	RESULT	TARGET	RESULT
HSV-1 (herpes simplex 1)	/	Candida albicans	/	Salmonella subterranea	/
HSV-2 (herpes simplex 2)	/	Enterococcus faecalis	/	Salmonella bongori	/
HHV-6 (human herpesvirus 6)	/	Salmonella enterica	/	Plasmodium falciparum	/
HHV-6B (human herpesvirus 6B)	/	Bacillus subtilis	/	Trypanosoma brucei	/
HHV-8 (human herpesvirus 8)	/	Pseudomonas aeruginosa	/	Leishmania major	/
HHV-5 (HCMV)	/	Staphylococcus epidermidis	/	Neisseria gonorrhoeae	/
EBV (epstein barr virus)	/	Clostridium perfringens	/	Neisseira lactamica	/
human gDNA (pool male/female)	/	Candida kefyr	/	Toxoplasma gondii	/
Staphylococcus aureus (Mu50)	/	Candida tropicalis	/	Chlamydia trachomatis D	/
Clostridium difficile	/	Candida glabrata	/	Chlamydia trachomatis LGV	/
Listeria monocytogenes	/	Streptococcus pneumoniae	/	VZV (varicella zoster virus)	/
Listeria innocua	/	Serratia marcescens	/	RSV	/
Listeria ivanovii	/	Shigella flexneri	/	Influenza A H1N1	/
Legionella pneumophila	/	Pseudomonas sp. AOP	/	Influenza A H3N2	/
TOP10 (E.coli)	/	Haemophilus influenzae	/	Influenza B	/
EPEC (E.coli)	/	Pseudomonas stutzeri	/	MERS-CoV	/
Cronobacter sakazakii	/	Enterococcus faecium	/	Artificial SARS-CoV-2	+
Chlamydia trachomatis	/	Acinetobacter baumannii	/	SARS-CoV-2 isolate	+
Helicobacter pylori	/	Campylobacter jejuni	/	TPC	+
Yersinia enterocolitica	/	Mycoplasma	/	NTC	/

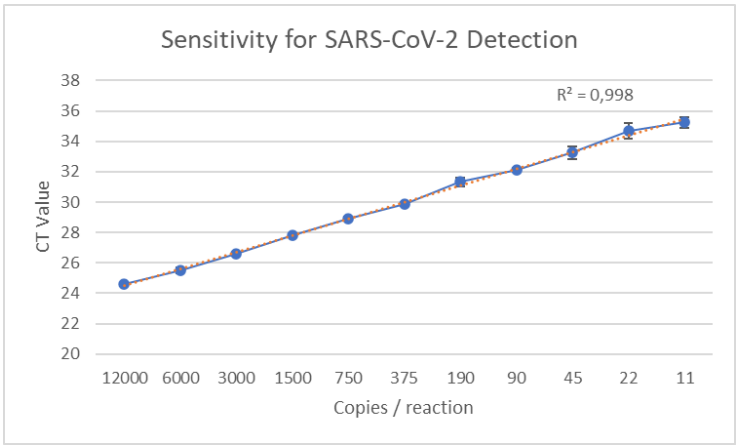
Table 3 List of organisms used for in vitro specificity testing for Influenza A detection.

TARGET	RESULT	TARGET	RESULT	TARGET	RESULT
HSV-1 (herpes simplex 1)	/	Candida albicans	/	Salmonella subterranea	/
HSV-2 (herpes simplex 2)	/	Enterococcus faecalis	/	Salmonella bongori	/
HHV-6 (human herpesvirus 6)	/	Salmonella enterica	/	Plasmodium falciparum	/
HHV-6B (human herpesvirus 6B)	/	Bacillus subtilis	/	Trypanosoma brucei	/
HHV-8 (human herpesvirus 8)	/	Pseudomonas aeruginosa	/	Leishmania major	/
HHV-5 (HCMV)	/	Staphylococcus epidermidis	/	Neisseria gonorrhoeae	/
EBV (epstein barr virus)	/	Clostridium perfringens	/	Neisseira lactamica	/
human gDNA (pool male/female)	/	Candida kefyr	/	Toxoplasma gondii	/
Staphylococcus aureus (Mu50)	/	Candida tropicalis	/	Chlamydia trachomatis D	/
Clostridium difficile	/	Candida glabrata	/	Chlamydia trachomatis LGV	/
Listeria monocytogenes	/	Streptococcus pneumoniae	/	VZV (varicella zoster virus)	/
Listeria innocua	/	Serratia marcescens	/	RSV	/
Listeria ivanovii	/	Shigella flexneri	/	Influenza A H1N1	+
Legionella pneumophila	/	Pseudomonas sp. AOP	/	Influenza A H3N2	+
TOP10 (E.coli)	/	Haemophilus influenzae	/	Influenza B	/
EPEC (E.coli)	/	Pseudomonas stutzeri	/	MERS-CoV	/
Cronobacter sakazakii	/	Enterococcus faecium	/	Artificial SARS-CoV-2	/
Chlamydia trachomatis	/	Acinetobacter baumannii	/	SARS-CoV-2 isolate	/
Helicobacter pylori	/	Campylobacter jejuni	/	TPC	+
Yersinia enterocolitica	/	Mycoplasma	/	NTC	/

Table 4 List of organisms used for in vitro specificity testing for Influenza B detection.

TARGET	RESULT	TARGET	RESULT	TARGET	RESULT
HSV-1 (herpes simplex 1)	/	Candida albicans	/	Salmonella subterranea	/
HSV-2 (herpes simplex 2)	/	Enterococcus faecalis	/	Salmonella bongori	/
HHV-6 (human herpesvirus 6)	/	Salmonella enterica	/	Plasmodium falciparum	/
HHV-6B (human herpesvirus 6B)	/	Bacillus subtilis	/	Trypanosoma brucei	/
HHV-8 (human herpesvirus 8)	/	Pseudomonas aeruginosa	/	Leishmania major	/
HHV-5 (HCMV)	/	Staphylococcus epidermidis	/	Neisseria gonorrhoeae	/
EBV (epstein barr virus)	/	Clostridium perfringens	/	Neisseira lactamica	/
human gDNA (pool male/female)	/	Candida kefyr	/	Toxoplasma gondii	/
Staphylococcus aureus (Mu50)	/	Candida tropicalis	/	Chlamydia trachomatis D	/
Clostridium difficile	/	Candida glabrata	/	Chlamydia trachomatis LGV	/
Listeria monocytogenes	/	Streptococcus pneumoniae	/	VZV (varicella zoster virus)	/
Listeria innocua	/	Serratia marcescens	/	RSV	/
Listeria ivanovii	/	Shigella flexneri	/	Influenza A H1N1	/
Legionella pneumophila	/	Pseudomonas sp. AOP	/	Influenza A H3N2	/
TOP10 (E.coli)	/	Haemophilus influenzae	/	Influenza B	+
EPEC (E.coli)	/	Pseudomonas stutzeri	/	MERS-CoV	/
Cronobacter sakazakii	/	Enterococcus faecium	/	Artificial SARS-CoV-2	/
Chlamydia trachomatis	/	Acinetobacter baumannii	/	SARS-CoV-2 isolate	/
Helicobacter pylori	/	Campylobacter jejuni	/	TPC	+
Yersinia enterocolitica	/	Mycoplasma	/	NTC	/

7.3) ANALYTICAL SENSITIVITY &LINEARITY



The LOD95 (Limit of Detection) defines the number of target sequences (copy number) that can be detected in ≥ 95% of reactions. The LOD95 was determined by testing a serial dilution of isolated SARS-CoV-2 RNA with 11 concentrations in 24 replicates per concentration. One copy of viral genomic RNA has been detected in 6 cases of 24 replicas. LOD95 for detection of SARS-CoV-2 is 2.75 copies/µl of the eluate. LOD95 for Influenza A (H3N2) is 20 copies/µl and LOD95 for Influenza B is 0.5 copies/µl of the eluate.

8) CLINICAL DATA

The performance of **PHOENIXDX® COFLUENZA 4-PLEX IVD** was tested in a paired comparison using collected nasopharyngeal swabs. **PHOENIXDX® COFLUENZA 4-PLEX IVD** was evaluated using clinical samples collected from patients with signs and symptoms of an upper respiratory infection against a validated CE IVD reference kit with the intended use of detecting SARS-CoV-2 RNA, Influenza A and Influenza B. RNA isolation was automatically performed using magnetic-bead-based isolation kit according to the instructions provided by the manufacturer.

Clinical samples were collected by qualified personnel according to the instructions provided by the manufacturer of the collection device. Samples were tested to be negative with a commercially available nucleic acid test for the qualitative detection of microorganisms associated with common upper respiratory tract infections.

Clinical data for **SARS-CoV-2** detection.

Reference Method	n	PhoenixDx® Cofluenza 4-Plex IVD	
		positive	negative
Positive	21	A= 21	B= 0
Negative	15	C= 0	D= 15
Clinical sensitivity = [a/(a+c)] ×100 = [21/(21+0)] x100 =			100%
Clinical specificity = [d/(b+d)] ×100 = [15/(0+15] x100 =			100%

Clinical data for **Influenza A** detection.

Reference Method	n	PhoenixDx® Cofluenza 4-Plex IVD	
		positive	negative
Positive	20	A= 17	B= 3
Negative	86	C= 0	D= 86
Clinical sensitivity = [a/(a+c)] ×100 = [17/(17+0)] x100 =			100%
Clinical specificity = [d/(b+d)] ×100 = [86/(3+86] x100 =			96,63%

Clinical data for **Influenza B** detection.

Reference Method	n	PhoenixDx® Cofluenza 4-Plex IVD	
		positive	negative
Positive	41	A= 40	B= 1
Negative	65	C= 0	D= 65
Clinical sensitivity = [a/(a+c)] ×100 = [40/(40+0)] x100 =			100%
Clinical specificity = [d/(b+d)] ×100 = [65/(1+65] x100 =			98,48%

9) Trademarks

PhoenixDx®, NucliSens® (bioMérieux), QIAamp®, RNeasy® (QIAGEN), ChargeSwitch® (Invitrogen), ROX™, FAM™ (Life Technologies), DNAZap™, DNA Away™, RNAse Away™

Registered names, trademarks, etc. used in this document, even if not specifically marked as such, are not to be considered unprotected by law.

10) Literature

Corman VM, Landt O, Kaiser M, et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. 2020;25(3):2000045. doi:10.2807/1560-7917.ES.2020.25.3.2000045

11) Technical Assistance

For questions or technical support, contact Procomcure Biotech:

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12) Symbol Definition (Manual & Packaging)

	Contains sufficient for <n> tests
	Catalogue Number
	Manufacturer
	Batch Code
	Temperature Limit
	Use-by Date
	Consult instructions for use
	*In vitro* diagnostic

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