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PhoenixDx® *SARS-CoV-2 IVD*

for diagnostic use

qualitative RT-PCR-based detection of SARS-CoV-2

INSTRUCTIONS FOR USE

CE IVD

50 Tests

REF **PCCSKU15261**

Procomcure Biotech GmbH
Breitwies 1
5303 Thalgau
+43 6229 39608
office@procomcure.com

qualityaustria SYSTEM CERTIFIED
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1) Intended Use

PhoenixDx® SARS-CoV-2 IVD is a real-time RT-PCR-based diagnostic test for the *in vitro* qualitative detection of 2019-Novel Coronavirus (SARS-CoV-2) in respiratory specimens and sera from patients who meet COVID-19 clinical and/or epidemiological criteria.

PhoenixDx® SARS-CoV-2 IVD detects SARS-CoV-2 RNA in nasopharyngeal and oropharyngeal swab samples during infection. Positive results indicate the presence of 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 a SARS-CoV-2 infection 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® SARS-CoV-2 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.

The kits follow CDC's and WHO's latest detection guidelines (03/2020).

2) PhoenixDx® Detection System

PhoenixDx® SARS-CoV-2 IVD is a real-time RT-PCR-based detection system for the 2019 Wuhan coronavirus (**SARS-CoV-2,** formerly **2019-nCoV**). SARS-CoV-2 is considered a novel human coronavirus that is genetically distinct from the common human coronaviruses (229E, NL63, OC43, HKU1), which cause seasonal acute respiratory illness. It is also genetically distinct from the two newer human coronaviruses, MERS-CoV and SARS-CoV.

PhoenixDx® SARS-CoV-2 IVD detects the presence of 2 different and highly specific gene sequences of corona viruses: one identifies SARS-CoV-2, SARS-CoV, and bat-SARS-related coronaviruses (**Sarbeco**), one specifically targets SARS-CoV-2 (**SARS-CoV-2**). Additionally, a non-infectious target positive control (**TPC**) and a negative human extraction control (**HEC**) are included. The positive control is used to confirm functionality of the assays and overall PCR performance, the negative human extraction control is included to evaluate the quality of the RNA isolation independently from the SARS-CoV-2 assays.

2.1) qPCR-based Detection of SARS-CoV-2

The first step in the detection of SARS-CoV-2 is the conversion of viral RNA into cDNA. Afterwards, the target sequences unique for SARS-CoV-2 are specifically amplified with amplification monitored in real time through the use of fluorescently labelled probes: upon incorporation into the newly amplified DNA strands, the fluorophore (FAM™) is released and an increase in fluorescence signal can be observed.

Due to the intrinsic mutation rate of coronaviruses, 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.

PHOENIXDX® SARS-COV-2 IVD addresses this issue by using 2 detection assays on 2 different target sequences to minimize the chance of false-negative results caused by an altered target sequence. The original target sequences for SARS-CoV-2 are included as a non-infectious target positive control (**TPC**) to check the integrity of the detection assays.

Samples tested positive should always be confirmed through complementary methods and additional analysis in an independent laboratory.

PHOENIXDX® SARS-COV-2 IVD is validated on the 7500 Fast System (ABI®), DTprime 5 (DNA Technology) and qTower^{3}G (Analytik Jena).

2.2) MATERIALS PROVIDED

QUANTITY AND VOLUME	COMPONENT
1 x 150 µl	PhoenixDx® **Enzyme Mix**
1 x 750 µl	PhoenixDx® **Sarbeco Mix**
1 x 750 µl	PhoenixDx® **SARS-CoV-2 Mix**
1 x 750 µl	PhoenixDx® **HEC Mix**
1 x 200 µl	SARS-CoV-2 **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™ 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).
- Protect the 2X qPCR mastermixes 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® SARS-CoV-2 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, broncheoalveolar 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® SARS-CoV-2 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® SARS-CoV-2 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. Always include the assay for the negative human extraction control **(HEC)** to evaluate the quality of your RNA isolate.
    c. When using the provided target positive control **(TPC)**, use **4 µl / reaction**.
    d. > 2 replicates / sample are strongly recommended.
    e. Prepare enough mastermix for all planned reactions. It is recommended to prepare mastermix for 2 additional reactions to compensate for pipetting inaccuracies.
    f. Distribute the mastermix to your strips/plate. An example setup is given in **Fig 1).**

COMPONENT	VOLUME
PhoenixDx® Enzyme Mix	1 µl
PhoenixDx® (Sarbeco / SARS-CoV-2 / HEC) 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.

Table 1 Example pipetting scheme for the distribution of mastermixes with the individual assay mixes.

	1	2	3	4	5	6	7	8	9	10	11	12
A	Sarbeco											
B	SARS-CoV-2											
C	HEC											
D												
E												
F												
G												
H												

Table 2 Example pipetting scheme for the addition of samples.

	1	2	3	4	5	6	7	8	9	10	11	12
A	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	TPC
B	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	TPC
C	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	TPC
D												
E												
F												
G												
H												

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

STEP	CYCLES	TEMPERATURE	DURATION
Reverse Transcription	1	45°C	10 minutes
	1	55°C	10 minutes
Initial Denaturation	1	95°C	10 minutes
Amplification	40	95°C	15 seconds
		58°C[1]	45 seconds

[1] Enable Data Collection for **FAM™.** If required, set Passive Reference to **ROX™**.

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 positive Ct for any assay**. If they do, the reaction was contaminated with sample RNA / cDNA. Decontaminate equipment and workspace and repeat the reactions. **If the contamination persists, use fresh reagents**.

- **For a sample to be considered positive for SARS-CoV-2, the assay for SARS-CoV-2 and /or Sarbeco must give a positive Ct value.** Amplification of the HEC is expected around Ct 22-29. Should the **HEC** fail to amplify, the sample must still be considered positive.

- **For a sample to be considered negative for SARS-COV-2, the SARS-CoV-2 and Sarbeco assay must not give a positive Ct value.** The **HEC must give a positive Ct value** (Ct 22-29) for these samples to ensure that sample material of suitable quality was present. If the assay for Sarbeco gives a positive Ct value, is considered presumptive positive for SARS-CoV-2. A negative SARS-CoV-2 result and a positive Sarbeco result is suggestive of low concentration of viral RNA, a mutation in the SARS-CoV-2 target sequence, or an infection with other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans).

- **A sample is considered negative for any of the tested corona viruses if the assays for Sarbeco and SARS-CoV-2 do not give a positive Ct value while the HEC still amplifies with the expected Ct value** (Ct 22-29).

- **If no amplification signal 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.

- **All reactions containing RNA isolate must give positive Ct values for the HEC assay. The Ct values are expected around 22-29.** 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.

- **When using the TPC for SARS-COV-2, a positive Ct for both assays must be observed. The Ct value for the TPC should be < 35 cycles. The HEC must not give a signal when using the TPC.** 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 3 Interpretation of amplification results with PhoenixDx® SARS-CoV-2

SARBECO	SARS-CoV-2	HEC	INTERPRETATION
+	+	+	**Sarbeco** and **SARS-CoV-2** target sequences & **HEC** were amplified. The sample is considered positive for SARS-CoV-2.
/	+	+	**SARS-CoV-2** target sequence is detected, and sample is considered positive for SARS-CoV-2. A positive SARS-CoV-2 result and a negative Sarbeco result is suggestive of low concentration of viral RNA, or mutation in the target region of **Sarbeco** sequence.
+	/	+	Sample is considered presumptive positive for SARS-CoV-2. A negative **SARS-CoV-2** result and a positive **Sarbeco** result is suggestive of low concentration of viral RNA, a mutation in the **SARS-CoV-2** target sequence, or an infection with other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans).
/	/	+	Only the target sequence for the **HEC** was amplified. The sample is considered negative for SARS-CoV-2 and other tested corona viruses.
/	/	/	PCR was inhibited, results are invalid.
+	+	/	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 sequence 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) NON-CLINICAL PERFORMANCE EVALUATION

6.1) ANALYTICAL SPECIFICITY – *IN SILICO* ANALYSIS

The *in silico* analysis for possible cross-reactions with the organisms listed in Table 4 was performed by mapping primers used with **PHOENIXDX® SARS-COV-2** to the sequences downloaded from NCBI. If any two of 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.

6.2) ANALYTICAL SPECIFICITY – *IN VITRO* ANALYSIS

PHOENIXDX® SARS-COV-2 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 4 List of targets used for in vitro specificity testing

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	/	Chlamydia trachomatis C.S.	/
Listeria innocua	/	Serratia marcescens	/	Chlamydophila pneumoniae	/
Listeria ivanovii	/	Shigella flexneri	/	VZV (varicella zoster virus)	/
Legionella pneumophila	/	Pseudomonas sp. AOP	/	Influenza A	/
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 (SARS-CoV-2)	+
Yersinia enterocolitica	/	Mycoplasma	/	NTC	/

6.3) Analytical Sensitivity & Linearity

The LOD_{95} (Limit of Detection) defines the number of target sequences (copy number) that can be detected in ≥ 95% of reactions. The LOD_{95} was determined by testing a serial dilution of isolated SARS-CoV-2 RNA with 8 concentrations in 24 replicates per concentration. One copy of viral genomic RNA has been detected in 6 cases of 24 replicas.

LOD95 = 50 copies / 20 µL reaction

Linearity of **PhoenixDx® SARS-CoV-2** was determined with a dilution series of isolated SARS-CoV-2 RNA ranging from 10^6 copies to 10^2 of the target sequences. Experiments were performed on the ABI 7500Fast PCR System.

6.4) Performance on ABI 7500 FAST

ABI 7500 FAST (Applied Biosystems)	
PCR Performance	CT Value of 16.5 at 10^6 copies per reaction
PCR Efficiency	96.7 %
Linearity	0.998 in Range 10^6 to 10^2 copies per reaction
Technical sensitivity	Less than 10 copies per reaction were detected in 16 of 24 replicas
LOD_{95}	50 copies per reaction
Standard Deviation	0.03 Standard Deviation CT at 10^6 copies per reaction
	0.13 Standard Deviation CT at 10^3 copies per reaction

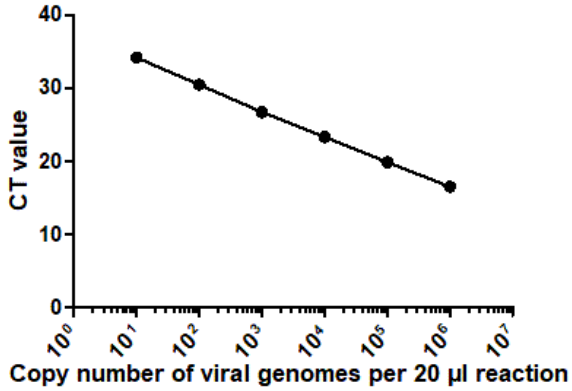

Fig 1 Standard Curve for SARS-CoV-2 viral genome detection of ABI 7500 FAST cycler

6.5) Performance on qTower³ G

qTower³ G (Analytik Jena)	
PCR Performance	CT Value of 18.4 10^6 at copies per reaction
PCR Efficiency	92.5 %
Linearity	0.999 in Range 10^6 to 10^2 copies per reaction
Technical sensitivity	Less than 10 copies per reaction were detected in 20 of 24 replicas
LOD_{95}	40 copies per reaction
Standard Deviation	0.19 Standard Deviation CT at 10^6 copies per reaction
	0.22 Standard Deviation CT at 10^3 copies per reaction

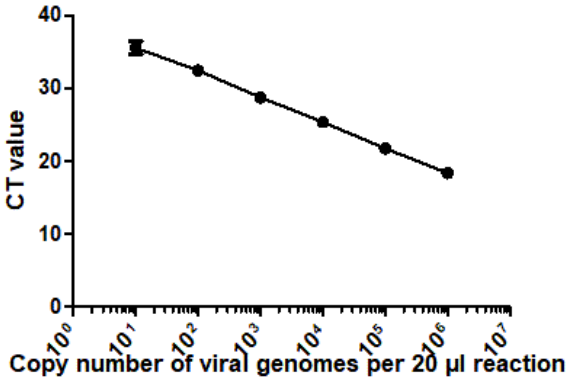

Fig 2 Standard Curve for SARS-CoV-2 viral genome detection of ABI 7500 FAST cycler

6.6) Performance on DTprime 5

DTprime 5 (DNA Technology)	
PCR Performance	CT Value of 16.4 at 10^6 copies per reaction
PCR Efficiency	95.03 %
Linearity	0.999 in Range 10^6 to 10^2 copies per reaction
Technical sensitivity	Less than 10 copies per reaction were detected in 16 of 24 replicas
LOD_{95}	50 copies per reaction
Standard Deviation	0.19 Standard Deviation CT at 10^6 copies per reaction
	0.23 Standard Deviation CT at 10^3 copies per reaction

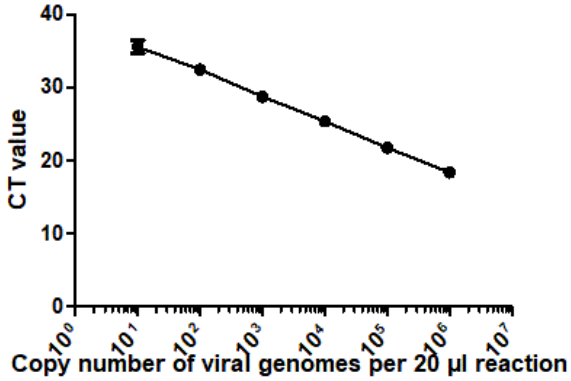

Fig 3 Standard Curve for SARS-CoV-2 viral genome detection of ABI 7500 FAST cycler

7) Clinical Data

The performance of **PhoenixDx® SARS-CoV-2 IVD** was tested in a paired comparison using collected nasopharyngeal swabs. **PhoenixDx® SARS-CoV-2 IVD** was evaluated using 100 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. RNA isolation was manually performed using spin-column-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.

Reference Method		PhoenixDx® SARS-CoV-2 IVD	
		Positive	Negative
Positive		A = 46	B = 2
Negative		C = 0	D = 54
Clinical sensitivity	= [a/(a+c)] ×100 = [46/(46+0)] x100 =		**100 %**
Clinical specificity	= [d/(b+d)] ×100 = [54/(2+54] x100 =		**96,4 %**

8) Quality Control

In accordance with Procomcure Biotech GmbH EN ISO 13485-certified Quality Management System, each lot of **PhoenixDx® SARS-CoV-2** is tested against predetermined specifications to ensure consistent product quality.

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:

Procomcure Biotech GmbH
Breitwies 1
5303 Thalgau
+43 6229 39608
support@procomcure.com

12) Symbol Definition (Manual & Packaging)

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

Procomcure Biotech GmbH
Breitwies 1
5303 Thalgau
+43 6229 39608
www.procomcure.com