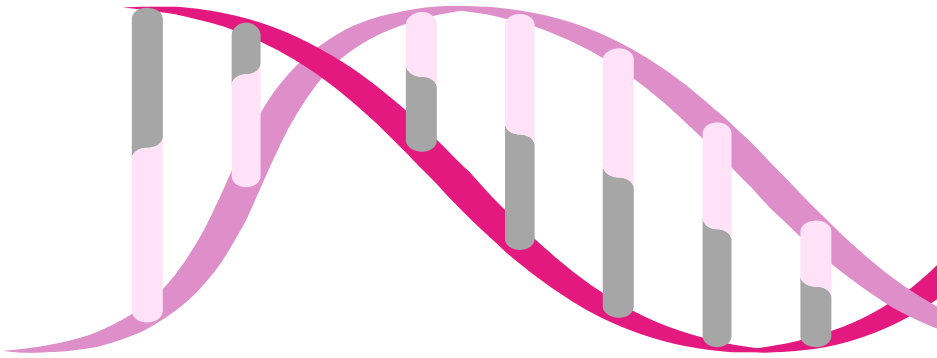
For professional use only



ULISSE BioMed

We build using DNA: the molecule of life

UBM SARS-CoV-2 Test

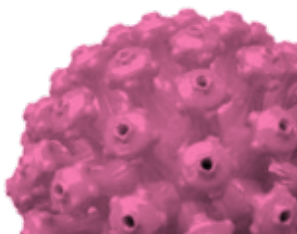
INSTRUCTIONS FOR USE

Real Time Detection of SARS-CoV-2 in nasopharyngeal specimen

CE IVD

REF UBM0016

HIGH SENSITIVITY & SPECIFICITY
Multiplex real-time PCR with high sensitivity and specificity



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1. Product description

Intended use

"UBM SARS-CoV-2 test" is an *in vitro* diagnostic (IVD) medical device intended for the qualitative of nucleic acids from SARS-CoV-2 virus with real-time polymerase chain reaction (PCR) from nasopharyngeal specimens collected from individuals suspected of COVID-19 infection by their healthcare provider.

UBM SARS-CoV-2 Test results are used for the identification of the presence or absence of SARS-CoV 2 RNA and its variants (20I/501Y.V1, B.1.1.529, BA.1, 20J/501Y.V3, 20H/501Y.V2, B.1.1.529 BA.2). Positive results indicate the presence of SARS-CoV-2 RNA, but do not provide information on the presence of bacterial infection or of co-infections with other viruses. In order to evaluate patient infection status, it is recommended to make clinical correlation between patient history and other diagnostic information.

Negative results do not preclude SARS-CoV-2 infection and therefore, UBM SARS-CoV-2 Test cannot be the only diagnostic tool to evaluate possible treatments and investigations. Negative results should be combined with clinical observations, patient history and epidemiological information. UBM SARS-CoV-2 Test is intended for use by clinical laboratory personnel trained in real-time PCR techniques and in vitro diagnostic procedures.

Principles and procedure overview

UBM SARS-CoV-2 Test is based on the in vitro multiplex detection of two different loci located in the ORF1ab gene of SARS-CoV-2 RNA via a one-step RT-PCR. UBM SARS-CoV-2 assay is carried out starting from a sample of RNA extracted from a nasopharyngeal swab specimen or saliva samples, which must be collected strictly following the manufacturer's instructions for use.

The SARS-CoV-2 Master Mix contains amplification primer pairs specific for the detection of the two SARS-CoV-2 loci, while the GAPDH Master Mix contains an amplification primer pairs specific for the detection of the RNA transcript of the human cellular gene GAPDH, used as an endogenous internal control (IC). The presence of SARS-CoV-2 RNA is defined an amplification curve overcomes the real-time detection threshold (Ct) set on the machine.

An Internal Control (IC) is incorporated into the product as an endogenous whole process control in order to monitor nucleic acid isolation, and to check for possible PCR inhibition. The IC is amplified simultaneously with the target nucleic acids. UBM SARS-CoV-2 uses GAPDH as an endogenous IC which can ensure purification of DNA, verification of PCR reaction and clarification of cell adequacy from each specimen.

The UBM SARS-CoV-2 assay consists of two PCR reactions:

- the first permitting the simultaneous amplification of two genomic regions of SARS-CoV-2 virus (SARS-CoV-2 PCR Mix);
- the second permitting the amplification of target DNA of the Human GAPDH (Control PCR Mix).

In PCR, efficiency can be reduced by inhibitors that may be present in the clinical specimens.

Storage and handling

The components of UBM SARS-CoV-2 should be stored at a temperature between -25 °C and -15 °C, in an upright position and away from light. All components are stable under recommended storage conditions until the expiry date stated on the label. Repeated thawing and freezing should be avoided, as this may reduce the sensitivity. UBM SARS-CoV-2 can be frozen and thawed for no more than 6 times; further freezing/thawing cycles may cause a loss of product performance. If the reagents are to be used only intermittently, they should be frozen in aliquots in RNase/DNase free tubes.

Materials provided

The reagents contained in one kit of UBM SARS-CoV-2 (Ulisse Biomed, S.p.A.; code #UBM0016-050) are sufficient for 50 tests in association with other systems, including controls.

The reagents contained in one kit of UBM SARS-CoV-2 (Ulisse Biomed, S.p.A.; code #UBM0016-100) are sufficient for 100 tests in association with other systems, including controls.

The reagents contained in one kit of UBM SARS-CoV-2 (Ulisse Biomed, S.p.A.; code #UBM0016-500) are sufficient for 500 tests in association with other systems, including controls.

UBM SARS-CoV-2 (REF UBM0016)			
Contents	Volume	Description	Color
SARS-CoV-2 primer Mix	1 X 0.12 mL (UBM0016-050) 1 X 0.24 mL (UBM0016-100) 1 X 1.20 mL (UBM0016-500)	Buffered solution containing synthetic DNA for the specific amplification of SARS-CoV-2 virus.	Red
Control Primer Mix	1 X 0.12 mL (UBM0016-050) 1 X 0.24 mL (UBM0016-100) 1 X 1.20 mL (UBM0016-500)	Buffered solution containing synthetic DNA for the specific amplification of GAPDH	Green
Reaction Mix	1 X 1.20 mL (UBM0016-050) 2 X 1.20 mL (UBM0016-100) 6 X 2.00 mL (UBM0016-500)	Buffered solution containing amplification and detection agents.	White
RT Enzyme Solution	1 X 0.12 mL (UBM0016-050) 1 X 0.24 mL (UBM0016-100) 1 X 1.20 mL (UBM0016-500)	Buffered solution containing the reverse transcriptase for specific cDNA synthesis	White
DTT Solution	1 X 0.12 mL (UBM0016-050) 1 X 0.24 mL (UBM0016-100) 1 X 1.20 mL (UBM0016-500)	Dithiothreitol solution.	Pink
$MgCl_2$ 15mM solution	1 X 0.12 mL (UBM0016-050) 1 X 0.24 mL (UBM0016-100) 1 X 1.20 mL (UBM0016-500)	Magnesium chloride 15mM solution.	Yellow
Positive Control	1 X 0.10 mL (UBM0016-050) 1 X 0.06 mL (UBM0016-100) 1 X 0.30 mL (UBM0016-500)	Buffered solution containing synthetic RNA segments of SARS-CoV-2 genome (5,000 copies/µl) and human RNA standard (0.05 ng/µl).	Blue
Negative Control	1 X 0.10 mL (UBM0016-050) 1 X 0.06 mL (UBM0016-100) 1 X 0.30 mL (UBM0016-500)	Molecular-biology grade water.	White

Materials required but not provided

A. Materials required for every compatible system:

The following materials are required to use UBM SARS-CoV-2 on every compatible system:

- molecular-biology grade water, RNase and DNase free.

- Nucleic acid isolation kit (see Nucleic acid isolation).
- 1.5 mL and 5 mL polypropylene capped tubes, sterile, RNase and DNase free.
- Precision calibrated pipettes capable of dispensing 2-20 µl (0.1-0.2 µl increment), 20-200 µl (0.1-0.2 µl increment), and 100-1,000 µl (1-2 µl increment).
- Anti-aerosol, single use, low-retention sterile filter tips for precision pipettes of 2-20 µl, 20-200 µl, and 100-1,250 µl, nuclease free.
- Desktop centrifuge.
- Vortex mixer.
- Class II laminar airflow biological hood.
- QuantStudio™ 5 Real-Time PCR System (Applied Biosystems, Inc.) and AriaDx Real-time PCR System (Agilent Technologies, Inc.) calibrated following manufacturer's instructions.
- Ice.
- Disposable nitrile powder-free gloves, or similar material, and adequate personal protective equipment.

B. Materials required for QuantStudio™ 5 Real-Time PCR System (Applied Biosystems, Inc.)

For use with QuantStudio™ 5 Real-Time PCR System (Applied Biosystems, Inc.) instrument the following materials are required:

- MicroAmp™ Optical 96-Well Reaction Plate (Applied Biosystems, Inc.; code #N8010560).
- MicroAmp™ Optical Adhesive Film (Applied Biosystems, Inc.; code #4311971).
- 1x Phosphate Buffered Saline solution (PBS).

C. Materials required for AriaDx Real-time PCR System (Agilent Technologies, Inc.)

For use with AriaDx Real-time PCR System (Agilent Technologies Inc.) instrument the following materials are required:

- 96-well plates, skirted and low profile (Agilent Technologies, Inc.; code #401490).
- Adhesive plate seals (Agilent Technologies, Inc.; code #401492).
- 1x Phosphate Buffered Saline solution (PBS).

2. Warnings and precautions

This product is exclusively designed for *in vitro* use.

General warnings and precautions

- Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite or autoclaved for one hour at 121 °C before disposal.
- Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be handled and disposed of in compliance with adequate safety standards.
- Wear suitable protective clothes and gloves; protect eyes and face.
- Never pipette solutions by mouth.
- Do not eat, drink, smoke or apply cosmetic products in the work areas.
- Carefully wash hands after handling samples and reagents.
- Dispose of leftover reagents and waste in compliance with the regulations in force.
- Carefully read all the instructions provided with the product before running the assay.
- While running the assay, follow the instructions provided with the product.
- Do not use the product after the indicated expiry date.
- Do not use the product if, upon receipt, the package is damaged, or the seal is broken.
- Only use the reagents provided with the product and those recommended by the manufacturer.
- Do not pool reagents from different lots or from different tubes of the same lot.
- Do not use reagents from other manufacturers.

Warnings and precautions for molecular biology

- Molecular biology procedures require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.
- Lab coats, gloves and tools dedicated to work session setup are needed.
- The samples must be suitable and, if possible, dedicated for this type of analysis. Samples must be handled under a laminar airflow hood. Pipettes used to handle samples must be exclusively used for this specific purpose.
- The PCR cassettes or plates must be handled in such a way to reduce as much as possible amplification product diffusion into the environment in order to avoid sample and reagent contamination.
- While running the assay, follow the instruction contained in the Human Papillomavirus laboratory manual published by the World Health Organization.

3. Protocol

Specimen collection, storage and transport

A. Specimen Collection

Nasopharyngeal specimen

Nasopharyngeal specimen collected using nasopharyngeal specimen has been validated for use with UBM SARS-CoV-2 . Follow the manufacturer's instructions for collecting cervical specimen.

B. Specimen Storage

The sensitivity of the assay may decrease if specimen is repeatedly frozen and thawed or stored for a long period of time. Nucleic acids should be extracted from the specimen as quickly as possible.

Nasopharyngeal specimen

WHO recommends to use Dacron or polyester flocked swabs in viral transport medium, stored at 4°C for a maximum of 3 days. For long term storage, store samples at -70°C for maximum 1 month.Cervical and vaginal swab specimens

C. Specimen Transport

To ensure a high quality of sample, specimens should be transported as soon as possible at indicated temperature.

Nasopharyngeal specimen

WHO recommends to use Dacron or polyester flocked swabs in viral transport medium, transported at 4°C and stored at 4°C for a maximum of 3 days.

Procedure for QuantStudio™ 5, Agilent AriaDx

The procedure to use UBM SARS-CoV-2 with the abovementioned real-time PCR systems consists of six steps:

A. nucleic acid isolation.
B. Preparation of amplification PCR mixes.
C. PCR plate assembly.
D. Real-time PCR instrument setup.
E. Interpretation of tests results.
F. Quality control.

A. Nucleic acid isolation

Various manufacturers offer nucleic acid isolation kits. Use the right amount of sample according to the protocol in use. The following isolation kits have been validated for use with UBM SARS-CoV-2.

a. Compatible isolation kits

The following isolation kits have been validated for use with UBM SARS-CoV-2:

- QIAamp® DNA Mini Kit (Qiagen, Inc.; code #51304); elute in molecular-biology grade water.
- Ulisse Faster RNA (Ulisse Biomed, S.p.A.; code #UBM0008).
- Ulisse Faster RNA light (Ulisse Biomed, S.p.A.; code #UBM0019).

B. Preparation of amplification PCR mix

Thaw the reagents at room temperature (~ + 25 °C) for 30 minutes. Mix gently, spin down the content for 5 seconds. Keep all the reagents on ice during the preparation.

Prepare two 1.5 mL polypropylene capped tubes which will contain the SARS-CoV-2 PCR Mix and the Control PCR Mix respectively; identify the tube with an indelible marker.

Prepare the SARS-CoV-2 PCR Mix and the Control PCR Mix: for each session, combine the following components sufficient for the number of samples to be tested plus one Positive Control and one Negative Control. All volumes include 10% overage for pipette error.

SARS-CoV-2 PCR Mix		
Reagent	Volume per sample or control	Volume for "n" samples plus 2 controls
Reaction Mix (RNA)	10.00 µL	11.00 x (n + 2) µL
$MgCl_2$ 15mM solution	1.0 µL	1.10 x (n + 2) µL
DTT Solution	1.0 µL	1.10 x (n + 2) µL
RT Enzyme Solution	1.0 µL	1.10 x (n + 2) µL
SARS-CoV-2 Mix	2.0 µL	2.20 x (n + 2) µL
Total Volume	15.00 µL	-
Control PCR Mix		

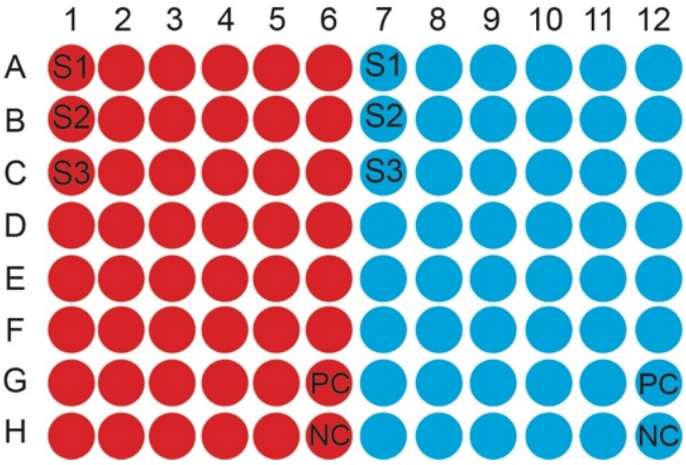
Reagent	Volume per sample or control	Volume for "n" samples plus 2 controls
Reaction Mix (RNA)	10.00 µL	11.00 x (n + 2) µL
$MgCl_2$ 15mM solution	1.0 µL	1.10 x (n + 2) µL
DTT Solution	1.0 µL	1.10 x (n + 2) µL
RT Enzyme Solution	1.0 µL	1.10 x (n + 2) µL
Control Mix	2.0 µL	2.20 x (n + 2) µL
Total Volume	15.00 µL	-

At the end, vortex the PCR mix and spin them briefly, avoiding the formation of bubbles.

C. PCR plate assembly

Load 15 µL of SARS-CoV-2 PCR Mix, and 15 µL of Control PCR Mix for each sample in two separate wells.

Load twice 5 µL of each biological sample (S1, S2, S3, etc), of Positive Control (PC) and of Negative Control (NC): once in the SARS-CoV-2 PCR Mix-loaded well and once in the Control PCR Mix-loaded well, as indicated in the figure below.



Seal the PCR plate using adequate adhesive seals following manufacturer's instructions.

D. Real-time PCR instrument setup

Template files for compatible real-time PCR systems are available upon request. To load the template file on the real-time PCR instrument, follow instrument software's instructions.

Before starting the run, insert the samples names.

If you do not want to use the template files or the template files are not available for the instrument, please setup the instrument and protocols according to the following indications:

Parameter	Setting
Volume	20 µL
Cover (Lid temperature)	105 °C
Reporter for each mix	SYBR
Quencher for each mix	None
Passive reference[1]	None

Step	Stage		Time	Temperature	Data collection
RT	Reverse Transcription		10 min	50.0°C	-
PCR	Polymerase activation		2 min	98.0 °C	-
	Denaturation	repeat 45 cycles	5 sec	98.0 °C	-
	Annealing		15 sec	62.0 °C	-
	Extension		5 sec	72.0 °C	yes
Melting curve	Denaturation		15 sec	95.0 °C	-
	Start melting		60 sec	60.0 °C	-
	Optimal ramp increment / Soak time[2]		0.1°C / 3 sec		yes
	End melting		1 sec	95.0 °C	-

E. Interpretation of tests results

The recorded values of the fluorescence in the amplification reactions must be analyzed by the instrument software. Data analysis is performed with the instrument system software, and according to manufacturer's instruction. The values of fluorescence allow determining the threshold cycle (Ct), the cycle in which the fluorescence reached the threshold value. Before starting the analysis, set the threshold as follows:

PCR Instrument	Threshold
QuantStudio™ 5 Real-Time PCR System (Applied Biosystems, Inc.)	100,000
AriaDx Real-time PCR System (Agilent Technologies, Inc.)	2,500

Output cycles of amplification (Ct) are expressed as a numeric value between 1 and 45. If the Ct result is "Undetermined" it means that no signal has been detected above the preset threshold value.

For the interpretation of the result, refer to the "Interpretation table" on the next page.

[1] "ROX" is often selected as default passive reference. If template files are not used, remember to deselect any passive reference.

Interpretation table

Ct SARS-CoV-2 PCR Mix	Ct CONTROL PCR Mix	Test status	Result	Suggested action
Numerical value	Numerical value	Valid	Detected SARS-CoV-2	-
Undetermined	Numerical value <= 40	Valid	Undetected SARS-CoV-2	-
Numerical value	Undetermined	Valid	Detected SARS-CoV-2	-
Undetermined	Numerical value > 40 or undetermined	Invalid	Undetermined SARS-CoV-2	See "Troubleshooting"

F. Quality control

To validate the test results, it is necessary to verify the validity of the PCR run (analysis). For this purpose, a Negative Control and a Positive Control are required for each PCR amplification run, for both the SARS-CoV-2 PCR Mix and the Control PCR Mix. Negative Control is used to check that no component has been contaminated with nucleic acids during the preparation of the amplification reactions. Positive Control allows to evaluate the assay performance. The analysis is considered valid when both the following conditions are met:

- Positive Control is characterized by amplification curves in the SARS-CoV-2 PCR Mix and the Control PCR Mix.
- Negative Control is characterized by no amplification curves neither in the SARS-CoV-2 PCR Mix, nor in the Control PCR Mix.

If an amplification signal exceeding the threshold value for SARS-CoV-2 PCR Mix or for Control PCR Mix is detected in the Negative Control, the plate is invalidated, and the test must be repeated after eliminating the contamination source. Clean the PCR sample preparation area and repeat the test with a new kit. Ensure that instrument parameters are correctly set.

If anomalies in the amplification of Positive Control are observed, the plate is invalidated, and it has to be repeated. In this case contact the supplier of the product.

Troubleshooting

Sample type	Issue / Error	Possible cause	Possible solution
Positive Control	Invalid Positive Control: no amplification curves	Pipetting error.	Take care when dispensing reagents into the microplate wells.
		PCR mix setup error.	Verify to have executed correctly the instructions described in the paragraph "Preparation of amplification PCR Mix".
		Inadequate storage of reagents.	Use a new aliquot of reagents or a new kit.
		RNase/DNase presence.	Use RNase/DNase-free consumables.
		PCR failure.	Ensure that instrument's parameters are correct.
		Bubbles in the PCR reaction.	Repeat the test ensuring to avoid bubbles formation in the well.
Negative Control	Invalid Negative Control: presence of amplification curves	Local contamination.	Clean PCR preparation area. Ensure that adequate Personal Protection Equipment are used to reduce contamination risk.
		Reagent contamination.	Use a new aliquot of contaminated reagent(s).
		Inadequate storage of reagents.	Use a new aliquot of reagents or a new kit.
		Pipetting error.	Always change tip between samples. Take care when dispensing reagents into the microplate wells.
		PCR mix setup error.	Verify to have executed correctly the instructions described in the paragraph "Preparation of amplification PCR Mix".
		Plate sealing error.	Take care when sealing the plate and follow the manufacturer's instructions.
Biological sample	Invalid test: no amplification curve in the SARS-CoV-2 PCR Mix and no amplification curve in the Control PCR Mix or amplification curve with Ct > 40	Inadequate sample collection, storage or transport.	Repeat DNA isolation or sample collection.
		Inadequate RNA isolation.	Verify RNA isolation compatibility. Repeat RNA isolation.
		PCR failure.	Ensure that instrument's parameters are correct.
		Bubbles in the PCR reaction.	Repeat the test ensuring to avoid bubbles formation in the well.
		PCR inhibitors presence.	Try to dilute isolated RNA 1:5. Repeat RNA isolation or sample collection.

4. Limits

UBM SARS-CoV-2 Test is intended for in vitro diagnostic use only. Use of UBM SARS-CoV-2 Test is limited to properly trained personnel.

UBM SARS-CoV-2 provides a qualitative result.

UBM SARS-CoV-2 Test should only be used with RNA samples extracted from nasopharyngeal swabs; consult the manufacturer's instructions for technical specifications, limitations, warnings and instructions on the use of the nasopharyngeal swabs. The performance of the method has not been evaluated with other types of samples. The presence of blood can interfere with UBM SARS-CoV-2 Test. For optimal assay performance, specimen collection, handling, and storage must be adequate. If the swab has been subjected to thermal stress (> 4 ° C) for more than 2 days, or if more than 7 days have passed between collection and proper storage at -20 ° C, the result is not reliable.

The results obtained with this product depend on an adequate identification, collection, transport, storage and processing of the samples. To avoid incorrect results, it is therefore necessary to take care during these steps and to carefully follow the instructions for use provided with the nucleic acid isolation kits.

Owing to its high analytical sensitivity, the real-time amplification method used in this product is sensitive to cross-contaminations from the positive samples, the positive control and the same amplification products. Cross-contaminations cause false positive results. The product format is able to limit cross-contaminations. However, cross-contaminations can be avoided only by good laboratory practices and following these instructions for use.

The presence of blood can interfere with UBM SARS-CoV-2.

A negative result obtained by UBM SARS-CoV-2 Test could require further investigation. Results obtained with UBM SARS-CoV-2 Test should be interpreted in conjunction with other clinical and laboratory results, as well as the results of any other diagnostic tests. A negative result does not exclude the possibility of SARS-CoV-2 infections as very low viral levels of infection. Sampling errors can also cause false-negative results.

Moreover, test results may be affected by improper specimen collection, technical error, or specimen mix-up, as well as by the presence of interfering substances.

Possible polymorphisms within the region of the target RNA covered by the product primers may impair detection of target RNA.

UBM SARS-CoV-2 should be used in conjunction with clinical information from other diagnostic and screening tests, physical medical inspection, and complete medical history, according to appropriate patient management. UBM SARS-CoV-2 should not be used as the sole method of diagnosing and treating patients.

As with any other diagnostic medical device, there is a residual risk of invalid, false positive and false negative results obtained with this product. This residual risk cannot be eliminated or further reduced. In some cases, this residual risk could contribute to wrong decisions with potentially dangerous effects for the patient.

5. Product performance

All performance characteristics data were determined using manual result interpretation and QuantStudio™ 5 Real-Time PCR System (Applied Biosystems, Inc.). Similar performance on AriaDx Real-time PCR System (Agilent Technologies, Inc.) has been established by equivalence studies.

Analytical sensitivity

The analytical sensitivity, or Limit of detection (LoD), is defined as the lowest concentration which >95% of the tested samples generate a positive result. LoD of UBM SARS-CoV-2 test was determined by spiking FDA-approved synthetic SARS-CoV-2 reference material (Twist Biosciences Control 48) at known concentration. The LoD of the UBM SARS-CoV-2 test is 10 copies/reaction.

Analytical specificity (cross-reactivity)

The potential cross-reactivity of the SARS-CoV-2 assay was evaluated through an in silico analysis to verify the homology of the probe sequences on a panel of bacteria, viruses and fungi, with a panel including organisms / families of organisms that can be found in the respiratory and oropharyngeal system, as suggested by FDA guidance. No homology more than 80% was observed with any of the organisms analyzed.

Interference

UBM SARS-CoV-2 uses well established conventional nucleic acid isolation methods and based on our experience with other similar assays, we do not expect interference from common endogenous substances.

Analytical reproducibility

The reproducibility of UBM SARS-CoV-2 Test was determined by analyzing a synthetic RNA analyte of SARS-CoV-2 and human RNA standard material; each comparison was performed by several operators, each of whom used different PCR machines. The inter-assay coefficient of variation (CV) calculated on the amplification cycles (Ct) is lower than 5%.

Analytical repeatability

The intra-assay Coefficient of Variation (CV) for the Ct value was measured on 10 replicates of different target SARS-CoV-2 RNAs diluted to 1000 copies / reaction, analyzed in the same PCR analysis. All CVs found are lower than 5%.

Clinical Performance

The clinical performance of UBM SARS-CoV-2 Test was evaluated on a library of 60 remnant clinical nasopharyngeal specimens, in combination with Ulisse Faster direct kit (Ulisse BioMed; ref. UBM0019). Reference test was CE IVD CoronaMelt SARS-CoV-2 test. Of 30 positive samples, 29 were positive to UBM SARS-CoV-2 test as well; on 30 negative samples 29 were negative for UBM SARS-CoV-2 test. Clinical sensitivity was 97% and clinical specificity was 97%. Overall agreement with CoronaMelt test was 97% (Kappa Cohen: 0.94, almost perfect agreement).

Intra- and inter-laboratory reproducibility

The intra-laboratory reproducibility of UBM SARS-CoV-2 Test was determined by analyzing a group of 48 biological samples (24 positive and 24 negative), which were analyzed twice within the same laboratory. The

agreement is 95.8%.

The inter-laboratory reproducibility of UBM SARS-CoV-2 Test was determined by analyzing a group of 40 biological samples (of which 50% positive), which were analyzed by two independent laboratories. The agreement found is equal to 97.5%.

6. Explanations of symbols

Key to symbols used in the manual and labels.

Symbol	Explanation
IVD	*In vitro* diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Use by date
	Temperature limit
CONTROL +	Positive Control (PC)
CONTROL –	Negative Control (NC)
	Consult instructions for use
	Manufacturer
	Contains sufficient for <n> tests
	Do not use if package is damaged and consult instructions for use

7. Contacts

Contact your local Ulisse Biomed representative for assistance.

Ulisse Biomed S.p.A.
Via Camillo Benso di Cavour 20
33100 - Udine (UD)
Italy

Customer Support & Technical Support: support@ulissebiomed.com

For more contact information visit www.ulissebiomed.com