CE IVD

REF 000055

COV19 qcLAMP kit

INSTRUCTIONS FOR USE (IFU)

For *in vitro* diagnostics use

For Professional use only

Not for Self-Testing

BIOPIX-T

Σ 100 tests

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PREAMBLE

Indication to EU IVD Directive 98/79/EEC
1. Product Category: IVD Kit
2. Product Name: COV19 qcLAMP kit
3. Product Catalogue Number: cat. no.#000055
4. Purpose of use: See Section “Intended Use”

Inquiries and customer service (A/S)
Send us an e-mail (info@biopix-t.com) to inquire about the product.

Contents

Intended Use

The COV19 qcLAMP kit is a molecular *in vitro* diagnostic test that is intended to be used for the detection of SARS-CoV-2 viral RNA in association with the Pebble qcLAMP Point-of-Care Platform.

The COV19 qcLAMP kit does not require RNA extraction and can be used with nasopharyngeal and oropharyngeal swab specimens, collected from individuals suspected of COVID-19. The kit can also be used with extracted RNA.

The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA.Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results should be considered as potentially negative and do not preclude SARS-CoV-2 infection and should 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 COV19 qcLAMP kit is intended to be used by trained personnel or healthcare professionals (experts), who are proficient in performing tests on the Pebble qcLAMP Platform. It is not intended to be used for self-testing.

Product description

The COV19 qcLAMP kit is a Nucleic Acid Amplification Test (NAAT) kit based on the real-time colorimetric LAMP method (qcLAMP) for the detection of SARS-CoV-2 N-gene RNA target. The COV19 qcLAMP kit does not require RNA extraction and can be used directly with nasopharyngeal and oropharyngeal swab specimens. Alternatively, the kit can also be used with extracted RNA.

The kit includes a 2X Enzyme mix which contains a mixture of Bst polymerase and thermostable reverse transcriptase, optimized reaction buffer, Mg^{2+} and dNTPs. It further comprises a separate 5X COV19 Primer mix which contains SARS-CoV-2 specific primers and hydroxynaphthol blue (HNB) indicator, and a 5X Control Primer mix for amplifying a human endogenous target (RNase P). The supplied 2X BPX sample buffer neutralizes common sample inhibitors for direct crude sample amplification and detection. The kit also includes Mineral oil which helps to prevent cross-contamination and minimize evaporation.

Each kit is sufficient for 100 reactions. Tests are performed in the Pebble qcLAMP Platform, which controls the reaction temperature, timing and facilitates the real-time digital colorimetric analysis of the amplification reactions. Total duration of the test in the Pebble qcLAMP Platform is 30 minutes for assessing a negative result. Time-to-positive can range between 10 and 27 minutes depending on the initial target concentration.

Kits contents and components

The COV19 qcLAMP kit contains the following components for performing **100 qcLAMP tests/reactions**:

COV19 qcLAMP kit components

Component	Quantity	Volume	Description
2X Enzyme mix	1 tube	1.25 mL	Colourless solution /Black cap
5X COV19 Primer mix	1 tube	0.5 mL	Purple solution/Purple cap
5X Control Primer mix	1 tube	0.25 mL	Purple solution / Green cap

Nuclease-free water	1 tube	1.0 mL	Colourless solution/White cap
2X BPX sample buffer	6 tubes	1.8 mL	Colourless solution/Neutral cap
Mineral oil	1 tube	1.8 mL	Colourless solution /Blue cap

Storage and handling conditions

On arrival, the components of the kits should be stored in the original packaging at -20°C.
During the preparation of the test reactions, all materials except Mineral oil must be kept on ice or in a refrigerated storage container (0-4°C). Mineral oil during the handling of materials can remain at room temperature.
Improper handling of the kit components can lead to deterioration of the COV19 qcLAMP kit and as a result to false results.
Before the first use of the COV19 qcLAMP kit, it is recommended to aliquot part of the initial volume of the reagents **2X Enzyme mix** and the **5X COV19 Primer mix** to reduce the risk of deterioration of the kit due to multiple freeze-thaw cycles. Avoid more than 2 freeze-thaw cycles.

Shelf-life of the kit

The kit is stable for 12 months at -20°C.

Additional Material & Equipment Required but Not Supplied

Materials and components required for detection of SARS-CoV-2 that are not included within the kit are:

For use with extracted RNA or crude samples:

A. Kits for the collection and transportation of specimens with viruses that affect the upper respiratory specimens
B. The Pebble qcLAMP Point-of-Care Platform (BIOPIX-T)
C. Positive (synthetic RNA template or plasmid) such as BIO-RAD Synthetic Molecular Standards for SARS-CoV-2 or equivalent and negative controls (Genomic DNA or RNase free water).
D. Other Equipment and Materials:
    1 Adjustable calibrated pipettes.
    2 Sterilized pipette filter tips (10 µL, 200 µL and 1000 µL).
    3 PCR tubes of 0.2 mL maximum volume (e.g., Multiply-Pro. PCR single tube, 0.2 ml from SARSTEDT).
        Specifications: safe lock, high-profile mini-PCR tubes.
        Dimensions: Height with lid: 21.6mm-21.7mm, outer diameter (OD): 5.9mm-6.1mm.
    4 PCR tubes of 1.5 mL maximum volume.
    5 DNA and RNA degradation solutions such as DNAZap™, RNAZap™, 10% bleach (1:10 dilution of commercial 5.25-6.0% sodium hypochlorite) or equivalent.
    6 Protective equipment (disposable powder-free gloves and laboratory coat).

For use with extracted RNA only:

E. RNA extraction kits and tools for extraction of total RNA from clinical samples.

Warnings and Precautions

1. For *in vitro* diagnostics (IVD) use.
2. The COV19 qcLAMP kit is certified only for the detection of nucleic acids from SARS-CoV-2, not for any other viruses or pathogens.

3. Reagents should be aliquoted into smaller volumes if not used directly to avoid multiple freeze thaw cycles.
4. Specimen processing should be performed following biosafety level 2 (BSL-2) or higher guidelines.
5. Do not open the tubes after the end of qcLAMP reactions to avoid contamination of the area with DNA amplicons.
6. Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where reagents are present and human specimens are handled.
7. The use of COV19 qcLAMP kit and data evaluation is restricted to trained personnel only.
8. Do not use any COV19 qcLAMP kit components beyond their expiration date.
9. The COV19 qcLAMP kit has been optimized to be used with the Pebble qcLAMP Platform.
10. Before processing the sample, please check the turbidity and viscosity of the sample. Turbid and viscous samples can influence the reaction and therefore the results. In case of very turbid samples, we recommend 1:10 or 1:100 dilutions of swab samples before proceeding with testing. However, this action will also lower the limit of detection (LOD) of COV19 qcLAMP test.
11. Dispose of any unused and used reagent, container, and human specimens in accordance with federal, state, and local regulations.
12. Wear appropriate personal protective equipment (e.g., gloves, coat, eye protection) when handling clinical specimens.

The following warnings should be considered when using the kit:

Warning	Cause	Recommendation
The initial color of the 5X COV19 Primer mix and 5X Control Primer mix is not purple.	Improper storage of the kit.	Store kit at -20°C.
	Kit reagents underwent too many freeze-thaw cycles.	Minimize the number of freeze-thaw cycles.
The initial color of the reaction is sky blue (before been placed in the Pebble qcLAMP Platform).	The reaction was not properly prepared.	Ensure the proper mixing of the reagents and the accuracy of the pipetted volumes.
	Improper storage of the kit.	Store kit at -20°C.
	Kit used after the expiration date.	Use before the expiration date.
	Kit reagents underwent too many freeze-thaw cycles.	Minimize the number of freeze-thaw cycles.
Positive control reactions do not show amplification.	Kit reagents underwent too many freeze-thaw cycles.	Minimize the number of freeze-thaw cycles.
	Improper storage of the kit.	Store kit at -20°C.
	Kit used after the expiration date.	Use before the expiration date.
	Reaction was not prepared correctly.	Ensure the proper mixing of the reagents and the accuracy of the pipetted volumes.
	No RNA was added.	Ensure that sample is added in the reaction.
	Positive RNA control has been degraded.	Avoid multiple freeze-thaw cycles and aliquot reagents appropriately.
	Kit reagents contaminated by RNases.	Use solutions (e.g., ethanol, chlorine solution, detergent) to clean the surfaces and the devices. Use protective equipment. Replace reagent stocks with new materials.
RNA Extracted samples do not show amplification.	Extraction process was not properly performed.	Use 5X Control Primer mix for the verification of the extraction process.

	Viral load is below the limit of detection.	Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Sampling and testing should be repeated at least after 24 h.
Crude samples do not show amplification.	Crude samples contain mucus or blood.	Reduce viscosity by diluting swab samples 10× or 100× before proceeding, or retake swab sample.
	Viral load is below the limit of detection.	Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Sampling and testing should be repeated at least after 24 h.
Negative reactions show amplification.	Sample Contamination with RNA.	Never open reaction tubes after amplification. Only use tubes with safe lids and that have not been used before. Use DNA degradation solution to clean the working space and equipment or 10% chlorine bleach solution. Replace reagent stocks with new materials. Change pipette tips between samples.
	Improper storage of the kit.	Store kit at -20°C.
	Kit reagents underwent too many freeze-thaw cycles.	Minimize the number of freeze-thaw cycles.
	Non-template amplification.	All reactions should be set up and kept on ice prior to amplification. Run the qcLAMP reactions immediately after preparation.

Preparation of the reagents

All reagents are ready to be mixed and used without prior preparation.
Before the first use of the COV19 qcLAMP kit, it is recommended to aliquot part of the initial volume of the reagents **2X Enzyme mix** and the **5X COV19 Primer mix** to reduce the risk of deterioration of the kit due to multiple freeze-thaw cycles.

Sample Collection, Handling and Preparation before testing

It is recommended to use all opened reaction tubes, as soon as possible. Use the kit components before the expiration date following the manufacturer's recommendations. It is very important to use tools and reagents free from RNases. In addition, it is recommended to carry out any preparation steps in areas free from nucleases, only using pipettes with filter tips.

To be followed for testing with extracted RNA:

Sample collection process:

1. Collect nasopharyngeal and oropharyngeal swab specimens in any solubilizing solution.
2. Remove 200 µL of the collected sample and perform RNA extraction. Elute extracted RNA in 30 to 50 µL of RNase free water and place immediately on ice or store at -20°C.

To be followed for testing with a crude sample:

To perform a test without RNA extraction, nasopharyngeal and oropharyngeal swab specimens should be solubilized in any of the following solutions:

CITOSWAB® (Viral Transport medium –VTM-, 3mL).

Improviral™ (Viral Preservative Medium –VPM-, 3mL).

Liofilchem® (Viral Transport Medium –VTM-, 3mL).

The following solutions are **NOT** compatible:

Biocommma, **MWE**, **LITUO** and therefore **SHOULD NEVER** be used in combination with this kit.

Sample collection should be done as following:

1. Collect nasopharyngeal and oropharyngeal swab specimens in a solubilizing solution.
2. Remove 100 µL of the collected sample and mix well with 100 µL of 2X BPX sample buffer solution. Use immediately.

Test procedure

Sample preparation has to be followed prior to the testing procedure. Keep the prepared samples on ice until use.

Keep on ice or in an ice box the COV19 qcLAMP kit tubes (2X Enzyme mix, 5X COV19 Primer mix, 5X Control Primer mix, Nuclease-free water) and the reactions during preparation. Mineral oil could be kept at room temperature during the preparation of the tests.

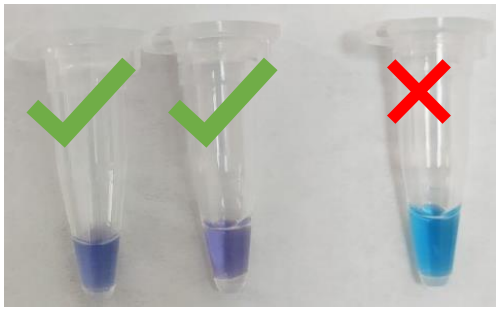
A. To be followed with extracted RNA samples:

1. Before preparing a mix, gently pipette up and down the solution of 2X Enzyme mix and the solution 5X COV19 Primer mix.
2. Prepare one or more tests as specified in the following table and place on ice. The preparation of a 25 µL for the detection of SARS-CoV-2 RNA into a 0.2 mL tube (it is not included in the kit) is performed according to the following instructions. Add the reagents to each tube in the following order:

Reagent	Volume per reaction (µL)
2X Enzyme mix	12.5
5X COV19/Control Primer mix	5
Nuclease-free water	5.5
Extracted RNA	2

Total volume per one reaction should be 25µL.

Note! The initial color of the 25 µL qcLAMP reaction should be purple or deep blue (see figure below – left tube). If the color is sky blue (see figure below – right tube) do not perform the test. For more information consult the warnings and precautions section.



3. Add carefully 15 µL of mineral oil at the side of each tube and wait approximately 30 sec until it forms a layer over the qcLAMP reaction. Make sure the oil is not mixed with the reaction.
4. Place the reactions in the Pebble qcLAMP Platform and perform the tests by following the instructions for use of the Pebble qcLAMP Platform. The maximum number of samples that can be analysed simultaneously is 6.

For the verification of a properly performed RNA extraction, the above procedure can be repeated for the detection of a human endogenous target (internal control, IC), the RNase P gene by replacing the 5X COV19 Primer mix with the 5X Control Primer mix. Use the 5X Control Primer mix solution to perform this test. In this case, follow steps 1-4 replacing the 5X COV19 Primer mix tube with the 5X Control Primer mix tube.

This test is optional and can be performed for each sample separately.

Note! Positive (synthetic RNA template or plasmid) and negative controls (Genomic DNA or Nuclease-free water) should be used during the sample's analysis or separately, to check the quality of the kit ingredients. Positive or negative controls are not included in the kit.

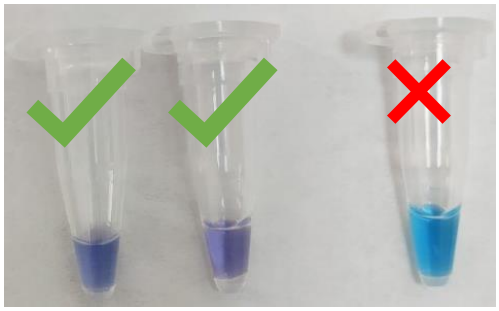
B. To be followed for crude sample direct detection:

1. Before the preparation of the mix, gently pipette up and down the 2X Enzyme mix and the 5X COV19 Primer mix.
2. Prepare one or more tests as specified in the following table and place on ice. The preparation of a 25 µL for the detection of SARS-CoV-2 RNA into a 0.2 mL tube (it is not included in the kit) is performed according to the following instructions. Add the reagents to each tube in the following order:

Reagent	Volume per reaction (µL)
2X Enzyme mix	12.5
5X COV19/Control Primer mix	5
Nuclease-free water	2.5
Crude sample mixed with 2X BPX buffer	5

Total volume per one reaction should be 25µL.

Note! The initial color of the 25 µL qcLAMP reaction should be purple or deep blue (see figure below – left tube). If the color is sky blue (see figure below – right tube) do not perform the test. For more information read the warnings and precautions section.



3. Add carefully 15 µL of mineral oil at the side of each tube and wait approximately 30 sec until it forms a layer over the qcLAMP reaction. Make sure the oil is not mixed with the reaction mixture.
4. Place the reactions in the Pebble qcLAMP Platform and perform the tests by following the instructions for use of the Pebble qcLAMP Platform. The maximum number of samples that can be analysed simultaneously is 6.

Interpretation of the Results

The Pebble qcLAMP Platform employs a mini digital camera for monitoring in real-time the transition through various color shades during colorimetric LAMP amplification. The camera collects non-calibrated images at predefined time intervals (10 sec interval) and automatically extracts the red, green, and blue (RGB) channel values.

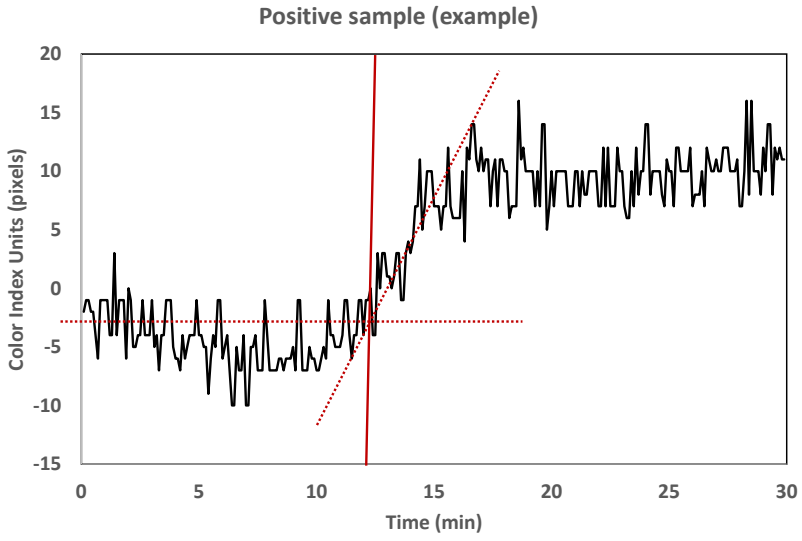
Color change is expressed as color index units (pixels) on the Y-axis of a real-time curve that is displayed on the screen of a smart device. Up to 6 (six) curves can be displayed simultaneously.

The duration of a test is 30 min. Evaluation of the results should be performed by the end-user (Please note that this is a test for professional use only).

Positive test results

The specific time-point at which a change in the slope of the real-time curve occurs (color index units increase) corresponds to the "time-to-positive" result (red solid line). This is the point at which the two dotted red lines cross each other see image below).

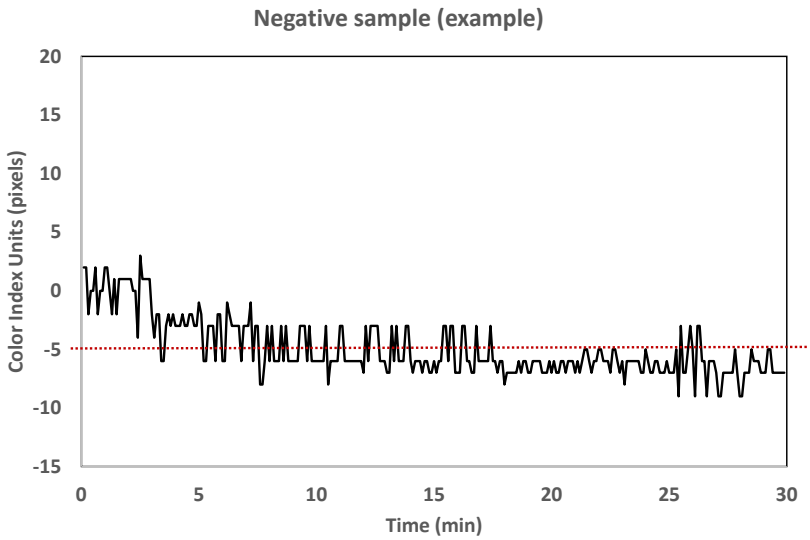
When a sample is positive for any target, the slope of the curve will change as shown in the figure below.



Negative test results

A negative result is indicated by a flat curve (color index units do not increase) maintained throughout the monitoring period.

When a sample is negative for any target the slope of the curve **WILL NOT CHANGE** (see figure below).



Invalid test results

Negative test results with extracted RNA and the 5X Control Primer mix should be considered invalid. The RNA isolation process and the preparation of the reactions should be repeated. For more information read the warnings and precautions section.

Positive results that appear after **27 minutes ARE NOT** valid and should be repeated.

Limitations of the method

1. For reliable results, it is essential to adhere to the instructions for use of the COV19 qcLAMP kit. Changes in the reaction setup or preparation may lead to the failure of the tests.
2. Results must be interpreted in consideration with all other data gathered for the sample. Interpretation must be performed by personnel trained and experienced with this kind of kit.
3. Mutations within the target sequence may result in failure to detect the in the target region.
4. Inhibitors or other types of interference may give a false-negative result. If this is the case, another sample type or isolation method may be beneficial. Interference studies of the effects of common drugs on colds, on reactions, have not been conducted.
5. This test cannot rule out diseases caused by other viral or bacterial pathogens.
6. Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely when the incidence of the disease is high. False-positive test results are more likely when the prevalence of the disease is moderate to low.
7. Tests with COV19 qcLAMP kit can only tell if a person is currently infected with this particular coronavirus. It cannot provide information on other diseases or symptoms and does not tell if a patient has been previously infected with the virus or if patient has any immunity to the virus.
8. A false negative test result may occur if the viral load level in a sample is below the limit of detection of the test or if the sample was improperly collected, handled or transported.
9. This kit has been validated with human samples.

Performance Characteristics

Limit of detection

To evaluate the detection capability claims of the kit, three independent measurements with six replicates each were performed with 5 µL of a positive control that contained 50 copies/µl and 25 copies/µl, respectively, of Bio-Rad SARS-CoV-2 Standard reference material (cat.no.#COV19) dissolved in H_2O. The evaluation was performed using one reagent lot and one device.

Analytical Sensitivity, Specificity and Accuracy evaluation

A technical validation of the COV19 qcLAMP kit with the Pebble qcLAMP Point-of-Care Platform was performed in compliance with EN 13612:2002.

The analytical sensitivity of the kit and specifically the detection capability was determined by following the recommendations published by the Clinical and Laboratory Standards Institute (CSLi).

Two matrix types were selected to account matrix variability – DNAse and RNAse free water and human RNA isolated from human saliva. RNA from human saliva was used to imitate the complexity of the matrix of the native patient samples. There were four individual, unique and natural patient samples used in the study according to CLSI EP17-A2 standards. Human saliva was collected from four healthy volunteers and RNA was isolated with Qiagen RNeasy kit (cat.no.#74192). Isolated human RNA was pooled to generate the representative matrix.

Low level samples were prepared by spiking the Bio-Rad SARS-CoV-2 Standard reference material (cat. no.#COV19) to each matrix type to achieve final concentration of 50 copies of the measurand/µl (LOD).

The experimental design consisted of replicate measurements on blank (NC) and low level (PC) samples using two different reagent lot with experiments performed on multiple days on a single instrument but with two different operators. The processing plan was set up according to the CLSI EP17-A2 standards, contained all the required design factors, and required number of replicates.

The rate of true positive and true positive samples correctly identified by the COV19 qcLAMP kit on the Pebble qcLAMP Platform should have been >95 %. The accuracy was expressed as the proportion of true positive and true negative in all evaluated cases.

Results of the qualification measurements

The performed measurements and the interpretation of the data are summarized in the following tables:

Sample Type	Regent Lot	Operator	Measurement	Collected datapoints			
				Positive Control (PC)_H2O_50		Positive Control (PC)_H2O_25	
				Correct	False	Correct	False
Positive Control	Lot 1	Operator 1	1	6	0	5	1
			2	6	0	4	2
			3	6	0	4	2

Based on the above data, the Limit of Detection (LOD) was found to be equal to 50 copies/µL.

				correct		false		% correct		% correct		% correct		
				Matrix human RNA	Matrix H2O	Matrix human RNA	Matrix H2O	Matrix human RNA	Matrix H2O	Matrix human RNA	Matrix H2O	Matrix human RNA	Matrix H2O	% correct
Positive	Lot 1	Operator 1	Day 1	6	6	0	0	100	100					
			Day 2	6	6	0	0	100.0	100.0					
		Operator 2	Day 1	4	6	2	0	66.7	100.0					
			Day 2	12	11	0	1	100.0	91.7	93.33	96.67	95		
	Lot 2	Operator 1	Day 1	6	6	0	0	100.0	100.0					
			Day 2	6	6	0	0	100.0	100.0					
			Day 3	6	4	0	2	100.0	66.7					
		Operator 2	Day 1	6	6	0	0	100.0	100.0					
			Day 2	6	6	0	0	100.0	100.0	100.00	93.33	96.7		95.8
Negative	Lot 1	Operator 1	Day 1	4	6	2	0	66.7	100.0					
			Day 2	6	6	0	0	100.0	100.0					
		Operator 2	Day 1	6	6	0	0	100.0	100.0					
			Day 2	12	12	0	0	100.0	100.0	93.33	100.00	96.7		
	Lot 2	Operator 1	Day 1	4	6	2	0	66.7	100.0					
			Day 2	6	6	0	0	100.0	100.0					
			Day 3	6	6	0	0	100.0	100.0					
		Operator 2	Day 1	6	6	0	0	100.0	100.0					
			Day 2	6	6	0	0	100.0	100.0	93.33	100.00	96.7		96.7

The true positive number was 115, the false positive number was 5, the true negative number was 116, and the false negative ratio was 4. Based on these numbers, sensitivity (true positive rate), specificity (true negative rate) and accuracy were calculated, as follows:

Analytical Sensitivity: 0.958 (95.8%)
Analytical Specificity: 0.967 (96.7%)
Accuracy: 0.9625 (96.3%)

Clinical Sensitivity and Specificity evaluation

Clinical tests were performed with a total of 645 nasopharyngeal or oropharyngeal samples tested for COVID-19 (347 negative and 298 positives, with and without RNA extraction), including samples from symptomatic or asymptomatic patients of all genders and ages. The clinical validation studies were performed with frozen samples (frozen extracted RNA as well as frozen crude samples), while it was attempted to balance inclusion of low, medium and high viral loads. Diagnostic specificity and sensitivity were determined based on RT-PCR sample testing, as the reference method and the qcLAMP as the test method.

A. Clinical tests with extracted RNA samples

Extracted RNA (frozen) from 318 samples (150 positive and 168 negative) was analysed using the COV19 qcLAMP kit with the Pebble qcLAMP Point-of-Care Platform. The positive samples had reported RT-qPCR Ct values ranging from 12 to 35. The fastest observed time-to-positive result with qcLAMP was 10.7 min for a sample with a Ct value of 16 while the maximum was 26.8 min for a Ct of 30.
The corresponding data are summarized in the following table:

Ct value	RT-PCR positive	Proportion	qcLAMP	PPA
<25	69	46%	69	100%
25-29	48	32%	43	91.7%
30-34	33	22%	24	75.8%

	RT-PCR method			
qcLAMP method	Positive	Negative	Total	
Positive	138	2	140	
Negative	12	166	178	
Total	150	168	318	

Total Sensitivity: 92% (95% CI: 87.7%-96.3%)
Total Specificity: 98.8% (95% CI: 97.2%-100%)
Accuracy: 95.6%

B. Clinical tests with crude samples (without RNA extraction)

326 frozen crude samples were analysed using the COV19 qcLAMP kit with the Pebble qcLAMP Point-of-Care Platform. The positive samples had reported RT-qPCR Ct values ranging from 12 to 31. The fastest observed time-to-positive result with qcLAMP was 11.5 min for a sample with a Ct value of 14 while the maximum was 23.8 min for a Ct of 26.

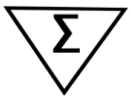
The corresponding data are summarized in the following table:

Ct value	RT-PCR positive	Proportion	qcLAMP	PPA
<25	104	70.7%	101	97.1%
25-29	36	24.5%	13	36.1%
30-34	7	4.8%	2	28.6%

	RT-PCR method			
qcLAMP method	Positive	Negative	Total	
Positive	125	1	126	
Negative	22	178	200	
Total	147	179	326	

Total Sensitivity: 85.0% (95% CI: 79.2%-90.8%)
Total Specificity: 99.4% (95% CI: 98.3%-100%)
Accuracy: 93%

Used symbols and explanation

Symbols	Explanation
	Website
	E-mail
	Phone number
	*In vitro* diagnostic use
	Batch code
	Catalog number
	Consult electronic instructions for use
	Manufacturer
	European conformity
	Do not use if package is damaged
	Keep dry
	IVD near patient
	Not for self-testing
	Temperature limit (for transportation)
 **100 tests**	Contains sufficient amount for 100 tests
	Serial number
	Use-by-day
	Unique device identifier
	Recyclable

Technical support

For technical support, please contact BIOPIX-T at:

Address: BIOPIX DNA TECHNOLOGY P.C., Science and Technology Park of Crete, N. Plastira 100, Vasilika Vouton, GR-700 13, Heraklion, Greece.
Phone: (+30) 281 0391986
E-mail: support@biopix-t.com / info@biopix-t.com

Literature references

Papadakis et al., "Real-time colorimetric LAMP methodology for quantitative nucleic acids detection at the Point-of-Care," no. 89, pp. 1–20, 2020, doi: 10.1101/2020.07.22.215251.
World Health Organization (WHO), "Coronavirus disease 2019 (2019-nCOV) Situation Report – 11," WHO Bull., no. January 31, pp. 1–7, 2020.

Abbreviations

Cat.no: Catalogue number
LAMP: Loop-mediated isothermal amplification
qcLAMP: Quantitative colorimetric loop-mediated isothermal amplification
PCR: Polymerase Chain Reaction
RNA: Ribonucleic Acid
DNA: Deoxyribonucleic Acid
mL: millilitre
µL: microlitre