DIAGNOVITAL

HS SARS-CoV-2 Real-Time PCR Kit v2.0

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

For *in vitro* diagnostic use. For professional use only

CE IVD

REF	Σ
09079025	25 tests
09079050	50 tests
09079100	100 tests

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Intended Use

This document describes the use of real-time RT-PCR assays intended for the qualitative detection of 2019-Novel Coronavirus (SARS-CoV-2) in respiratory specimens. The SARS-CoV-2 primer and probe sets are designed for the specific detection of SARS-CoV-2.

DIAGNOVITAL® HS SARS-CoV-2 Real-Time PCR Kit v2.0 is an *in vitro* nucleic acid amplification assay for the qualitative detection of 2019-Novel Coronavirus (SARS-CoV-2) in nasopharyngeal/oropharyngeal swabs, bronchoalveolar lavage (BAL).

The kit follow CDC's and WHO's latest detection guidelines.

Product Description

DIAGNOVITAL® HS SARS-CoV-2 Real Time PCR Kit v2.0 is a real-time RT-PCR-based detection system for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). 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 two newer human coronaviruses, MERS-CoV and SARS-CoV.

DIAGNOVITAL® HS SARS-CoV-2 Real Time PCR Kit v2.0 detects the presence of two different and highly specific gene sequences of SARS-CoV-2: N1 and N2 regions of the Nucleocapsid gene.

DIAGNOVITAL® HS SARS-CoV-2 Real-Time PCR Kit v2.0 is an in vitro nucleic acid amplification assay for the qualitative detection of 2019-Novel Coronavirus (SARS-CoV-2) in nasopharyngeal/ oropharyngeal swabs, bronchoalveolar lavage (BAL), using BIO-RAD CFX96, Rotor-Gene Q, and QuantStudio 5 Real-time PCR Systems.

Additionally, a non-infectious positive control and an internal control are included. The internal control is needed to ensure RNA extraction, reverse transcription and all reagents involved. DIAGNOVITAL® HS SARS-CoV-2 PCR master mix contains primers and probe for the endogenous human target (RNaseP). It is not essential for an additional external DNA or RNA template as extraction control, since the human target is obtained during extraction. 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.

REAL TIME PCR-BASED DETECTION OF SARS-CoV-2

The first step in the detection of SARS-CoV-2 is conversion of viral RNA into cDNA. Afterwards, the target sequences unique for SARS-CoV-2 are amplified with and monitored in real time through the use of fluorescent-labeled probes. The fluorophore is released and an increase in fluorescence signal can be observed when the probes incorporate with the newly amplified DNA strands.

DIAGNOVITAL HS SARS-CoV-2 Real Time PCR v2.0 addresses this issue by using 2 different target sequences to minimize the chance of false-negative results caused by an altered target sequence. 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.

If samples are tested negative in one or more assays, additional complementary testing may be required. The original target sequences for SARS-CoV-2 are included as a non-infectious positive control to check the integrity of the detection assays.

Materials Provided

	Reagents	Quantity and Volume (25 tests)	Quantity and Volume (50 tests)	Quantity and Volume (100 tests)
1	PCR Master Mix	1 × 375 µl	1 × 750 µl	1 × 1500 µl
2	Positive Control	1 × 38 µl	1 × 75 µl	1 × 150 µl
3	Nuclease-free dH_2O	1 × 38 µl	1 × 75 µl	1 × 150 µl

IMPORTANT! The table above reflects the standard kit color scheme. Due to supplier issues during the COVID-19 crisis, individual tube cap colors may be substituted due to availability. Always check the labeling of the reagent prior to use.

Additional Materials Required

- Suitable consumables & equipment for nucleic acid extraction
- Real-time PCR detection system equipped for FAM and HEX detection
- Adjustable pipettes & fitting filtered pipette tips
- Appropriate personal protective equipment & 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, master mixes etc.
- Nuclease-free tubes / strips / plates corresponding to the PCR device
- Suitable storage options for reagents and specimen (4°C, -20°C, -70°C)

Storage

- Store all components between -15°C to -25°C and avoid repeated freeze and thaw cycles.
- Protect the qPCR Master mixes from light; prolonged exposure can diminish the performance of the fluorophores.
- If the kit components have been damaged during transport, contact RTA Laboratories. Do not use as performance may be compromised.
- Keep reagents separate from specimens to avoid contamination.
- Do not use after the designated expiry date.

Performance Characteristics

Analytical sensitivity for NP/ OP Swabs with RTA Viral RNA Isolation Kit

Analytical sensitivity for NP/OP SWABS was analyzed by use of a dilution series of DIAGNOVITAL HS SARS-CoV-2 Target Positive Control (TPC) which concentration is 10^8. A dilution series of a Target Positive Contro was prepared to give the final concentrations of 300, 100, 30 and 10 copies/ml. Dilutions were extracted by RTA Viral RNA Isolation Kit (Cat No: 09010) according to RTA Viral RNA Isolation Kit Handbook. Each dilution was tested

in Biorad CFX96 instrument. Lower limit was calculated by probit analysis done by PASW Statistics 18 program. For each genotype/subtype, Limit of Detection (LoD) values and 95% confidence ranges are summarized in Table 1.

Target gene	Limit of Detection (copies/ml)	95% confidence lower limit	95% confidence upper limit
N1+N2	38	32	53

Table 1: *DIAGNOVITAL® HS SARS-CoV-2 PCR Kit v2.0 with RTA Viral RNA Isolation Kit - Limit of Detection (LoD) values 95% confidence ranges*

Analytical sensitivity for NP/ OP Swabs MAGICPREP 2 Fast RNA Extraction Kit *(Direct HS RT-PCR test)*

Analytical sensitivity for NP/ OP swabs was analyzed by use of a dilution series of SeraCare Reference Samples (AccuPlex SARS-CoV-2 Reference Material Kit, Cat: 0505-0126). A dilution series of SeraCare Reference samples was prepared to give the final concentrations of 2500, 1750, 875, 312.5, 156.25 and 78.125 copies/ml in QuantStudio 5 Real-time PCR Systems. Dilutions were extracted by MAGICPREP 2 Fast RNA Extraction Kit. Firstly, each dilution was tested in 5 replicates. Then 156,25 was tested in 20 replicates. Limit of Detection (LoD) value were determined to be at 156.25 cp/ µl. The results can be found in the table below.

Target gene	Limit of Detection (copies/ml)	95% confidence lower limit	95% confidence upper limit
N1+N2	206	164	376

Table 2: *DIAGNOVITAL® HS SARS-CoV-2 PCR Kit v2.0 with MAGICPREP 2 Fast RNA Extraction Kit - Limit of Detection (LoD) values 95% confidence ranges*

Precision

To determine the precision, which is the repeated testing of the same sample to get similar results, we have used contrived samples with 3xLoD which corresponds to ~120 copies /ml using Seracare AccuPlex SARS-CoV-2 Positive Reference samples which have a concentration of 5000 copies/ml. Samples were processed as 15 replicates and were extracted by RTA Viral RNA Isolation Kit (Cat No: 09010) according to RTA Viral RNA Isolation Kit Handbook. In addition, 15 replicates of Seracare AccuPlex SARS-CoV-2 Negative Reference samples were also included in the study. It was concluded that repeated positive samples corresponding to 3xLoD, which is ~120 copies/ml produced similar results. Also, all negative reference samples gave negative results. Results were summarized in Table 3.

Table 3: Overall descriptive statistics of SARS-CoV-2 precision data.

	Mean	Std. Deviation	Variance	Coefficient of variation (%)
120 copies/ ml (FAM)	36.82	0.31	0.10	0.93

120 copies/ ml (HEX)	33.55	0.37	0.14	1.11
Negative (FAM)	N/A	N/A	N/A	N/A
Negative (HEX)	33.40	0.58	0.34	1.74

Repeatability

The repeatability of **DIAGNOVITAL HS SARS-CoV-2 Real Time PCR Kit v2.0** has been assessed using a low positive (3xLoD) sample which corresponds to ~120 copies /ml in 20 replicates. The sample was extracted by RTA Viral RNA Isolation Kit (Cat No: 09010) according to RTA Viral RNA Isolation Kit Handbook. PCR reactions were setup by DIAGNOVITAL HS SARS-CoV-2 Real Time PCR Kit v2.0 according to DIAGNOVITAL HS SARS-CoV-2 Real Time PCR Kit v2.0 Handbook. BIO-RAD CFX96-Touch Real-Time PCR Detection System was used for amplification, detection and analysis. Descriptive statistics were analyzed by IBM SPSS Statistics program. Coefficient of variation (%) was calculated by the following formula: standard deviation*100/mean.

Table 4: Descriptive statistics of DIAGNOVITAL HS SARS-CoV-2 v2.0 repeatability data

Descriptive Statistics					
	N	**Mean**	**Std. Deviation**	**Variance**	**Coefficient of Variation (%)**
FAM	21	36,996	0,45	0,20	1,28
HEX	21	31	4	18	14

Specificity

SARS-CoV-2 RNA negative clinical specimens were analyzed to determine the specificity of DIAGNOVITAL® HS SARS-CoV-2 Real Time PCR Kit v2.0. 27 SARS-CoV-2 RNA negative clinical oropharyngeal swab specimens and 77 SARS-CoV-2 RNA negative clinical nasopharyngeal swab specimens and 31 bronchoalveolar lavage specimens were used. None of the 135 SARS-CoV-2 negative clinical specimens yielded positive test results for SARS-CoV-2. Diagnostic specificity of DIAGNOVITAL® HS SARS-CoV-2 Real Time PCR Kit v2.0 is 100 %. All of the Internal Controls (RNAseP) have been tested positive.

Table 5: Oropharyngeal swab descriptive statistics of SARS-CoV-2 diagnostic specificity data.

Descriptive Statistics						
Oropharyngeal Swab		**N**	**Mean**	**Std. Deviation**	**Variance**	**Coefficient of Variation (%)**
	FAM	27	NA	NA	NA	NA
	HEX	27	28.43185	1.49378	2.231378	5.253896

Table 6: Nasopharyngeal swab descriptive statistics of SARS-CoV-2 diagnostic specificity data.

Descriptive Statistics

Nasopharyngeal Swab		N	Mean	Std. Deviation	Variance	Coefficient of Variation (%)
	FAM	77	NA	NA	NA	NA
	HEX	77	29.273	1.321	1.745	4.513

Table 7: Bronchoalveolar lavage descriptive statistics of SARS-CoV-2 diagnostic specificity data.

Descriptive Statistics						
Bronchoalveolar Lavage		N	Mean	Std. Deviation	Variance	Coefficient of Variation (%)
	FAM	31	NA	NA	NA	NA
	HEX	31	26.028	1.218	1.484	4.681

Cross-reactivity

To examine the specificity of an assay, cross-reactivity studies should be performed for potential cross-reactive markers. In this study, the specificity of the assay was evaluated by testing 20 reference organisms. **DIAGNOVITAL® HS SARS-CoV-2 Real Time PCR Kit v2.0** did not show any cross-reactivity with other potential cross-reactive markers given in Table 8 below:

Table 8: Potential cross-reactive markers tested in the study

Sample	Source
Human Adenovirus	NIBSC (Cat. No: 16/324)
Parainfluenza virus	ATCC VR-93
Influenza A	ATCC VR-95
Influenza A H5N1	ATCC VR-1609
Influenza A H1N1	ATCC VR-1672
Influenza A H3N2	ATCC VR-822
Influenza A H7N7	ATCC VR-1641
Influenza B	ATCC VR-101
Parainfluenza 1	ATCC VR-94
Parainfluenza 2	ATCC VR-92

Sample	Source
Parainfluenza 3	ATCC VR-93
Parainfluenza 4	ATCC VR-579
Human Metapneumovirus (hMPV)	ATCC VR-3250SD
Human Enterovirus V71	ATCC VR-1432
Human respiratory syncytial virus	ATCC VR-154
Human Coronavirus NL63	ATCC VR-3263SD
Human Coronavirus HKU1	ATCC VR-3262SD
Human Coronavirus 229E	ATCC VR-740
Betacoronavirus 1 OC43	ATCC VR-1558D
MERS Coronavirus	ATCC VR-3248SD

Considerations Before Starting

BIOSAFETY

- Wear appropriate personal protective equipment (e.g. gowns, powder-free gloves, eye protection) when working with clinical specimen(s).

- Specimen processing should be performed in a certified class II biological safety cabinets (BSCs) 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/lab/guidelines-clinical-specimens.html
- Biosafety in Microbiological and Biomedical Laboratories 6th Edition available at http://www.cdc.gov/biosafety/publications
- The use of **DIAGNOVITAL® HS SARS-CoV-2 v2.0** is restricted to trained laboratory personnel only.

SPECIMENS

Only use appropriate specimens for testing, such as:

- Specimens including nasopharyngeal/oropharyngeal swabs, bronchoalveolar lavage.
- Swab specimens should be collected only on swabs with a synthetic tip (such as polyester or Dacron®) with plastic shafts. Swabs with calcium alginate or cotton tips with wooden shafts are not acceptable.

SPECIMENS - HANDLING AND STORAGE

- Specimens can be stored between 2°C to 8°C for up to 72 hours after collection.
- If a delay in extraction is expected, store specimens at -20°C or lower.
- Extracted nucleic acids should be stored at -20°C or lower.

Do not use specimens if:

- they were not kept at 2-4°C (≤ 4 days) or frozen at -20°C or below.
- they are insufficiently labelled or lack documentation.
- it is not a suitable specimen for this purpose (see above for suitable sample material).
- the specimen volume is insufficient.

Sample Preparation for NP/OP swabs

- 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 **DIAGNOVITAL DETECTION KITS** include: RTA Viral RNA Isolation Kit, 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, and Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit, Invitrogen ChargeSwitch® Total RNA Cell Kit, Tianlong Generotex96 automatic nucleic acid extractor, Zinext ZiExpress-32 Automated Nucleic Acid Purification Instrument.
- DIAGNOVITAL® HS SARS-CoV-2 Real Time PCR Kit v2.0 is also validated with DIAGNOVITAL® MAGICPREP 2Fast RNA Isolation Kit. In case of using MAGICPREP 2, there is no need for RNA Isolation process.
- *Compatible Real Time PCR systems*: Roche LightCycler 480, Roche LightCycler 96, Qiagen Rotor Gene Q, Qiagen Rotor Gene Series, Corbett Realtime PCR, BMS Mic, Biorad CFX Connect, Biorad CFX96, Biorad CFX Touch, Applied Biosystem ABI 7500, Applied Biosystem ABI 7500 Fast, Applied Biosystem ABI StepOne, Applied Biosystem ABI StepOne Plus, Thermo Scientific Quant Studio 5,

Slan Realtime PCR, Tianlog Gentier 96E, Tianlong Gentier 96R, Stratagene Mx3500p, Azure Biosystems™ Cielo™ 3 and 6 real-time PCR Systems.

- Store and keep residual specimens and extracted nucleic acids at -20°C/ -80°C.
- Only thaw the number of specimen extracts 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.
- It may be possible to use patient samples directly, depending on the sample type. However, this may require a prior lysis step and titration of the amount on sample that can be used without inhibiting the reaction.

Reaction Setup

1. Ensure all necessary equipment(s) and devices are suitable, calibrated and functional before starting the experiments.

2. Decontaminate equipment(s) and workspace(s) and prepare everything needed for the following experiment to keep workflow short and reproducible.

3. Switch on the PCR detection system and program to avoid delays after setting up the reactions.

4. Thaw all components of **DIAGNOVITAL® HS SARS-CoV-2 Real Timer PCR Kit v2.0** 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 (via microcentrifuge).

5. The **PCR Master Mix** provided with **DIAGNOVITAL® HS SARS-CoV-2 Real-Time PCR Kit v2.0** is ready to use. One reaction will be prepared for each sample. A separate reaction should be prepared for Negative Control (NTC) and Positive Control (PC).

Component	Volume (µl)
PCR Master Mix	15
RNA Isolate/ MAGICPREP 2 Swab extract/ PC/ NTC	5
Total	**20**

6. Distribute 15 µl PCR Master Mix to your strips/plate and add 5 µl your samples. (An example setup is given in **Fig.1**)

	1	2	3	4	5	6	7	8	9	10	11	12
A	S1	S9	S17	S25	S33	S41	S49	S57	S65	S73	S81	PC
B	S2	S10	S18	S26	S34	S42	S50	S58	S66	S74	S82	S89
C	S3	S11	S19	S27	S35	S43	S51	S59	S67	S75	S83	S90
D	S4	S12	S20	S28	S36	S44	S52	S60	S68	S76	S84	S91

E	S5	S13	S21	S29	S37	S45	S53	S61	S69	S77	S85	S92
F	S6	S14	S22	S30	S38	S46	S54	S62	S70	S78	S86	S93
G	S7	S15	S23	S31	S39	S47	S55	S63	S71	S79	S87	S94
H	S8	S16	S24	S32	S40	S48	S56	S64	S72	S80	S88	**NTC**

Figure 1: Example pipetting scheme for the distribution of master mixes with the individual assay mixes

7. Transfer the reactions to the PCR device, then proceed according to these guidelines:

Step	Cycles	Temperature	Duration
Reverse Transcription	1	45°C	10 minutes
Initial Denaturation	1	95°C	2 minutes
Amplification	40	95°C	3 seconds
		60°C* 📷	10 seconds

📷 *Enable Data Collection for **FAM** and **HEX**.

8. 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.

Analysis & Troubleshooting

EXEMPLARY RESULT

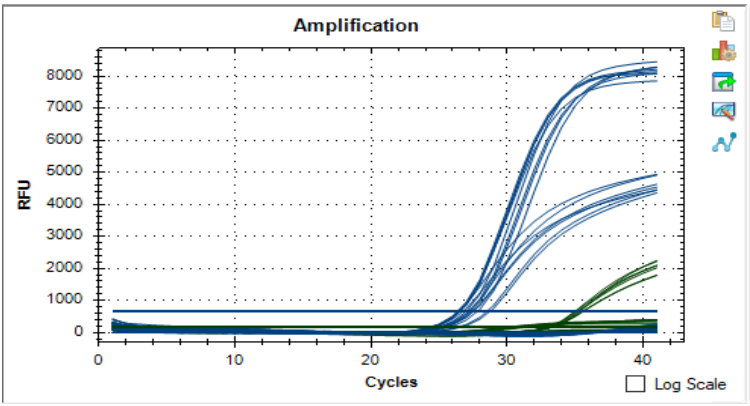

Figure 2: Blue Curves: positive samples at the FAM channel, Green Curves: internal control at the HEX channel, Curves Running Straight: Negative Control

- For a sample to be considered **positive for SARS-CoV-2, its amplification in the FAM channel (*N1 / N2*) must give positive Ct values (Ct<38)**. If the internal control fails to amplify, the sample must still be considered positive. Inhibition of internal control is possible, for example, if it has a high viral load or if the sample is derived from cell culture rather than human origin. If the Ct value of the sample is >38, the sample can be evaluated as negative.

- For a sample to be considered **negative for SARS-CoV-2, the FAM channel (*N1 / N2*) must NOT give positive Ct values or must be Ct>38**. The internal control in the **HEX channel (RNAseP)** must give a positive Ct value (<38 cycles) for these samples to ensure that sample material of suitable quality was present. Failure to amplify the internal control indicates a flawed RNA extraction or loss of RNA isolate due to RNase contamination. The sample is not sufficient, results cannot be interpreted.

- **For the positive control,** an increase in the **FAM** channel (Ct 25 <Ct <30) should be observed**.** The Ct value for the positive control should be **25<Ct<30**. If the Ct value does not correspond to the expected value or the positive control was not tested positive, the performance of the PCR was degraded. Check the reaction setup and PCR device settings and repeat the reactions. More than 3 replicates of freeze-thaw may result in late Ct values, compromising the quality of the positive control.

- No amplification should be observed in both the FAM and HEX channel for the **negative control** (NTC). Amplification in the negative control indicates that the reaction is contaminated with a sample RNA/ DNA. Equipment(s) and workplace(s) should be decontaminated and reactions repeated.

- **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.

N1-N2 (FAM)	RNAseP (HEX)	Interpretation
+ (Ct<38)	- (Ct>38)	The sample is considered **positive** for SARS-CoV-2.
+ (Ct<38)	+ (Ct<38)	The sample is considered **positive** for SARS-CoV-2.
- (Ct>38)	+ (Ct<38)	Only the internal control target sequence was duplicated. The sample is considered negative for SARS-CoV-2. *
- (Ct>38)	- (Ct>38)	PCR inhibition; results are invalid **
- (Ct>38)	- (Ct>38)	It is the expected result for the negative control.

* Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation suggest that 2019-nCoV infection is possible, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection is still suspected, re-testing should be considered in consultation with public health authorities.

** Invalid sample results can be generated due to insufficient amounts or quality of sample RNA or due to inhibitory substances within the sample or RNA extract. Sample retesting can be attempted from the RT-PCR only, however, re-extraction of the sample is needed if the RT-PCR is repeatedly invalid. Re-extraction can be attempted if left over sample material if adequately stored. If no additional material is available or if the re-extracted sample is still invalid a new sample needs to be requested.

Baseline Setting

The amplification curve baseline is one of the parameters that can affect PCR results. In case the baseline is incorrectly set, a Ct value can be displayed even if no real amplification occurred. Signal intensity can vary from one run to another depending on many factors including the consumables used in the reaction. Therefore, the threshold value may need to be adjusted differently for each study. It is recommended to apply the following parameters for different devices.

BIORAD CFX96; The threshold level should be set for the 10% RFU of the sample with the highest RFU in operation. Depending on the study, the baseline setting from the Setting section and then Apply Fluorescense Drift Correction setting is selected.

Qiagen Rotor-Gene Q; When the reaction is completed, Cycling Green and Cycling Yellow are selected for all channels and it is made sure that the "Outlier Removal" to be set to 5%. Depending on the study, both the "Dynamic Tube" and the "Slope Correct" can be selected as either active or passive. "Dynamic Tube" must be enabled, "Slope Correct" must be selected passively. The "Threshold" and "Eliminate Cycles Before" parameters in the "CT Calculation" tab in the lower right corner of the screen should be set as 0.02-0.04 and 0 respectively.

Troubleshooting

PROBLEM	POTENTIAL REASONS	SOLUTION
Negative Result for Internal Control	PCR Master Mix may not have been homogenous.	Pipetting should be performed for PCR Master Mix.
	RNA isolation may not be performed as properly.	The study should be repeated from isolation.
	Isolate may include inhibitor.	Real Time PCR stage should be repeated by diluting the isolate 1/10.
Positive increases of NTC samples were observed	Contamination may have occurred.	Contamination may have occurred from the work area to the consumable items being worked on. It is recommended to dispose of consumables and open new ones and clean the environment first with 10% NaClO solution and then with 70% Alcohol.
Results observed at Low Ct	For positive results having Ct > 38	The study should be repeated. If the same result is obtained, the sample is considered negative.

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 properly trained.

Trademarks

DIAGNOVITAL®, NucliSens® (bioMérieux), QIAamp®, RNeasy® (QIAGEN), ChargeSwitch® (Invitrogen), ROX™, FAM™ (Life Technologies), DNAZap™, DNA Away™, RNAse Away™, Zinext, Tianlong Registered names, trademarks, etc. used in this document, even if not specifically marked as such, are not to be considered unprotected by law.

Symbols


Expiry Date

Lot/ Batch

Catalog number


Temperature Limitation


Caution


Manufacturer

In Vitro Diagnostic Medical Device


Consult instructions for use or
consult electronic instructions for use


Contains sufficient for (n) amount tests

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GEPOSB Cumhuriyet Cad. No:3 41400
Gebze/ Kocaeli/ Turkey

Tel: +90 262 648 5300
E-mail: rta@rtalabs.com.tr
Web: www.rtalabs.com.tr