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RealStar®
hMPV RT-PCR Kit 1.0

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RealStar®

hMPV RT-PCR Kit 1.0

For use with

m2000rt (Abbott Diagnostics)

Mx 3005P™ QPCR System (Stratagene)

VERSANT™ kPCR Molecular System AD (Siemens)

ABI Prism® 7500 SDS and 7500 Fast SDS (Applied Biosystems)

LightCycler® 480 Instrument II (Roche)

Rotor-Gene™ 3000/6000 (Corbett Research)

Rotor-Gene Q5/6 plex Platform (QIAGEN)

CE

IVD For *in vitro* diagnostic use

REF Product No.: 251013

Σ 96 rxns

Store at -25°C ... -15°C

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altona Diagnostics GmbH • Mörkenstraße 12 • D-22767 Hamburg

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Content

1. Intended Use

The RealStar® hMPV RT-PCR Kit 1.0 is an *in vitro* diagnostic test, based on real-time PCR technology, for the qualitative detection of human metapneumovirus (hMPV) specific RNA. Furthermore, the test allows the differentiation between hMPV subtype A (hMPV A) and hMPV subtype B (hMPV B) specific RNA.

2. Kit Components

Lid Color	Blue	Purple	Green	Red	Orange	White
Component	Master A	Master B	Internal Control	Positive Control hMPV A	Positive Control hMPV B	PCR grade Water
Number of Vials	8	8	1	1	1	1
Volume [µl/Vial]	60	120	1000	250	250	500

3. Storage

- The RealStar® hMPV RT-PCR Kit 1.0 is shipped on dry ice. The components of the kit should arrive frozen. If one or more components are not frozen upon receipt, or if tubes have been compromised during shipment, contact altona Diagnostics GmbH for assistance.
- All components should be stored at -20°C upon arrival.
- Repeated thawing and freezing of Master reagents (more than twice) should be avoided, as this might affect the performance of the assay. The reagents should be frozen in aliquots, if they are to be used intermittently.
- Storage at +4°C should not exceed a period of two hours.
- Protect Master A and Master B from light.

RealStar® hMPV RT-PCR Kit 1.0

4. Material and Devices required but not provided

- Appropriate real-time PCR instrument (chapter 6. Product Description)
- Appropriate nucleic acid extraction system or kit
- Desktop centrifuge with a rotor for 2 ml reaction tubes
- Centrifuge with a rotor for microtiter plates, if using 96 well reaction plates
- Vortex mixer
- Appropriate 96 well reaction plates or reaction tubes with corresponding (optical) closing material
- Pipettes (adjustable)
- Pipette tips with filters (disposable)
- Powder-free gloves (disposable)

NOTE

> ⚠ ***Please ensure that instruments have been installed, calibrated, checked and maintained according to the manufacturer´s instructions and recommendations.***

5. Background Information

Human metapneumovirus (hMPV) are negative sense, single stranded RNA viruses of the family *Paramyxoviridae.* Like Respiratory Syncytial Virus (RSV), hMPV belong to the genus *Pneumovirus*. HMPV are subdivided into two major genetic lineages, hMPV A and hMPV B. Different genotypes of both subgroups can co-circulate within one epidemic. Human metapneumovirus is a common respiratory virus causing upper and lower respiratory tract infections with symptoms very similar to those caused by RSV. Symptoms range from mild rhinorrhea to severe respiratory illness with bronchiolitis and pneumonia, the latter particularly in infants, young children, elderly, persons with cardiopulmonary diseases and immunocompromised individuals. The virus is spread by infectious droplets or by contact with nasal or oral secretions from infected people. Outbreaks of hMPV infections occur predominantly in winter and spring in temperate climates, often overlapping or following RSV outbreaks.

6. Product Description

The RealStar® hMPV RT-PCR Kit 1.0 is an *in vitro* diagnostic test system, based on real-time PCR technology, for the detection and differentiation of hMPV A and hMPV B specific RNA. The assay includes a heterologous amplification system (Internal Control) to identify possible RT-PCR inhibition and to confirm the integrity of the reagents of the kit.

The test is based on real-time RT-PCR technology, utilizing reverse transcriptase (RT) reaction to convert RNA into complementary DNA (cDNA), polymerase chain reaction (PCR) for the amplification of specific target sequences and target specific probes for the detection of the amplified DNA. The probes are labelled with fluorescent reporter and quencher dyes.
Probes specific for hMPV A are labelled with a fluorophore showing the same characteristics as Cy5, whereas probes specific for hMPV B are labelled with the fluorophore FAM. The probe specific for the target of the Internal Control is labelled with the fluorophore JOE.

Using probes linked to distinguishable dyes enables the parallel detection of hMPV A, hMPV B and the Internal Control in the corresponding detector channels of the real-time PCR instrument.

The test consists of three processes in a single tube assay:

- Reverse transcription of target RNA to cDNA
- PCR amplification of target cDNA and Internal Control
- Simultaneous detection of PCR amplicons by fluorescent dye labelled probes

The RealStar® hMPV RT-PCR Kit 1.0 was developed and validated to be used with the following real-time PCR instruments:

- m2000rt (Abbott Diagnostics)
- Mx 3005P™ QPCR System (Stratagene)
- Versant™ kPCR Molecular System AD (Siemens)
- ABI Prism® 7500 SDS and 7500 Fast SDS (Applied Biosystems)
- LightCycler® 480 Instrument II (Roche)
- Rotor-Gene™ 3000/6000 (Corbett Research)
- Rotor-Gene Q 5/6 plex Platform (QIAGEN)

The RealStar® hMPV RT-PCR Kit 1.0 consists of:

- Two Master reagents (Master A and Master B)
- Template Internal Control (IC)
- Two Positive Controls: Positive Control (hMPV A)
  Positive Control (hMPV B)
- PCR grade water

Master A and Master B reagents contain all components (buffer, enzymes, primers, and probes) to allow reverse transcription, PCR mediated amplification and target detection (hMPV A, hMPV B, and Internal Control) in one reaction setup.

7. Warnings and Precautions

- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.
- Specimens should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures.
- Wear protective disposable powder-free gloves, a laboratory coat and eye protection when handling specimens.
- Avoid microbial and nuclease (DNase/RNase) contamination of the specimen and the components of the kit.
- Always use DNase/RNase-free disposable pipette tips with aerosol barriers.
- Always wear protective disposable powder-free gloves when handling kit components.
- Use separated and segregated working areas for (i) specimen preparation, (ii) reaction set-up and (iii) amplification/detection activities. Workflow in the laboratory should proceed in unidirectional manner. Always wear disposable gloves in each area and change them before entering different areas.
- Dedicate supplies and equipment to the separate working areas and do not move them from one area to another.
- Store positive and/or potentially positive material separated from all other components of the kit.
- Do not open the reaction tubes/plates post amplification, to avoid contamination with amplicons.
- Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations.
- Do not use components of the kit that have passed their expiration date.
- Discard sample and assay waste according to your local safety regulations.

8. Instructions for Use

8.1 Sample Preparation

Extracted RNA is the starting material for the RealStar® hMPV RT-PCR Kit 1.0. The quality of the extracted RNA has a profound impact on the performance of the entire test system. It has to be ensured that the system used for nucleic acid extraction is compatible with real-time PCR technology.

The following nucleic acid extraction systems and kits are recommended:

- KingFisher® Flex (Thermo Scientific) with ExtraStar® Purification Kit (altona Diagnostics)
- VERSANT™ Modular System SP (Siemens)
- HighPure® Viral Nucleic Acid Kit (Roche)
- QIAamp® Viral RNA Mini Kit (QIAGEN)

If using a spin column based sample preparation procedure including washing buffers containing ethanol, an additional centrifugation step for 10 min at approximately 17000 x g (~ 13000 rpm), using a new collection tube, prior to the elution of the nucleic acid is highly recommended.

NOTE

> ⚠ ***The use of carrier RNA is crucial for extraction efficiency and stability of the extracted nucleic acid.***
>
> ⚠ ***Ethanol is a strong inhibitor in real-time PCR. If your sample preparation system is using washing buffers containing ethanol, you need to make sure to eliminate any traces of ethanol prior to elution of the nucleic acid.***

For additional information and technical support regarding pre-treatment and sample preparation please contact our Technical Support:

e-mail: **support@altona-diagnostics.com**
phone: **+49-(0)40-5480676-0**

8.2 Master Mix Setup

All reagents and samples should be thawed completely, mixed (by pipetting or gentle vortexing) and centrifuged briefly before use.

The RealStar® hMPV RT-PCR Kit 1.0 contains a heterologous Internal Control (IC), which can either be used as a RT-PCR inhibition control or as a control of the sample preparation procedure (nucleic acid extraction) and as a RT-PCR inhibition control.

- If the IC is used as a RT-PCR inhibition control, but not as a control for the sample preparation procedure, the Master Mix is set up according to the following pipetting scheme:

Number of Reactions (rxns)	1	12
Master A	5 µl	60 µl
Master B	10 µl	120 µl
Internal Control	1 µl	12 µl
Volume Master Mix	**16 µl**	**192 µl**

- If the IC is used as a control for the sample preparation procedure and as a RT-PCR inhibition control, the IC has to be added during the nucleic acid extraction procedure.

- No matter which method/system is used for nucleic acid extraction, the IC **must not** be added directly to the specimen. The IC should always be added to the specimen/lysis buffer mixture. The volume of the IC which has to be added depends always and only on the elution volume. It represents 10% of the elution volume. For instance, if the nucleic acid is going to be eluted in 60 µl of elution buffer or water, 6 µl of IC per sample must be added to the specimen/lysis buffer mixture.

NOTE

⚠ ***Never add the Internal Control directly to the specimen!***

- If the IC was added during the sample preparation procedure, the Master Mix is set up according to the following pipetting scheme:

Number of Reactions (rxns)	1	12
Master A	5 µl	60 µl
Master B	10 µl	120 µl
Volume Master Mix	**15 µl**	**180 µl**

8.3 Reaction Setup

- Pipette 15 µl of the Master Mix into each required well of an appropriate optical 96-well reaction plate or an appropriate optical reaction tube.
- Add 10 µl of the sample (eluate from the nucleic acid extraction) or 10 µl of the controls (Positive or Negative Control).
- Make sure that each of the Positive Controls and at least one Negative Control is used per run.
- Thoroughly mix the samples and controls with the Master Mix by up and down pipetting.
- Close the 96-well reaction plate with an appropriate optical adhesive film, the reaction tubes with appropriate lids.
- Centrifuge the 96-well reaction plate in a centrifuge with a microtiter plate rotor for 30 seconds at approximately 1000 x g (~ 3000 rpm).

Reaction Setup	
Master Mix	15 µl
Sample or Control	10 µl
Total Volume	**25 µl**

9. Programming the Real-Time PCR Instruments

For basic information regarding the setup and programming of the different real-time PCR instruments, please refer to the manual of the respective instrument.
For detailed programming instructions regarding the use of the RealStar® hMPV RT-PCR Kit 1.0 on specific real-time PCR instruments please contact our Technical Support.

9.1 Settings

- Define the following settings:

Settings	
Reaction Volume	25 µl
Ramp Rate	Default
Passive Reference	None

9.2 Fluorescent Detectors (Dyes)

- Define the fluorescent detectors (dyes):

Detection	Detector Name	Reporter	Quencher
hMPV A specific RNA	hMPV A	Cy5	(None)
hMPV B specific RNA	hMPV B	FAM	(None)
Internal Control	IC	JOE	(None)

9.3 Temperature Profile and Dye Acquisition

- Define the temperature profile and dye acquisition:

	Stage	Cycle Repeats	Acquisition	Temperature	Time
Reverse Transcription	Hold	1	-	50 °C	10:00 min
Denaturation	Hold	1	-	95 °C	10:00 min
Amplification	Cycling	45	-	95 °C	0:15 min
			√	55 °C	0:45 min
			-	72 °C	0:15 min

10. Data Analysis

For basic information regarding data analysis on specific real-time PCR instruments, please refer to the manual of the respective instrument.
For detailed instructions regarding data analysis of the RealStar® hMPV RT-PCR Kit 1.0 on different real-time PCR instruments please contact our Technical Support.

10.1 Validity of Diagnostic Test Runs

10.1.1 Valid Diagnostic Test Run

For a **valid** diagnostic test run, the following control conditions must be met:

Control ID	FAM Detection Channel	Cy5 Detection Channel	JOE Detection Channel
Positive Control hMPV A	NEGATIVE	POSITIVE	POSITIVE
Positive Control hMPV B	POSITIVE	NEGATIVE	POSITIVE
Negative Control	NEGATIVE	NEGATIVE	POSITIVE

10.1.2 Invalid Diagnostic Test Run

A diagnostic test run is **invalid**, (i) if the run has not been completed or (ii) if any of the control conditions for a **valid** diagnostic test run are not met.

In case of an **invalid** diagnostic test run, repeat testing by using the remaining purified nucleic acids or start from the original samples again.

10.2 Interpretation of Results

Sample ID	FAM Detection Channel	Cy5 Detection Channel	JOE Detection Channel	Result Interpretation
A	POSITIVE	NEGATIVE	POSITIVE*	hMPV B specific RNA detected.
B	NEGATIVE	POSITIVE	POSITIVE*	hMPV A specific RNA detected.
C	NEGATIVE	NEGATIVE	POSITIVE	Neither hMPV A nor hMPV B specific RNA detected. The sample does not contain detectable amounts of hMPV A or hMPV B specific RNA.
D	NEGATIVE	NEGATIVE	NEGATIVE	RT-PCR inhibition or reagent failure. Repeat testing from original sample or collect and test a new sample.

* Detection of the Internal Control in the JOE detection channel is not required for positive results either in the FAM detection channel or in the Cy5 detection channel. High hMPV load in the sample can lead to reduced or absent Internal Control signal.

11. Performance Evaluation

Performance evaluation of the RealStar® hMPV RT-PCR Kit 1.0 was done by using a CE marked hMPV Working Reagent from NIBSC, hMPV positive specimens as well as characterized isolates from the German reference center for metapneumovirus covering different strains of the subtypes hMPV A and hMPV B. HMPV A and B specific *in vitro* transcripts of known concentration were utilized for quantitative purposes.

The RealStar® hMPV RT-PCR Kit 1.0 enables the parallel detection of hMPV A (Cy5), hMPV B (FAM) and the Internal Control (JOE) using different detector channels of the real-time PCR instrument (see Figure 1).

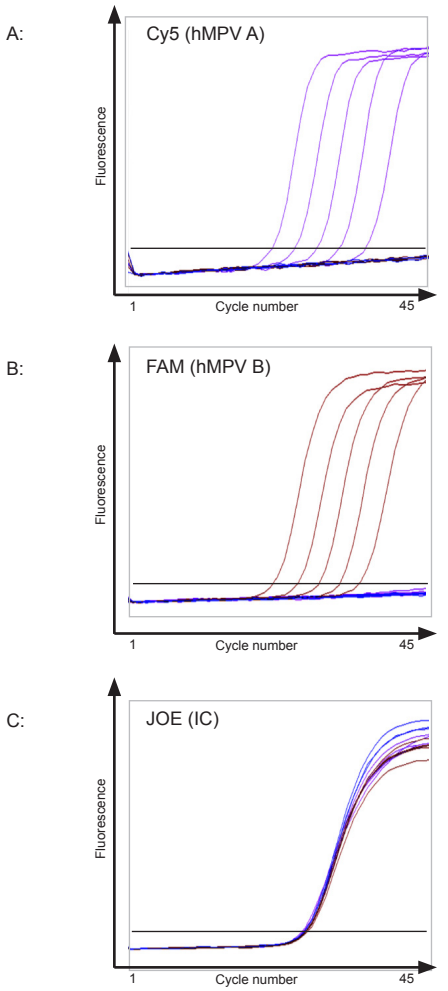

Figure 1: Representative amplification curves obtained with the RealStar® hMPV RT-PCR Kit 1.0 and hMPV A (panel A) and B (panel B) specific *in vitro* transcripts. Each reaction contained the Internal Control (C). RT-PCR was performed on the LightCycler® 480 II (Roche). The concentration of the dilution series shown in the screenshots ranges from 4.5 x 10^4 to 4.5 copies/µl for both hMPV subtypes.

In terms of reference strains and most hMPV-isolates tested so far, the RealStar® hMPV RT-PCR Kit 1.0 clearly distinguishes between hMPV A and hMPV B specific RNA. Depending on the hMPV isolates and the real-time PCR instrument used for the analysis, slight cross-reactivity might occur between the hMPV A and hMPV B system. This has no impact on the outcome of the assay.

11.1 Analytical Sensitivity

The analytical sensitivity of the RealStar® hMPV RT-PCR Kit 1.0 is defined as the concentration (copies per µl of the eluate) of hMPV A or hMPV B specific RNA molecules that can be detected with a positivity rate of ≥ 95%. The analytical sensitivity was determined by analysis of dilution series of hMPV A and B specific *in vitro* transcripts of known concentration.

Table 1: RT-PCR results used for the calculation of the analytical sensitivity of the hMPV A specific system of the RealStar® hMPV RT-PCR Kit 1.0

Input Conc. [copies/µl]	Number of Replicates	Number of Positives	Hit Rate [%]	Internal Control
14.11	16	16	100	valid
4.46	16	16	100	valid
1.41	16	16	100	valid
0.45	16	11	69	valid
0.14	16	9	56	valid
0.0446	16	2	13	valid
0.0141	16	0	0	valid
0.0045	16	0	0	valid
NTC	16	0	0	valid

Table 2: RT-PCR results used for the calculation of the analytical sensitivity of the hMPV B specific system of the RealStar® hMPV RT-PCR Kit 1.0

Input Conc. [copies/µl]	Number of Replicates	Number of Positives	Hit Rate [%]	Internal Control
14.56	16	16	100	valid
4.61	16	16	100	valid
1.46	16	16	100	valid
0.46	16	12	75	valid
0.15	16	10	63	valid
0.046	16	2	13	valid
0.015	16	1	6	valid
0.0046	16	0	0	valid
0.0015	16	0	0	valid
NCT	16	0	0	valid

The analytical sensitivity of the RealStar® hMPV RT-PCR Kit 1.0 was determined by Probit analysis. For the hMPV A specific system, the analytical sensitivity amounts to 1.06 copies/µl (95% confidence interval: 0.58-3.15 copies/µl), and for the hMPV B specific system, the analytical sensitivity is 1.02 copies/µl (95% confidence interval: 0.55-2.98 copies/µl).

11.2 Analytical Specificity

The analytical specificity of the RealStar® hMPV RT-PCR Kit is ensured by the thorough selection of the oligonucleotides (primers and probes). The oligonucleotides were checked by sequence comparison analysis against public available sequences to ensure that all relevant hMPV genotypes will be detected.
The analytical specificity of the RealStar® hMPV RT-PCR Kit 1.0 was evaluated by testing a panel of genomic RNA/DNA extracted from different hMPV isolates and other pathogens that are related to hMPV and/or can cause symptoms similar to hMPV.

Table 3: Organisms tested to demonstrate the analytical specificity the RealStar® hMPV RT-PCR Kit 1.0

	RealStar® hMPV RT-PCR Kit 1.0		
Organisms	Cy5 Channel (hMPV A)	FAM Channel (hMPV B)	JOE Channel (IC)
Human Metapneumovirus A1	Positive	Negative	Positive
Human Metapneumovirus A2	Positive	Negative	Positive
Human Metapneumovirus B1	Negative	Positive	Positive
Human Metapneumovirus B2	Negative	Positive	Positive
Parainfluenzavirus (PIV) Species 1-4	Negative	Negative	Positive
Influenzavirus A	Negative	Negative	Positive
Influenzavirus B	Negative	Negative	Positive
Influenzavirus H1N1nv („swine flu“)	Negative	Negative	Positive
Measles Virus	Negative	Negative	Positive
Mumps Virus	Negative	Negative	Positive
Coronavirus 229E	Negative	Negative	Positive
Chlamydia pneumoniae	Negative	Negative	Positive
Mycoplasma pneumoniae	Negative	Negative	Positive
Staphylococcus aureus	Negative	Negative	Positive
Streptococcus pneumoniae	Negative	Negative	Positive
Adenovirus Serotypes (1, 3, 4)	Negative	Negative	Positive
Hemophilus influenzae	Negative	Negative	Positive
Pseudomonas aeruginosa	Negative	Negative	Positive
Streptococcus pyogenes	Negative	Negative	Positive
Neisseria meningitis	Negative	Negative	Positive
Cytomegalovirus	Negative	Negative	Positive
Epstein-Barr Virus	Negative	Negative	Positive

The RealStar® hMPV RT-PCR Kit 1.0 did not cross-react with any of the specified organisms.

11.3 Diagnostic Evaluation

The diagnostic sensitivity and specificity of the RealStar® hMPV RT-PCR Kit 1.0 gets constantly evaluated by analysing reference samples (e.g. proficiency panels) and diagnostic samples pre-analysed with a reference method (like *in-house* PCR, Luminex technology, etc.).
So far, 144 samples derived from nasopharyngeal aspirates and swabs collected in different laboratories were tested for determining the diagnostic sensitivity and specificity of the RealStar® hMPV RT-PCR Kit 1.0 (Table 4). Out of these 144 samples, 76 samples were predicted to be hMPV positive and 68 samples were predicted to be hMPV negative by using reference methods.

The results of the reference methods could be confirmed by analysis using the RealStar® hMPV RT-PCR Kit 1.0

Table 4: Evaluation results of the diagnostic sensitivity and specificity of the RealStar® hMPV RT-PCR Kit 1.0.

		RealStar®hMPV RT-PCR Kit		
		NEGATIVE	POSITIVE	
			hMPV A	hMPV B
Reference Methode	NEGATIVE	68	0	
			0	0
	POSITIVE	0	76	
			72	4

11.4 Precision

Precision data of the RealStar® hMPV RT-PCR Kit 1.0 were determined as intra-assay variability (variability within one experiment), inter-assay variability (variability between different experiments) and inter-lot variability (variability between different production lots).

The variability data are expressed in terms of average value, standard deviation, variance and coefficient of variation based on threshold cycle (C_t) values. At least six replicates per sample were analysed for intra-assay variability, inter-assay and inter-lot variability. Total variance was calculated by combining the three analyses.

Table 5: Precision data for the hMPV specific system of the RealStar® hMPV RT-PCR Kit 1.0

Precision		Average C_t-values	Standard Deviation	Variance	Coefficient of Variation (%)
Intra-Assay Variability	hMPV A specific System	29.58	0.07	0.01	0.24
	hMPV B specific System	30.50	0.09	0.01	0.28
Inter-Assay Variability	hMPV A specific System	29.55	0.11	0.01	0.38
	hMPV B specific System	30.49	0.15	0.02	0.49
Inter-Lot Variability	hMPV A specific System	29.69	0.12	0.01	0.41
	hMPV B specific System	30.68	0.22	0.05	0.72
Total Variance	hMPV A specific System	29.62	0.14	0.02	0.46
	hMPV B specific System	30.59	0.21	0.04	0.68

Table 6: Precision data for the Internal Control of the RealStar® hMPV RT-PCR Kit 1.0 (C_t-values)

Precision		Average C_t-values	Standard Deviation	Variance	Coefficient of Variation (%)
Intra-Assay Variability	Internal Control	28.14	0.16	0.03	0.58
Inter-Assay Variability	Internal Control	28.09	0.24	0.06	0.84
Inter-Lot Variability	Internal Control	28.27	0.23	0.05	0.81
Total Variance	Internal Control	28.18	0.24	0.06	0.86

11.5 Repeatability

To ensure repeatability of the RealStar® hMPV RT-PCR Kit 1.0 specificity and sensitivity are evaluated by analysing established proficiency panels for hMPV as well as characterized diagnostic samples on a regular base.

12. Limitations and Precautions

- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time PCR and in *in vitro* diagnostic procedures.
- Good laboratory practice is essential for proper performance of this assay. Extreme care should be taken to preserve the purity of the components of the kit and reaction setups. All reagents should be closely monitored for impurity and contamination. Any suspicious reagents should be discarded.
- Appropriate specimen collection, transport, storage and processing procedures are required for the optimal performance of this test.
- This assay must not be used on the specimen directly. Appropriate nucleic acid extraction methods have to be conducted prior to using this assay.
- The presence of RT-PCR inhibitors may cause false negative or invalid results.
- Potential mutations within the target regions of the virus genome covered by the primer and/or probes of the test may result in failure to detect the presence of the pathogens.
- Depending on the hMPV isolates and the real-time PCR instrument used for the analysis, slight cross reactivity might occur between the hMPV A and hMPV B system.
- As with any diagnostic test, results of the RealStar® hMPV RT-PCR Kit 1.0 should be interpreted in consideration of all clinical and laboratory findings.

13. Quality Control

In accordance with the altona Diagnostics GmbH ISO EN 13485-certified Quality Management System, each lot of RealStar® hMPV RT-PCR Kit 1.0 is tested against predetermined specifications to ensure consistent product quality.

14. Technical Assistance

For customer support, please contact our Technical Support:

e-mail: **support@altona-diagnostics.com**
phone: **+49-(0)40-5480676-0**

15. Trademarks and Disclaimers

RealStar®, ExtraStar® (altona Diagnostics GmbH); Mx 3005P™ (Stratagene); ABI Prism® (Applied Biosystems); HighPure®, LightCycler® (Roche); Rotor-Gene™, QIAamp® (QIAGEN); VERSANT™ (Siemens); KingFisher® (Thermo Scientific).

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The RealStar® hMPV RT-PCR Kit 1.0 is a CE-marked diagnostic kit according to the European *in vitro* diagnostic directive 98/79/EC.

Not available in all countries.

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16. Explanation of Symbols

IVD	*In vitro* diagnostic medical device
REF	Product number
LOT	Batch code
	Contains sufficient for “n” tests/reactions (rxns)
	Temperature limitation
	Version
	Use until
	Caution
	Consult instructions for use
	Manufacturer

NOTES