Instructions for Use

LyteStar™
MERS-CoV RT-PCR Kit 1.0

LyteStar™
MERS-CoV RT-PCR Kit 1.0

For detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) from human specimens

For use with

CFX Opus 96 (BioRad)
CFX96™ (BioRad)
Rotor-Gene Q5/6 plex Platform (Qiagen)
Magnetic Induction Cycler (Mic; Bio Molecular Systems)

IVD For *in vitro* diagnostic use

REF Product No.: 889103

96 reactions

Please refer to Storage and Shelf Life in this IFU

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Content

1. Intended Use

The LyteStar™ MERS-CoV RT-PCR Kit 1.0 is intended for the specific detection of MERS-CoV RNA in human respiratory specimens (bronchoalveolar lavage, trachael aspirate, sputum, nasopharyngael and oropharyngeal swabs placed in VTM, and nasopharyngeal wash/aspirate). The LyteStar™ MERS-CoV RT-PCR Kit 1.0 is a dual target assay comprising a screening assay targeting the up*E* gene and a confirmatory assay targeting the *Orf1a* gene.

The LyteStar™ MERS-CoV RT-PCR Kit 1.0 is for professional use only.

2. Kit Components

Catalog no.	889103
Master A	2 x 312 µl
Master B	4 x 324 µl
Internal Control (IC)	800 µl
Positive Control (PC)	200 µl
PCR grade water	500 µl

3. Storage and Shelf Life

- The LyteStar™ MERS-CoV RT-PCR Kit 1.0 has a shelf life of 12 months from the manufacturing date.
- Store all reagents at -15°C to -25°C upon arrival.
- Repeated thawing and freezing should be avoided, as this might affect the performance of the assay. Master B should be frozen in aliquots, if they are to be used intermittently.
- Mix Master A thoroughly by vortex mixing, and centrifuge briefly before use.
- Protect Master B from light.
- All frozen reagents should be completely thawed to room temperature before use. Immediately return unused portions to the freezer for storage.

4. Quality Control

In compliance with AstronDX Technologies' EN ISO 13485 certified Quality Management System, each lot of the LyteStar™ MERS-CoV RT-PCR Kit 1.0 is tested against pre-determined specifications to ensure consistent product quality.

5. Product Use Limitations and Precautions

- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time PCR 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.

- Wash hands thoroughly after handling specimens and test reagents.
- Do not use kits from different lots together.
- Do not use an expired kit.
- In case of damage to the packaging and leaking vials, do not use the kit (possible contamination or deterioration that can cause false interpretation).

6. Product Warranty

AstronDX Technologies guarantees the performance of the LyteStar™ MERS-CoV RT-PCR Kit 1.0 for applications as described in the manual. The user must determine the suitability of the product for the particular intended use. Should the product fail to perform satisfactorily in the described applications, please contact AstronDX Technologies Technical Support (**16. Technical Support**) for troubleshooting.

AstronDX Technologies reserves the right to change, alter, or modify any product to enhance its performance and design.

7. Product Safety Information

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles/face masks. For more information, please consult the appropriate material safety data sheets (MSDSs).

8. Introduction

Middle East Respiratory Syndrome (MERS) is a viral respiratory disease elicited by MERS Coronavirus (MERS-CoV) infection. MERS-CoV is currently one of the most lethal β-coronaviruses for human, alongside with SARS-CoV and SARS-CoV-2. It first emerged in Saudi Arabia in year 2012 and was found to have a zoonotic origin from dromedary camels [1]. MERS-CoV has expanded to 27 countries since then, and the largest outbreak recorded outside of Saudi Arabia has been found in Republic of Korea (in year 2015), which caused 38 deaths out of 186 laboratory-confirmed cases.

The epidemic peaked in the year 2014/2015 and was gradually flattened out in the years after. Nevertheless, intermittent sporadic cases were found in Saudi Arabia which related to camel exposure, health-care associated infection and also community transmission. According to a recent update from WHO, at the end of February 2022, there were altogether 2,585 laboratory-confirmed MERS cases recorded worldwide and 84.5% was identified from Saudi Arabia. The global case fatality rate (CFR) reported for MERS infection was 34.4% [2].

MERS-CoV infections range from asymptomatic to mild and severe respiratory diseases and death. Majority of MERS cases showed symptoms such as fever, cough and shortness of breath; some accompanied by diarrhea. In mild to severe cases, pneumonia and severe respiratory failure can occur and lead to death. No vaccine or treatment is currently available for MERS-CoV infection. Since MERS shares common and highly similar clinical features to flu and also COVID-19, specific laboratory screening/diagnosis is much needed to identify the infection as early as possible.

Various real-time RT-PCR assays have been published to detect MERS-CoV. The LyteStar™ MERS-CoV RT-PCR Kit 1.0 was developed based on two assays previously described [3, 4]. One assay targets the up*E* gene (Screening assay), and the second assay targets the *Orf1a* gene (Confirmatory assay).

[1] Ebrahim, SH., Maher, AD., Kanagasabai, U., Alfaraj, SH., Alzahrani, NA., Alqahtani, SA., Assiri, AM. & Memish, ZA. (2021) MERS-CoV Confirmation among 6,873 Suspected Persons and Relevant Epidemiologic and Clinical Features, Saudi Arabia − 2014 to 2019. EClinicalMedicine. 41: 101191.

[2] WHO. (2022) MERS Situation Update, February 2022. http://www.emro.who.int/health-topics/mers-cov/mers-outbreaks.html

[3] Corman, VM., Eckerle, I., Bleicker, T., Zaki, A., Landt, O., Eschbach-Bludau, M., van Boheemen, S., Gopal, R., Ballhause, M., Bestebroer, TM., Muth, D., Müller, MA., Drexler, JF., Zambon, M., Osterhaus, AD., Fouchier, RM. & Drosten, C. (2012a) Detection of A Novel Human Coronavirus by Real-Time Reverse-Transcription Polymerase Chain Reaction. Eurosurveillance. 17(39):20285.

[4] Corman, VM., Müller, MA., Costabel, U., Timm, J., Binger, T., Meyer, B., Kreher, P., Lattwein, E., Eschbach-Bludau, M., Nitsche, A., Bleicker, T., Landt, O., Schweiger, B., Drexler, JF., Osterhaus, AD., Haagmans, BL., Dittmer, U., Bonin, F., Wolff, T. & Drosten, C. (2012b) Assays for Laboratory Confirmation of Novel Human Coronavirus (hCoV-EMC) Infections. Eurosurveillance. 17(49):20334.

9. Product Description

The LyteStar™ MERS-CoV RT-PCR Kit 1.0 is an *in vitro* diagnostic test system, based on real-time PCR technology, for the qualitative detection of Middle East Respiratory Syndrome (MERS-CoV) specific RNA.

The LyteStar™ MERS-CoV RT-PCR Kit 1.0 consists of two assays, one targeting the upstream region of *E* gene (up*E*) and the other targeting open reading frame 1a gene (*Orf1a*) of the MERS-CoV genome. The LyteStar™ MERS-CoV RT-PCR Kit 1.0 includes a heterologous amplification system (Internal Control) to identify possible RT-PCR inhibition and to confirm the integrity of the reagents in the kit. The Internal Control used in the LyteStar™ MERS-CoV RT-PCR Kit 1.0 is an *in vitro* transcribed RNA of an artificial sequence with no homology to any known genomes.

Real-time RT-PCR technology utilizes reverse transcriptase (RT) reaction to convert RNA into complementary DNA (cDNA), and 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 dyes.

In the assays, probes specific for up*E* gene of MERS-CoV RNA are labeled with the fluorophore FAM™, and probes specific for *Orf1a* gene of MERS-CoV RNA are labeled with fluorophore Cy5. The up*E* gene probe detects upstream region of MERS-CoV *E* gene, while the *Orf1a* gene probe is targeting the open reading frame 1a of MERS-CoV. Both probes are specific to MERS-CoV only. The probe specific for the target of the Internal Control (IC) is labelled with the fluorophore HEX™. Using probes linked to distinguishable dyes enables the parallel detection of MERS-CoV specific RNA and the Internal Control in the corresponding detector channels of the real-time PCR instrument.

The oligonucleotides included in the two assays were adapted and modified from Corman *et al*., 2012a [3], and Corman *et al*., 2012b [4].

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

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

The LyteStar™ MERS-CoV RT-PCR Kit 1.0 consists of:

- Two Master reagents (Master A and Master B)
- The template of the Internal Control (IC)
- The template of the Positive Control (PC)
- PCR grade water (for setting up of “No Template Control”, NTC)

Master A and Master B reagents contain all components (buffer, enzymes, primers and probes) to allow PCR mediated reverse transcription, amplification and target detection of up*E* gene and *Orf1a* gene specific for MERS-CoV, and also the Internal Control in one single reaction setup.

The Positive Control (PC) contains *in vitro* transcripts of synthesized target genes of MERS-CoV.

The LyteStar™ MERS-CoV RT-PCR Kit 1.0 was developed and validated to be used with the following real-time PCR instruments:

- CFX Opus 96 (BioRad)
- CFX96™ (BioRad)
- Rotor-Gene Q 5/6 plex Platform (Qiagen)
- Magnetic Induction Cycler (Mic; Bio Molecular Systems)

10. Material and Devices required but Not Provided

- Appropriate real-time PCR instrument
- Appropriate nucleic acid extraction system or kit
- 1.5 ml microcentrifuge tubes (with safe-lock or screw cap)
- Microcentrifuge (with speed ≥ 13,000 rpm)
- Pipettes, adjustable (range: 10 µl, 100 µl, 200 µl, 1000 µl)
- Pipette tips (with aerosol barriers)
- Disposable gloves (powder-free)
- Heating block for lysis of specimens during extraction
- Vortex mixer
- Appropriate 96-well reaction plates or reaction tubes with corresponding (optical) closing material

11. Specimen Storage

- Suitable specimens include bronchoalveolar lavage, tracheal aspirate, sputum, nasopharyngeal and oropharyngeal swabs (placed in the same VTM), and nasopharyngeal wash/aspirate.

- Follow specimen transport and storage conditions outlined in the following guidelines:

  - WHO Interim guidance (revised) on Laboratory Testing for Middle East Respiratory Syndrome Coronavirus, January 2018.
  - CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Middle East Respiratory Syndrome Coronavirus (MERS-CoV) – Version 2, August 2019.

12. Instructions for Use

12.1. Sample Preparation

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

The following nucleic acid extraction kits / systems are suitable for use with the LyteStar™ MERS-CoV RT-PCR Kit 1.0:

- SpinStar™ Viral Nucleic Acid Kit (AstronDX Technologies)
- QIAamp® MinElute Virus Spin Kit (Qiagen)
- QIAamp® Viral RNA Mini Kit (Qiagen)
- HighPure® Viral Nucleic Acid Kit (Roche)
- QIAsymphony® (Qiagen)
- NucliSENS® easyMag (bioMérieux)
- MagNA Pure 96 System (Roche)
- MagCore® Plus II Automated Nucleic Acid Extractor (RBC Bioscience)

Alternative nucleic acid extraction systems and kits might also be appropriate. The suitability of the nucleic acid extraction procedure for use with LyteStar™ MERS-CoV RT-PCR Kit 1.0 has to be validated by the user.

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

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.

12.2. Master Mix Setup

1. All reagents and samples should be thawed completely, mixed (by gentle vortex mixing) and centrifuged briefly before use. Prepare a marginal excess (additional 0.5 reaction) of the required Master Mix volume.

2. The LyteStar™ MERS-CoV RT-PCR Kit 1.0 contains a heterologous Internal Control (IC), which can either be used as (i) a PCR inhibition control or as (ii) a control of the sample preparation procedure (nucleic acid extraction) and PCR inhibition control.

   (i) **If the IC is used as a 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	1	12
Master A	6.5 µl	78 µl
Master B	13.5 µl	162 µl
IC	0.5 µl	6 µl
Volume Master Mix	**20.5 µl**	**246 µl**

(ii) If the IC is used as a control for the sample preparation procedure and as a 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 into the specimen/lysis buffer mixture.

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	1	12
Master A	6.5 µl	78 µl
Master B	13.5 µl	162 µl
Volume Master Mix	**20 µl**	**240 µl**

NOTE

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

12.3. Reaction Setup

1. Pipette 20 µl Master Mix into each required well of an appropriate optical 96-well reaction plate or an appropriate optical reaction tube.

2. Add 5 µl of the sample (eluate from the nucleic acid extraction) or 5 µl of the controls (Positive Control; or water as No Template Control, NTC).

3. Make sure at least one Positive Control and one NTC are used per run.

4. Thoroughly mix the samples and controls with the Master Mix by pipetting up and down.

5. Close the 96-well reaction plate with an appropriate optical adhesive film and the reaction tubes with appropriate caps.

6. Centrifuge the 96-well reaction plate at 1,000 xg (~3,000 rpm) for 30s.

Reaction Setup	
Master Mix	20 µl
Sample or Control	5 µl
Total Volume	**25 µl**

13. Programming the Real-Time PCR Instrument

13.1 Settings

• Define the following settings:

Settings	
Reaction Volume	25 µl
Ramp Rate	Default

13.2 Fluorescent Detectors (Dyes)

• Define the following fluorescent detectors:

Detection	Detector Name	Reporter	Quencher
up*E* gene	upE	FAM	BHQ 1
Orf1a gene	Orf1a	Cy5	BHQ 1
Internal Control	IC	HEX	BHQ 1

13.3 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	2:00 min
Amplification	Cycling	45	-	95 °C	5 sec
			√	52 °C	30 sec

√ Signal acquisition: activate FAM, HEX, and Cy5 channels in all runs

14. 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 LyteStar™ MERS-CoV RT-PCR Kit 1.0 on different real-time PCR instruments please contact our Technical Support (**16.Technical Support**).

14.1. Validity of Diagnostic Test Runs

14.1.1 Valid Diagnostic Test Runs (Qualitative)

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

Control ID	FAM/Cy5 Detection Channel	HEX Detection Channel
Positive Control	POSITIVE	POSITIVE
Negative Control	NEGATIVE	POSITIVE

14.1.2 Target CT values of PC and IC

	Positive Control (upE gene)	Positive Control (Orf1a gene)	Internal Control
Target CT value	< 35 cycles	< 35 cycles	≤ 40 cycles*

*Required for unknown samples that do not amplify in FAM and Cy5 channels

Note: The above CT target values are exclusively given for **monitoring the integrity of the product and validated assay conditions** and should be achieved **ONLY for the provided Positive Control (PC) and Internal Control (IC)** when used as per the instructions given under section 12.3. Reaction set up. **The target CT values for PC MUST NOT be misinterpreted as the diagnostic cut-off values for clinical samples.**

14.1.3 Invalid Diagnostic Test Runs (Qualitative)

A **qualitative** 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.

14.2 Interpretation of Results

FAM up*E gene*	**Cy5** *Orf1a gene*	**HEX** *Internal Control*	**Result Interpretation**
+	+	+*	Both MERS-CoV up*E* and *Orf1a* specific RNA detected. *Positive for MERS-CoV*
+	-	+*	MERS-CoV up*E* specific RNA detected. MERS-CoV *Orf1a* specific RNA not detected. *Presumptive positive for MERS-CoV*[A,B]
-	+	+*	MERS-CoV up*E* specific RNA not detected. MERS-CoV *Orf1a* specific RNA detected. *Presumptive positive for MERS-CoV*[A,B]
-	-	+	Both MERS-CoV up*E* and *Orf1a* specific RNA not detected. The sample does not contain detectable amounts of MERS-CoV specific RNA.
-	-	-	PCR inhibition or reagent failure. Repeat testing from original sample or collect and test a new sample.

Note: For up*E* gene (FAM channel) and *Orf1a* gene (Cy5 channel), "+" refers to amplification curve detected at CT ≤ 45 cycles. "-" refers to no amplification / no CT obtained.

* Detection of the Internal Control in the HEX channel is not required for positive results in the FAM/Cy5 detection channels. A high MERS-CoV load in the sample can lead to reduced or absent Internal Control signals.

[A] Detection of either up*E* gene or *Orf1a* gene alone might be due to low viral RNA concentration close to the limit of detection of the respective genes, OR due to mutation of one of the target sequences.

[B] Sample should be repeated from extraction. If the repeat result remains either up*E* gene or *Orf1a* gene positive only, then additional confirmatory assay may be needed.

14.2.1 Threshold Settings for Cycler Software

Cycler	Threshold		
	upE (FAM channel)	*Orf1a* (Cy5 channel)	IC (HEX channel)
Rotor-Gene	0.05 norm. fluoro	0.05 norm. fluoro	0.05 norm. fluoro
CFX96™	100 RFU	100 RFU	100 RFU
CFX Opus 96	100 RFU	100 RFU	100 RFU
Mic qPCR	Auto	Auto	Auto

14.2.2 CT Cut-Off Values for Clinical Samples

	upE (FAM channel)	*Orf1a* (Cy5 channel)
CT Cut-Off Value	< 45 cycles	< 45 cycles

15. Performance Evaluation

The analytical performance evaluation of the LyteStar™ MERS-CoV RT-PCR Kit 1.0 was accomplished using quantified MERS-CoV specific RNA.

15.1 Analytical Sensitivity

The analytical sensitivity (limit of detection:LoD) of the LyteStar™ MERS-CoV RT-PCR Kit 1.0 is defined as the concentration of MERS-CoV RNA molecules that can be detected with a positivity rate of ≥ 95%. The analytical sensitivity was determined by analyzing MERS-CoV genomic RNA of known concentration.

A dilution series of the Amplirun® MERS Coronavirus RNA Control was prepared by using 1× TE buffer as diluent. Dilutions of MERS-CoV RNA were tested with LyteStar™ MERS-CoV RT-PCR Kit 1.0. Results were analyzed by Probit analysis (Table 1 and Table 2).

The analytical sensitivity of the LyteStar™ MERS-CoV RT-PCR Kit 1.0 in combination with the CFX Opus 96 (Biorad) platform was determined at 1.45 copies/µl for up*E* gene target and 1.49 copies/µl for *Orf1a* gene target (p≤ 0.05).

Table 1. PCR results used for the calculation of the analytical sensitivity of up*E* gene target for the LyteStar™ MERS-CoV RT-PCR Kit 1.0 in combination with the CFX Opus 96 (Biorad) platform.

Concentration (copies/µl)	No. of Samples Tested	No. of Samples Positive	Hit rate (%)
10	12	12	100
3.16	12	12	100
1	12	10	83.3
0.316	12	2	16.7
0.1	12	0	0
0.0316	12	0	0
0.01	12	0	0
0.00316	12	0	0
0.001	12	0	0
0.000316	12	0	0

Table 2. PCR results used for the calculation of the analytical sensitivity of *Orf1a* gene target for the LyteStar™ MERS-CoV RT-PCR Kit 1.0 in combination with the CFX Opus 96 (BioRad) platform.

Concentration (copies/µl)	No. of Samples Tested	No. of Samples Positive	Hit rate (%)
10	12	12	100
3.16	12	12	100
1	12	11	91.7
0.316	12	5	41.7
0.1	12	3	25
0.0316	12	0	0
0.01	12	0	0
0.00316	12	0	0
0.001	12	0	0
0.000316	12	0	0

15.2 Analytical Specificity

The analytical specificity of the LyteStar™ MERS-CoV RT-PCR Kit 1.0 is ensured by the thorough selection of the oligonucleotides (primers and probes). The oligonucleotides were checked by sequence comparison analysis against publicly available sequences to ensure that the applied primer/probes in LyteStar™ MERS-CoV RT-PCR Kit 1.0 specifically detect MERS-CoV.

The specificity of the LyteStar™ MERS-CoV RT-PCR Kit 1.0 was evaluated by testing genomic RNA/DNA extracted from other pathogens likely to be present in the same sample material as MERS-CoV virus, or that cause similar symptoms to the MERS-CoV virus (Table 3).

Table 3. Microorganisms tested to demonstrate the analytical specificity of the LyteStar™ MERS-CoV RT-PCR 1.0 Kit.

LyteStar™ MERS-CoV RT-PCR 1.0			
Organisms	**up*E* gene (FAM channel)**	***Orf1a* gene (Cy5 channel)**	**Internal Control (HEX channel)**
Human metapneumovirus	negative	negative	valid
Human respiratory syncytial virus	negative	negative	valid
Human coronavirus OC43	negative	negative	valid
Human coronavirus HKU1	negative	negative	valid
Human coronavirus 229E	negative	negative	valid
Human coronavirus Strain NL63	negative	negative	valid
Influenza A virus (H1N1)	negative	negative	valid
Influenza A virus (H3N2)	negative	negative	valid
Influenza B virus	negative	negative	valid
Human parainfluenza virus 2	negative	negative	valid
Human parainfluenza virus 3	negative	negative	valid
Human enterovirus 71	negative	negative	valid
Human rhinovirus 16	negative	negative	valid
Human coronavirus SARS-CoV-2	negative	negative	valid

The LyteStar™ MERS-CoV RT-PCR 1.0 did not cross-react with any of the specified organisms.

16. Technical Support

For customer support, please contact our Technical Support:

e-mail: **techsupport@astrondx.com**
phone: **+603 7931 6760**

17. Appendix

Explanation of Symbols

Symbol	Explanation
IVD	*In vitro* diagnostic medical device
REF	Product Number
LOT	Batch Code
	Manufacturer
	Date of Manufacture
	Contains sufficient for "n" tests/rxns
	Temperature limitation
	Version
	Use-By Date

18. Ordering Information

Products	Packing (reactions)	Order No.
LyteStar™ MERS-CoV RT-PCR Kit 1.0	96	889103
SpinStar™ Viral Nucleic Acid Extraction Kit 1.0	100	811803
MagCore® Viral Nucleic Acid Extraction Kit, High Sensitivity (200µl/400µl), CART CODE 203	96	MVN400-06

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