magtivio

Instructions For Use

MagSi-DX Pathogen

CE

REF
MDDX00010096
MDDX00010960
MDDX0001005K
MDDX0001025K

Σ
96 Preps
960 Preps
5000 Preps
25000 Preps

IVD
For *in-vitro* diagnostic use

Rev. 2.3
11/01/2023

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Revision history		
Revision	**Release date**	**Remarks**
1	29/09/2021	Initial release
2	23-11-2021	Minor text corrections, table in section 2.2 corrected, layout chapter 5 adjusted
2.1	04-01-2022	CE-mark added
2.2	19-05-2022	Correction in sections 2.6.1 and 6, update section 9
2.3	21-12-2022	New company style

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Table of Contents

1 Components

1.1 Kit contents

	MagSi-DX Pathogen			
Component Name	Pack size: 96 preps Art.No.: MDDX00010096	Pack size: 960 preps Art.No.: MDDX00010960	Pack size: 5000 preps Art.No.: MDDX0001005K	Pack size: 25000 preps Art.No.: MDDX0001025K
Lysis Buffer PA1	20 mL	200 mL	1000 mL	5000 mL
Binding Buffer U1	40 mL	400 mL	2 x 1000 mL	2 x 5000 mL
Wash Buffer I	2 x 80 mL	2 x 800 mL	8 x 1000 mL	8 x 5000 mL
Wash Buffer II	80 mL	800 mL	4 x 1000 mL	4 x 5000 mL
Elution Buffer	20 mL	200 mL	1000 mL	5000 mL
Proteinase K	20 mg (for 1.1 mL working solution)	200 mg (for 11 mL working solution)	1x 1000 mg (for 55 mL working solution)	5 x 1000 mg (for 5 x 55 mL working solution)
Poly-A-RNA	0.3 mg (for 120 µL working solution)	3 mg (for 1.2 mL working solution)	15 mg (for 6 mL working solution)	3 x 25 mg (for 3 x 10 mL working solution)
Poly-A-RNA Buffer	0.5 mL	5 mL	20 mL	3 x 20 mL
MagSi-PA VII	2 mL	20 mL	100 mL	5 x 100 mL

1.2 Reagents, consumables and equipment to be supplied by user

The required equipment may vary depending on method of processing and instrument setup or configuration. Please refer to the automated system manufacturer regarding platform-specific consumables. Additionally, refer to section 2.7for further details regarding the automation of MagSi-DX Pathogen.

Product	REF	Quantity
MM-Separator 96 Deepwell	MDMG0013	1 Unit

Reagents:

- Molecular biology grade water

Consumables:

- 96 well microplates with U-bottom and square wells (2 mL) for sample processing (Suggested: Riplate®SW 96, PP, 2 mL, Ritter, 43001–0020)
- 96 well microplates with U-bottom (300 µL) for transfer of the processed sample (Suggested: Nunc 96-Well Microplates, Round, Nonsterile, Thermo Scientific, 267245)
- Pipette tips (aerosol barrier and nuclease-free are recommended)

Equipment:

- Micropipettes, single and 8 or 12 channel (10-100 µL and 100-1000 µL)
- Microplate shaker (suggested: ThermoMixer C, Eppendorf)

1.3 About these Instructions For Use

It is recommended to thoroughly read these instruction for use before using the product.

2 Product description

2.1 Intended Purpose

MagSi-DX Pathogen is intended to be used for the isolation and purification of viral RNA for subsequent in-vitro diagnostic purposes. The kit can be used with human respiratory swabs and saliva. The kit is designed to be used with any downstream application with amplification and detection of viral RNA (in particular RT-qPCR, sequencing). The kit has been specifically validated for SARS-CoV-2 diagnostic workflows.

MagSi-DX Pathogen does not provide a diagnostic result. It is the sole responsibility of the user to use and validate the kit in conjunction with a downstream in vitro diagnostic assay depending on the target pathogen and to use suitable controls for downstream applications (e.g., internal controls, extraction controls, positive / negative controls). Any diagnostic results generated using nucleic acids isolated with MagSi-DX Pathogen in conjunction with an in-vitro diagnostic assay should be interpreted with regard to additional clinical or laboratory findings.

MagSi-DX Pathogen is intended for use by professional users such as technicians and physicians experienced and trained in molecular biological techniques including experience with swabs and other potentially infectious, human sample materials.

MagSi-DX Pathogen is not suitable for self-testing or near-patient testing.

2.2 Product specifications

Parameter	MagSi-DX Pathogen
Technology	Magnetic beads and choatropic nucleic acid binding chemistry
Sample material	Respiratory swabs and saliva
Sample volume	200 µL
Elution volume	50 - 100 µL
Processing time	~35 min per 96 samples (depending on method of use)
Processing method	Manual or automated

2.3 Limitations of use

MagSi-DX Pathogen is suitable for use with human respiratory swabs and saliva. MagSi-DX Pathogen has not been validated for other sample materials. Product performance has been tested in SARS-CoV-2 diagnostic workflows. Performance characteristics for every RNA-virus species in the respective clinical samples or sample stabilization reagent have not been established and must be validated by the user. Additionally, extraction of viral RNA using MagSi-DX Pathogen on different automated systems must be validated by the user. Strict compliance with the instructions for use is required for nucleic acid purification. Following good laboratory practices is crucial for the successful usage of the product. Appropriate handling of the reagents is essential to avoid contaminations or impurities.

2.4 Principle of operation

The procedure is based on the reversible adsorption of nucleic acids to magnetic beads under appropriate buffer conditions. Sample lysis is achieved by incubation with Lysis Buffer PA1 containing chaotropic ions supported by Proteinase K digestion. For binding of nucleic acids to the magnetic beads, Binding Buffer U1 and MagSi-PA VII beads are added to the lysate. After magnetic separation, the magnetic beads are washed to remove contaminants and salts using Wash Buffers I and II. Residual ethanol from previous wash steps is removed by air-drying. Finally, highly pure viral RNA is eluted with low salt Elution Buffer or water. Purified viral RNA can directly be used for downstream applications. MagSi-DX Pathogen can be used either manually or automated on standard liquid handling instruments or automated magnetic separators.

2.5 Quality Control

In accordance with the manufacturer's Quality Management System, each lot of kits and its components are tested against predetermined specifications to ensure consistent quality.

2.6 Sample collection, handling and storage

MagSi-DX Pathogen is suitable for fresh non-treated human respiratory swabs and fresh or frozen saliva in sample collection buffers. It is strongly recommended to use sample collection devices that are validated for complete inactivation of viruses. Please refer to applicable guidelines and manufacturer instructions for collection, handling and storage of clinical samples and other pre-analytical requirements. Samples should be thoroughly mixed before use.

2.6.1 Swab samples

Remove the swab from the collection buffer and transfer 200 µL of the solution into a microplate for RNA extraction. If needed, press the swab against the wall of the tube to squeeze out the liquid.

2.6.2 Saliva

Saliva should be collected in devices suitable for saliva sample collection and preservation. Mix by inverting the sample and transfer 200 µL of the solution into a microplate for RNA extraction.

2.7 Use on automated systems

MagSi-DX Pathogen can be used on many different automated liquid handling systems or magnetic particle processing systems. However, the performance of MagSi-DX Pathogen in combination of any specific automated system must be validated by the user in conjunction with an in-vitro diagnostic assay and in combination with suitable controls for the downstream application.

2.7.1 Handling of magnetic beads

A homogeneous suspension of magnetic beads is required to ensure a correct amount of magnetic beads per sample and a consistent extraction quality. Before use, shake the bottle of beads well. In automated extraction procedures, a mixing step before aspirating the beads must be integrated.

2.7.2 Liquid handling systems

MagSi-DX Pathogen can be used on liquid handling workstations in combination with the MM-Separator 96 DeepWell and square-well U-bottom 96 deepwell plates, using a suitable shaking device for resuspending and mixing magnetic beads and a microplate gripper tool to transport the sample plate to and away from the magnetic separator.

2.7.3 Shaker settings

The speed settings for the microplate shaker described in the protocols that follow were defined with a specific instrument and microplate. When first using a plate shaker for incubation steps, the speed settings have to be set carefully for each specific plate to prevent cross contamination and spillage. Setting the speed of the shaker can be done by loading a microplate with a volume of dyed water equal to the working volume during each step, and step-wise increasing the shaker speed until droplets are observed on the surface of the plate. Set the shaker speed lower again.

2.7.4 Magnetic particle processing systems

MagSi-DX Pathogen can be used on magnetic particle processing systems, such as the PurePrep 96 Nucleic Acid Purification System, using the consumables intended for the specific system. The magnetic beads are resuspended and mixed by moving a magnetic rod cover (tip-comb) up and down, and collected by magnetic rods covered by the tip-comb. The kit components are pre-dispensed into the consumables before starting the system, and removed from the system afterwards. It is important not to exceed the maximum working volumes of the consumables.

2.8 Elution conditions

Target RNA can be directly eluted with Elution Buffer between 50 and 100 µL. The magnetic beads must be completely submerged and resuspended in Elution Buffer. Elution may be performed at 60°C to slightly increase RNA recovery.

Eluted RNA can be stored short term (<24 hours) at 2-8°C, for long term storage (>24 hours) store at -20°C.

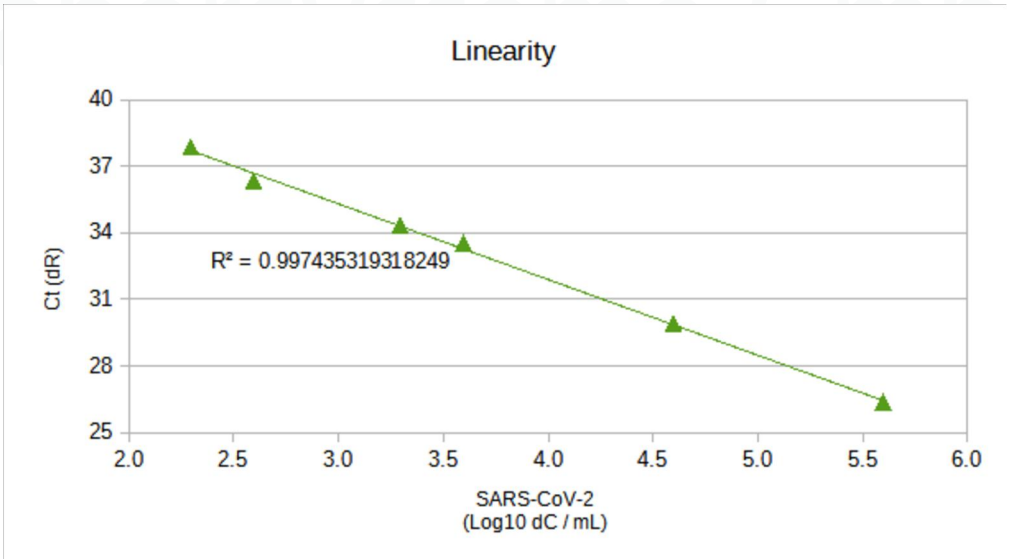
2.9 Performance characteristics

2.9.1 Analytical performance characteristics

The repeatability was tested using a positive patient sample and a commercial heat-inactivated SARS-CoV-2 viral sample spiked into in pooled negative sample, taken from 15 healthy donors.

The LOD and the linearity of the extraction procedure combined with RT-qPCR analysis was determined using a commercially available heat-inactivated whole virus SARS-CoV-2 Analytical Q Panel (Qnostics) consisting of 8 positive samples with different concentrations and 1 negative. Each sample was diluted in InActive Blue Saliva Collection Buffer, in accordance with manufacturer's instructions for the Saliva Collection Kit in which the buffer is used. RNA was extracted from each diluted sample, followed by RT-qPCR using the Kylt® SARS-CoV-2 Complete 2.0 Real-Time PCR kit for SARS-CoV-2 (COVID-19).

Parameter	Positive patient sample	Heat-inactivated commercial sample
Intra-assay CV	2.0%	1.4%
Inter-assay CV	Not tested	3.2%
LOD	-	2.3 Log10 dC / mL
Linearity	-	R2 = 0.997



2.9.2 Diagnostic performance characteristics

MagSi-DX Pathogen has been validated in SARS-CoV-2 diagnostic workflows. Clinical performance is exemplified using the LEQA panel produced and quantified at the RIVM by dPCR. Workflows including MagSi-DX Pathogen scored a 100% score on the panel, consisting of 10 simulated clinical specimen, containing heat inactivated SARS-CoV-2, including one variant of concern (VOC) B.1.1.7; 20B/501Y.V1, or other respiratory viruses or genetic material [1].

3 Storage and shelf life after first opening

All kit components, including Proteinase K (lyophilized), Poly-A-RNA (lyophilized) and MagSi-PA VII, can be stored at 18-25°C. When stored under the conditions mentioned, the kit is stable as reported on the expiry date on the label.

Store ready solutions of Proteinase K in aliquots at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for 3 months.

Store ready solutions of Poly-A-RNA at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for 3 months.

MagSi-PA VII beads can be premixed with Binding Buffer U1 for simultaneous addition to samples. However, the mixture must be prepared fresh on each day of use, and mixed well by vortexing before transfer to samples.

Attention:

- Check all components included in the package for damages. If there are any damages or leakages, contact magtivio technical support and customer service.
- Do not use damaged components.
- Use RNase-free equipment
- All buffers are ready to use.
- Do not freeze the product.

4 Warnings and precautions

The following components of MagSi-DX Pathogen contain hazardous ingredients.

Wear suitable protection clothing, gloves and goggles and follow the safety instructions given in this section.

GHS classification

Only harmful features do not need to be labelled with H and P phrases until 125 mL or 125 g.

Component	Hazardous ingredients	GHS Symbol	Hazard phrases	Precaution phrases
Lysis Buffer PA1	Guanidine Hydrochloride (20-25%) CAS 50-01-1	 WARNING	H302 H319 H315	P264, P280, P302+P352 P305+P351+P338 P337+P313, P501
Binding Buffer U1	Sodium Perchlorate (50-55%) 2-Propanol (20-25%) CAS 67-63-0, 7791-07-3	 DANGER	H225 H319 H336 H373	P210, P233, P260, P280, P403+P235, P501
Wash Buffer I	Sodium Perchlorate (35-40%) 2-Propanol (50-55%) CAS 67-63-0, 7791-07-3	 DANGER	H225 H302 H319 H336 H373	P210, P233, P260, P280, P403+P235, P501
Wash Buffer II	Ethanol (70-75%) CAS 64-17-5	 DANGER	H225 H319	P210, P233, P305+P351+P338 P403+P235, P501
Proteinase K	Proteinase K (100%) CAS 39450-01-6	 DANGER	H315 H319 H334 H335	P261, P280 P284, P304+P340 P342+P311, P501
Poly-A-RNA Buffer	Guanidine Thiocyanate (30-35%) CAS 593-84-0	 DANGER	H302+H332 H314 H412	P260, P264 P280, P303+P361+P353, P305+P351+P338, P310

Hazard Phrases:

H225	Highly flammable liquid and vapour.
H302+332	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs through prolonged or repeated exposure.

Precaution Phrases:

P210 sources. No	Keep away from heat, hot surfaces, sparks, open flames and other ignition smoking.
P233	Keep container tightly closed.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P284	Wear respiratory protection.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 lenses,	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P337+P313	If eye irritation persists: Get medical advice/attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P403+P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of waste according to applicable legislation.

The symbol shown on the labels refers to further safety information in this section.

When working with MagSi-DX Pathogen wear suitable protective clothing (e.g. lab coat, disposable gloves, and protective goggles). For more information consult the appropriate Safety Data Sheets (available through support@magtivio.com).

CAUTION:

Lysis Buffer PA1, Binding Buffer U1, Wash Buffer I and Poly-A-RNA Buffer contain chaotropic salt (e.g. guanidine hydrochloride and/or sodium perchlorate) which can form highly reactive compounds when combined with bleach (sodium hypochlorite)! DO NOT bring bleach directly into contact with materials exposed to the buffers mentioned. Wear suitable protective clothing, gloves and safety goggles!

The waste generated with MagSi-DX Pathogen has not been tested for residual infectious material. A contamination of the liquid waste with residual infectious material is highly unlikely due to strong denaturing lysis buffer and Proteinase K treatment but it cannot be excluded completely. Therefore, liquid waste must be considered infectious and should be handled and discarded according local safety regulations.

Disposal

Dispose hazardous, infectious or biologically contaminated materials in a safe and acceptable manner and in accordance with all local and regulatory requirements.

5 Reagent preparation

5.1 Reconstitution of Proteinase K

- MDDX00010096 (96 preps), add 1.1 mL of molecular biology grade water to the vial of Proteinase K and vortex to dissolve. Store solutions of Proteinase K in aliquots at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for at least 3 months.
- MDDX00010960 (10x96 preps), add 11 mL of molecular biology grade water to the vial of Proteinase K and vortex to dissolve. For aliquotation per 96 samples, make aliquots of 1.05 mL and store solutions at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for at least 3 months.
- MDDX0001005K (5000 preps) and MDDX0001025K (25000 preps), add 55 mL of molecular biology grade water to each vial of Proteinase K and vortex to dissolve. For aliquotation per 96 samples, make aliquots of 1.05 mL and store solutions at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for at least 3 months.

5.2 Reconstitution of Poly-A-RNA

- MDDX00010096 (96 preps), add 120 µL of Poly-A-RNA Buffer to the vial of Poly-A-RNA (0.3 mg) and vortex to dissolve. Store solutions of Poly-A-RNA at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for at least 3 months.
- MDDX00010960 (10x96 preps), add 1.2 mL of Poly-A-RNA Buffer to the vial of Poly-A-RNA (3 mg) and vortex to dissolve. For aliquotation per 96 samples, make aliquots of 110 µL and store solutions at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for at least 3 months.
- MDDX0001005K (5000 preps), add 6 mL of Poly-A-RNA Buffer to the vial of Poly-A-RNA (15 mg) and vortex to dissolve. For aliquotation per 96 samples, make aliquots of 110 µL and store solutions at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for at least 3 months.
- MDDX0001025K (25000 preps), add 10 mL of Poly-A-RNA Buffer to each vial of Poly-A-RNA (25 mg) and vortex to dissolve. For aliquotation per 96 samples, make aliquots of 110 µL and store solutions at -20°C. Avoid repeated freezing and thawing. When stored accordingly, solutions are stable for at least 3 months.

If there is any precipitate present in the buffers, warm the buffer to 25-37°C to dissolve the precipitate before use.

5.3 Preparation of the Lysis Master Mix

For each sample, prepare Lysis Master Mix:

Lysis Buffer PA1	200 µL
Poly-A-RNA solution	1 µL
Proteinase K solution	10 µL
Total	211 µL

Prepare an excess of the Lysis Master Mix to compensate for pipetting inaccuracy especially when using multichannel pipettes etc. Use the Lysis Master Mix immediately after preparation.

5.4 Preparation of the Binding Buffer / Beads premix (optional)

MagSi-PA VII beads can be premixed with Binding Buffer U1 for simultaneous addition to samples. For each sample, prepare Binding Buffer / Beads premix:

Binding Buffer U1	400 µL
MagSi-PA VII	20 µL
Total	420 µL

The mixture must used on the day of preparation, and mixed well by vortexing before transfer to samples.

6 Protocol for the extraction of viral RNA

Before starting:

- Prepare Lysis Master Mix according to section 5.3.
- Pre-treat samples (if required) according to section 2.6
- Vortex magnetic beads thoroughly into a homogeneous suspension.

This protocol is intended for manual use of the kit. It can also be used as a guideline to set up an automated procedure on liquid handling instruments. For this suitable 96-well plates and accessories can be used. Make sure that the liquid handling system is equipped with the required devices (shaker, incubator, magnetic separator etc.).

1. Transfer 200 µL sample into a microplate for processing.
2. Add 211 µL Lysis Master Mix to each sample. Incubate on a shaker for 10 min with shaking at 1000 RPM.
3. Add 20 µL MagSi-PA VII beads and 400 µL Binding Buffer U1. Incubate on a shaker for 5 min with shaking at 1000 RPM.
4. Place the processing microplate on the magnetic separator and wait at least 1 minute to collect the beads. Remove supernatants without disturbing the attracted magnetic bead pellet.
5. Remove the sample plate from the magnetic separator and add 800 µL Wash Buffer I to the tubes. Resuspend the beads by incubation of the samples on a shaker for 1 min at 1000 RPM. Place the samples in a magnetic separator and wait at least 1 minute to collect the beads. Remove the supernatants without disturbing the attracted bead pellet.
6. Repeat step 5 one more time with 800 µL Wash Buffer I and one more time with 800 µL Wash Buffer II.
7. Dry the beads on air for 10 min to evaporate the ethanol completely. If necessary, briefly spin down and remove any buffer residues before drying the attracted magnetic beads.
8. Remove the samples from the magnetic separator and add 100 µL Elution Buffer. Incubate on a shaker for 10 min at 1000 RPM.
9. Place the tubes in a magnetic separator and wait at least 1 minute to collect the beads. Transfer the eluates to new tubes. The purified nucleic acids in the eluate are now ready to use for downstream applications.

7 Control procedure

MagSi-DX Pathogen does not include a control procedure. It is the sole responsibility of the user to use suitable controls for downstream applications. It is recommended to use RNA-based internal controls for RT-qPCR assays to eliminate risks of false negative results as a consequence from potential RNase contamination.

8 Interpretation of results

MagSi-DX Pathogen does not provide a diagnostic result. It is the sole responsibility of the user to use and validate the kit in conjunction with a downstream in-vitro diagnostic application depending on the target pathogen.

9 Compatibility

MagSi-DX Pathogen has been validated in conjunction with the following devices:

- Saliva Collection Kit, REF: IB_COL, InActiv Blue
- eNAT®, REF: 608CS01R, Copan Italia
- eSWAB, REF: 480CE, Copan Italia
- ORAcollect, REF: ORE-100, DNA Genotek
- OMNIgene Oral, REF: OME-505, DNA Genotek
- SARS-CoV-2 Complete RTU 2.0 100, REF: 31469, LaBorga Service
- Bio-T kit® SARS-CoV-2 UK & N501Y Variants, BIOTK125, BioSellal
- SARS-CoV-2 RealFast™ Assay, REF 8-410 / 8-412, ViennaLab Diagnostics
- SARS-CoV-2 Q Control 01, REF: SCV2QC01-A, Qnostics
- SARS-CoV-2 Analytical Q Panel 01, REF: SCV2AQP01-A, Qnostics

MagSi-DX Pathogen is compatible with the following instruments for nucleic acid extraction (protocol files and instructions for MagSi-DX Pathogen are available on request):

- PurePrep 96 Nucleic Acid Purification System, REF AS0001, magtivio
- PurePrep 32 Nucleic Acid Purification System, REF AS0002, magtivio
- KingFisher™ Flex Purification System, KingFisher with 96 Deep-well Head, REF 5400630, Thermo Fisher Scientific

10 Appendix

10.1 Troubleshooting

Problem	Possible cause	Comments and suggestions
Low RNA acid yield	RNA degradation	- Use and store the sample collection device according to manufacturer's instructions
	Inefficient binding to the magnetic particles	- Use correct amount of all reagents - Increase mixing steps and incubation time for binding step - Mix sample during lysis / binding incubation
	Insufficient washing procedure	- Make sure that beads are completely resuspended in the washing steps.
	Incomplete elution	- Drying of Wash Buffer II may have been incomplete, increase drying time - Completely resuspend the beads in the elution step
Problems in downstream applications / contamination in sample	Ethanol in the eluted DNA	- Increase the drying time to 15 minutes
	Salt in the eluate	- Use buffers in the correct order - Make sure that all supernatants are properly removed. - Avoid carry-over of Lysis Master Mix, Binding Buffer U1 or Wash Buffers to the eluate.
	High amount of Magnetic beads remaining in the eluate	- Place the tubes with eluates in the magnetic separator again, and transfer the supernatant to a new container.

10.2 Literature references

1. National Institute of Public Health and the Environment (RIVM). External Quality Assessment of laboratories Performing SARS-CoV-2 Diagnostics for the Dutch Population, February 2021. John Sluimer, Garbiel Goderski, Sharon van den Brink, Lisa Wijsman, Chantal Reusken, Marion Koopmans, Richard Molenkamp, Adam Meijer.
2. Fox, J. D. Nucleic Acid amplification tests for detection of respiratory viruses, Elsevier, Journal of Clinical Virology 40 Suppl. 1, S15 – S23 (2007).
3. Wang et al. An Overview of Nucleic Acid Testing for the Novel Coronavirus SARS-CoV-2, Frontiers in Medicine, Volume 7, Article 571709 (2021).
4. Mizoguchi, M. et al. Comparative performance and cycle threshold values of 10 nucleic acid amplification tests for SARS-CoV-2 on clinical samples, PloS ONE 16(6): e0252757 (2021).
5. Wölfel, R. et al. Virological assessment of hospitalized patients with COVID-2019, Nature, Vol. 581, 465-469 (2020).

10.3 Notification requirements

Please note that any serious incident that has occurred in relation to the product shall be reported immediately to the manufacturer and the competent authority of the European member state in which the incident occurred. European vigilance contact points: https://ec.europa.eu/health/md_sector/contact_en.

10.4 Explanation of symbols

REF	Article number
LOT	Lot number
	Manufacturer
	Date of manufacturing
IVD	In vitro diagnostic medical device
	Consult Instructions For Use
Σ	Sufficient for <n> tests
	Temperature limitation
	Use by
	Caution: Further information in Instruction for Use
	Do not reuse

10.5 Product Use Restriction / Warranty

This product is shipped with documentation stating specifications and other technical information. magtivio warrants to meet the stated specifications. magtivio's sole obligation and the customer's sole remedy is limited to replacement of products free of charge in the event products fail to perform as warranted. Supplementary reference is made to the general business terms and conditions of magtivio, which are printed on the price list. Please contact us if you wish to get an extra copy.

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