



21120.9152 KingFisher MagMax Viral Pathogen Nucleic Acid Isolation 2.2

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Copy of version 2.2 (approved and current)

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Organization ViraCor

Comments for version 2.0 (last major revision)

Added steps to include internal control addition to sample wells.

Comments for version 2.2 (this revision)

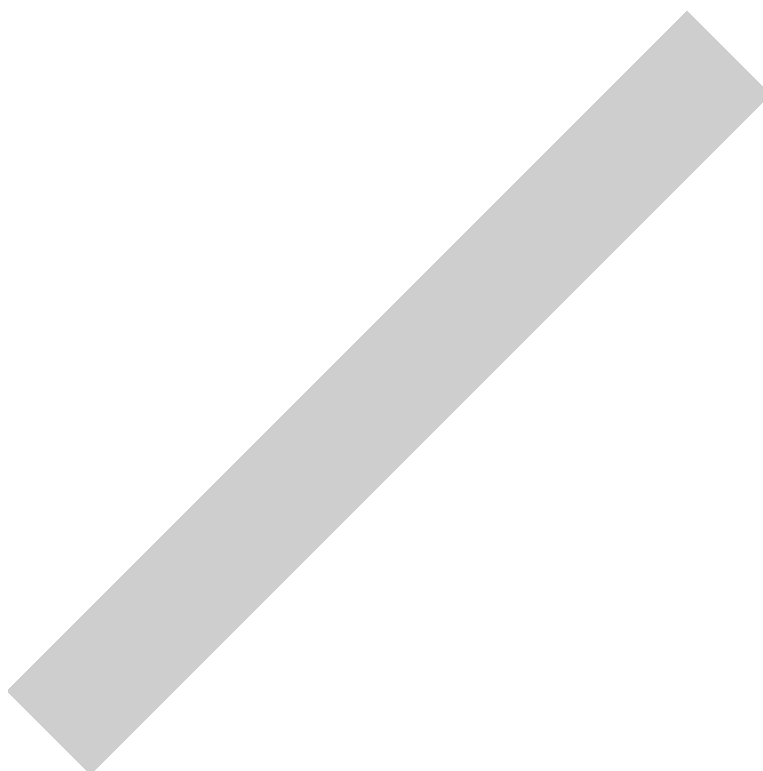
Updated Warnings per FDA guidance

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	(b) (6)	18-May-2020 20:58	2.0	(b) (6)	
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Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.2	Approved and Current	Minor revision	16-Oct-2020	16-Oct-2020	Indefinite
2.1	Retired	Minor revision	13-Oct-2020	13-Oct-2020	16-Oct-2020
2.0	Retired	Major revision	14-May-2020	18-May-2020	13-Oct-2020
1.0	Retired	Initial version	11-May-2020	18-May-2020	18-May-2020



KingFisher MagMax Viral Pathogen (MVP) Nucleic Acid Isolation

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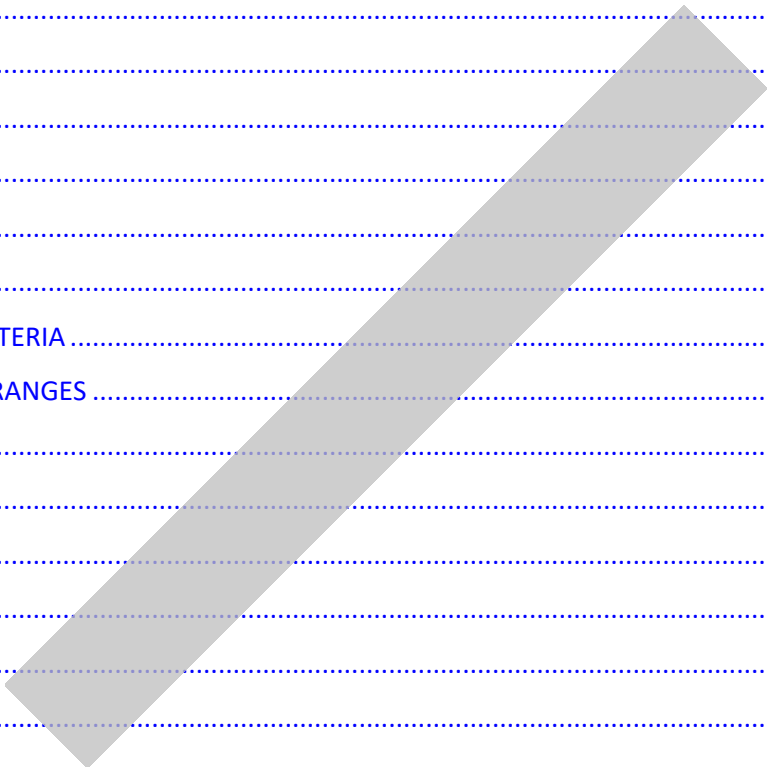
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INTENDED USE

The Applied Biosystems™ MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit is developed for scalable, rapid purification of high quality nucleic acid (RNA and DNA) from virus and easy to lyse bacteria in biofluid and transport media samples. You can use the nucleic acid purified with this kit in a broad range of molecular biology downstream applications, such as sequencing and qPCR.

This protocol guides users through automated isolation of nucleic acid using the KingFisher™ Flex instrument.

TEST INFORMATION

Applied Biosystems™ MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit uses Total Nucleic Acid Binding Beads for the isolation of nucleic acid.

This SOP applies to nucleic acid extraction of specimens for SARS-CoV-2 designated for KingFisher Flex platforms as indicated in *Specimen Processing Guide* or as otherwise directed by laboratory management.

METHOD PRINCIPLE

The MagMAX Viral/Pathogen Nucleic Acid Isolation Kit is designed to recover RNA and DNA from virus and gram-negative bacteria in samples such as blood, swabs, urine, and viral transport media (VTM). The kit utilizes MagMAX magnetic-bead technology, ensuring reproducible recovery of high-quality nucleic acid compatible with a broad range of applications, including real-time PCR, digital PCR, and next-generation sequencing.

The optimized reagents included in the MagMAX Viral/Pathogen kit allow you to maximize the amount of sample input, thereby increasing the amount of RNA and/or DNA recovered. Up to 400 µL of sample can be processed per well in a KingFisher 96-deep well plate.

Magnetic beads offer many benefits compared to other technologies for isolating nucleic acid. Beads bind the nucleic acid more efficiently than glass-fiber filters, resulting in higher and more consistent yields. Additionally, because filters and vacuum manifolds are not used, there is no risk of filter clogging due to cellular particulates in samples. This clogging issue is of particular concern with protein-rich, large-volume samples such as whole blood or plasma that are commonly used for viral testing.

The Dynabeads MyOne Silane contained in the MagMAX Viral/Pathogen Total Nucleic Acid Isolation Kit have an optimized silica-like surface chemistry with a highly specific surface area that allows efficient kinetics and high sensitivity in nucleic acid capture. These aspects make Dynabeads MyOne Silane ideal for the recovery viral RNA and DNA present at low concentrations in body fluids. Once captured, these nucleic acids can then be eluted in 50 µL of elution buffer for use in downstream applications.

SPECIMEN REQUIREMENTS

Patient Preparation

None

Specimen Type and Handling

Refer to the *Specimen Processing Guide* for acceptable assays, specimen types, volume requirements, comments, and reject conditions.

REAGENTS AND MATERIALS

Description	Source	Part/Cat No	Storage	Expiration
MagMAX™ Viral/ Pathogen Nucleic Acid Isolation Kit	Applied BioSystems	A42352 (100 preps) or A48310 (1000 preps)	(b) (4) °C	labeled expiry
Binding Solution*	(b) (4)	(b) (4) preps)	(b) (4) °C	labeled expiry
Wash Buffer*	(b) (4)	(b) (4) preps)	(b) (4) °C	labeled expiry
Elution Solution*	(b) (4)	(b) (4) preps)	(b) (4) °C	labeled expiry
Proteinase K*	(b) (4)	(b) (4) preps)	(b) (4) °C	labeled expiry
Total Nucleic Acid Binding Beads*	(b) (4)	(b) (4) preps)	(b) (4) °C	labeled expiry
Ethanol, 100% (molecular biology grade)	(b) (4)	(b) (4) mL (or equivalent)	(b) (4) °C	labeled expiry
Molecular grade H ₂ O	(b) (4) or equivalent	(b) (4)	(b) (4) °C	labeled expiry

*Components are included in the MagMax Viral/ Pathogen Nucleic Acid Isolation Kit.

Reagent Handling

Store reagents at temperature conditions listed above when not in use.

CALIBRATORS AND STANDARDS

Refer to 21120.369 *Analytical Quality Control: Assay Calibration and Calibration Verification* for instructions and guidelines for maintaining the analytical accuracy of laboratory test methods through regular calibration and calibration verification procedures.

QUALITY CONTROL

The quality control program for this test is established in accordance with 21120.369 *Analytical Quality Control: Assay Calibration and Calibration Verification*.

Quality control specimens are prepared and control ranges are established and maintained in accordance with 21120.369 *Analytical Quality Control: Assay Calibration and Calibration Verification*.

The positive extraction control and NEC are evaluated for each (b) (4)

Establishing QC Control range for new control lot number

Positive extraction control material is qualified using the following procedure:

(b) (4)

Negative extraction control material is qualified according to 21120.551 *Quality Control Testing of the Negative Extraction Controls (NECs) for Clinical Testing*. (b) (4)

Quality control Acceptance Criteria/Repeat Criteria

Refer to 21120.578 *PCR and RT PCR Acceptance and Retest Criteria* for acceptance criteria and corrective actions for NECs and Positive Extraction Controls.

PROFICIENCY TESTING

(b) (4) ated with this procedure shall be challenged by in-house and external proficiency testing no less than twice per year.

EQUIPMENT AND SUPPLIES

Description	Source	Part/Cat No
KingFisher™ Flex (b) (4)	(b) (4)	(b) (4)
Computer with (b) (4) software	Various	Various
(b) (4) deep-well 96 plate	(b) (4)	(b) (4)
(b) (4) 96 KF plate	(b) (4)	(b) (4)
(b) (4) 96 tip comb for deep-well magnets	(b) (4)	(b) (4)
Conical Tubes (b) (4) mL	Various	Various
Conical Tubes (b) (4) mL	Various	Various
Reagent reservoirs	Various	Various
Pipette tips (b) (4) (b) (4) μL, (b) (4) μL, (b) (4) μL and (b) (4) μL sizes	Various	Various
Pipettes to accommodate above listed tip sizes	Various	Various
(b) (4) (Electronic multichannel pipette)	(b) (4) or equivalent	Various

Handling of Consumables

All consumables must be handled with clean gloves.

PCR testing process requires specific handling of consumables to prevent potential contamination. Consumables must be removed from packing using clean gloves.

Plates must not be taken out of the packaging until immediately prior to use. Other consumables must be covered when not in use to prevent potential contamination (tips, reagent reservoirs, etc.).

Preventative Maintenance

Follow maintenance procedures for equipment as indicated in 21120.9034 *KingFisher Flex System Operation, Maintenance, and Calibration SOP*.

PROCEDURE

(b) (4)

(b) (4)

CALCULATIONS

Refer to Related Documents section

RESULT REPORTING AND REPEAT CRITERIA

Refer to Related Documents section

EXPECTED VALUES AND REFERENCE RANGES

Refer to Related Documents section

CLINICAL SIGNIFICANCE

N/A

PROCEDURE NOTES

Documenting Errors

All anomalies, errors, deviations, and exceptions must be documented on the run report. For those which require management approval, the person approving must notate their approval and any justification and further comments required, followed by their initials and the date of the approval.

Testing System Unavailable

Viracor Laboratories takes precautions to ensure that testing systems do not have prolonged outages (b) (4)

LIMITATIONS OF THE METHOD

N/A

PERFORMANCE SPECIFICATIONS

N/A

WARNINGS

- The Viracor SARS-CoV-2 assay has not been FDA cleared or approved;
- The Viracor SARS-CoV-2 assay has been authorized by FDA under an EUA for use by the authorized laboratory: Viracor Eurofins Clinical Diagnostics Laboratory located at (b) (6), certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests;
- The Viracor SARS-CoV-2 assay has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The Viracor SARS-CoV-2 assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

SAFETY

The following personal protective equipment will be applied as directed in currently effective Safety SOPs, including but not limited to, gloves, masks, lab coats, face shields and eye protection.

Personnel executing these procedures must be trained on effective Safety SOPs as listed in 21120.265 *Safety Program*.

See Material Safety Data Sheet (MSDS) manual for further details regarding all agents in the kit.

RELATED DOCUMENTS

21120.265 *Safety Program*

21120.369 *Analytical Quality Control: Assay Calibration and Calibration Verification*

21120.554 *Real-time PCR and RT-PCR Results Calculation and Rounding*

21120.578 *PCR and RT-PCR Acceptance and Retest Criteria*

(b) (4) *User Procedures*

21120.595 *Specimen Processing Guide*

21120.596 *Clinical Laboratory Processing Guide*

21120.600 *Pre-processing Procedures for ID tests and Pre-processing Temperature Requirements for ID and AI*

21120.716 *Acceptance and Retest Criteria for PCR and RT-PCR Assays*

21120.9034 *KingFisher Flex System Operation, Maintenance, and Calibration SOP*

21120.9035 *KingFisher Flex System Maintenance Log*

REFERENCES

MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit User Guide, Pub. No. MAN0018073, Rev. A.0, 14 Mar 2019

ATTACHMENTS

N/A