


MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput

Magnetic bead technology-based nucleic acid purification for high-throughput workflows

REF. A50884

Pub. No. MAN0019941 Rev. A.0

 **WARNING!** Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from [thermofisher.com/support](https://www.thermofisher.com/support).

Intended use

Applied Biosystems™ MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput is intended for the isolation and purification of viral nucleic acid from human respiratory specimens. The magnetic bead technology-based nucleic acid purification reagents have been validated for the following workflows:

- **Automated, high-throughput workflows**—for isolation and purification of RNA from nasal and nasopharyngeal specimens
- **Manual and semi-automated workflows**—for isolation and purification of RNA and DNA from nasopharyngeal specimens

The MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of magnetic bead purification, either manual or automated, and *in vitro* diagnostic procedures. The MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput is intended for use in a qualified laboratory environment according to the sample type.

Product information

MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput (REF. A50884) is specifically designed to recover nucleic acid from viral particles contained in viral transport media (VTM). The kit utilizes MagMAX™ magnetic-bead technology, ensuring reproducible recovery of high-quality RNA.

MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput is intended for *in vitro* diagnostic use and includes the following features:

- Automated, high-throughput workflow using the Amplitude™ Platform to allow for up to 8,000 samples to be processed in a 24-hour period
- No requirement for carrier RNA
- Elution volume of 50 µL

Note: Protocol options also support a manual workflow or a semi-automated workflow, accommodating sample volume inputs from 200 to 400 µL of VTM. Semi-automated workflows using the KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head allow for 96 nasopharyngeal swab specimens to be processed in <30 minutes.

For product information on manual or semi-automated protocols, see the *MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit Instructions For Use* (Pub. No. MAN0019746).

Contents and storage

MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput (REF. A50884) is compatible with the Amplitude™ Platform. The reagents are supplied in 2 distinct modules that are designed to align with Amplitude™ Platform Module 1 and Module 2:

- MagMAX™ MVPII HT Module 1 Sample Prep (Cat. No. A50770)
- MagMAX™ MVPII HT Module 2 Sample Prep (Cat. No. A50771)

The MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput contains sufficient reagents for 20,000 reactions.



For In Vitro Diagnostic Use.

Table 1 MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput (REF. A50884)

Amplitude™ Platform Module	Component	REF.	Quantity	Amount	Storage
MagMAX™ MVPII HT Module 1 Sample Prep (Cat. No. A50770)					
Module 1	MagMAX™ MVPII HT Binding Solution	B32430F4	3	800 mL	15°C to 25°C
	MagMAX™ MVPII HT Binding Beads	109-00-502F4	3	30 mL	
	MagMAX™ MVPII HT Proteinase K	EO2180F4	3	20 mL	
MagMAX™ MVPII HT Module 2 Sample Prep (Cat. No. A50771)					
Module 2	MagMAX™ MVPII HT Wash Solution	B32440F4	3	1,500 mL	15°C to 25°C
	MagMAX™ MVPII HT Elution Solution	B29880F9	1	700 mL	

Required materials not supplied

Unless otherwise indicated, all materials are available through thermofisher.com. "MLS" indicates that the material is available from fisherscientific.com or another major laboratory supplier.

Item	Source
Amplitude™ Platform Module 1 and Module 2 equipment	See the user guide for the Amplitude™ Platform (Pub. No. MAN0019842) ^[1]
80% Ethanol	
Silicone oil	
Amplitude™ High-Throughput Consumable Package 3 Plastics	
(Optional) Extraction control, if required for your assay	

^[1] See also "Module 1 Required samples, reagents, and consumables" on page 4 and "Module 2 Required sample input, reagents, and consumables" on page 8.

Product limitations

- The system performance was established using nasal and nasopharyngeal swab samples only. Specimen types other than nasal and nasopharyngeal swab should not be tested with this kit.
- Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.
- Chemical inactivation and other known clinically relevant interfering substances and techniques can lead to inappropriate primary samples and interfere with test results.
- The Amplitude™ Platform workflow must be performed according to the specified methods described in the user guide for the system.
- The quality of the biological samples is essential for the quality of the results generated with this kit.
- False-negative results may arise from:
 - Improper sample collection
 - Degradation of the SARS-CoV-2 RNA during shipping/storage
 - Specimen collection after SARS-CoV-2 RNA can no longer be found in the specimen matrix
 - Using unauthorized extraction or assay reagents
 - Failure to follow instructions for use
- False-positive results may arise from:
 - Cross contamination during specimen handling or preparation
 - Cross contamination between patient samples
 - Specimen mix-up
 - RNA contamination during product handling

Warnings and precautions

The reagents should only be used in a qualified laboratory environment according to the sample type by qualified and trained staff to avoid cross-contamination and the risk of erroneous results. For information about operator roles and requirements, see the user guide for your system.

- Before using this product, read and understand the information provided in this guide and the user guide for your system.
- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Samples and controls should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures.
- Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples.
- Always use pipette tips with aerosol barriers. Tips that are used must be sterile and free from DNases and RNases.
- Do not eat, drink, smoke, or apply cosmetic products in the work areas.
- Modifications to assay reagents, assay protocol, or instrumentation are not permitted.
- Reagents must be stored and handled as specified in "Contents and storage" on page 1.
- Do not use system consumables or reagents after the indicated expiry date.
- Dispose of waste in compliance with local, state, and federal regulations.

Sample collection, transport, and storage



CAUTION! Handle all samples and controls as if they are capable of transmitting infectious agents.

- Patient samples must be collected according to appropriate laboratory guidelines. The Amplitude™ Platform can be used with patient samples collected via nasopharyngeal or nasal swab.
- Store samples at 2–8°C for up to 72 hours after collection. If a delay in testing is expected, store samples at ≤-70°C.

Guidelines for sample tubes

- Only use sample tubes meeting the specifications listed in the table below:

Tube runner type	Tube diameter range		Maximum tube height	Tube bottom type
	Minimum	Maximum		
13 mm, 32-position	12 mm	14 mm	140 mm	Skirted, internal conical only
16 mm, 26-position	15 mm	17 mm	140 mm	Skirted, internal conical only
17 mm, 24-position	16 mm	18 mm	140 mm	Non-skirted, external conical or Skirted, internal conical

IMPORTANT!

- For each Module 1 run, all 376 sample tubes must be within the same diameter range. Individual tube heights can vary, but should not exceed 140 mm.
 - For each Module 1 run, all 376 sample tubes must be loaded in the same type of tube runner. Tube runner types cannot be mixed within a run.
- Ensure that you have the minimum volume of sample required for the sample tube size.

Sample tube size	Minimum volume required
12–14 mm	0.5 mL
15–17 mm	1 mL
16–18 mm	1 mL

- All sample tubes must be barcoded with a unique ID. For sample tube barcode requirements, see the user guide for your system.

Note: The Amplitude™ Platform does not perform sample accessioning. If required, perform sample accessioning according to guidelines established by your laboratory prior to processing the samples on Module 1. After testing, the results can be ported into your laboratory system.

- For sample collection devices containing swabs, the swabs must be removed from sample tube before loading into the tube runners. Alternatively, the sample can be transferred to a fresh, barcoded sample tube that is then loaded into an appropriate runner type.
- The Amplitude™ Platform cannot run fewer than 376 samples at a time. If you have fewer than 376 sample tubes, you must include additional empty, barcoded tubes to fill any empty positions in the tube runners.

Guidelines for sample inactivation

Follow the sample inactivation guidelines and requirements established by your laboratory and local regulatory bodies. If your laboratory inactivates samples, do so before you begin the Module 1 workflow.

Chemical inactivation is not recommended and may interfere with test results.

In-use reagent stability

Table 2 In-use reagent stability

Reagent	Stability information
MagMAX™ MVPII HT Binding Solution	Store capped at 15°C to 25°C long-term.
MagMAX™ MVPII HT Binding Beads	Store capped at 15°C to 25°C long-term.
Binding Bead Mix (prepared by customer)	Once the MagMAX™ MVPII HT Binding Solution and MagMAX™ MVPII HT Binding Beads are combined, the mix is stable for 24 hours after preparation. Store capped at 15°C to 25°C.
MagMAX™ MVPII HT Proteinase K	Once placed in the Tecan™ Fluent™ 1080 Automation Workstation reagent carrier (15°C to 25°C), the reagent has long-term stability.
Purified sample nucleic acid	Once extracted, purified sample nucleic acid is stable at 4°C for 48 hours. For long term storage, store according to the guidelines established by your laboratory.

Perform a Module 1 run

Module 1 overview

Module 1 operation is controlled by the Tecan™ FluentControl™ Software, via the Tecan™ Fluent™ 1080 Automation Workstation touchscreen. For more information, see the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).

During Module 1 operation:

- Technicians load prepared sample tube runners, reagents, and consumables on the Tecan™ Fluent™ 1080 Automation Workstation deck and start runs.
- The instrument prepares 4 sample extraction plates containing the following components:
 - 200 µL of sample from the sample tubes
 - MagMAX™ MVPII HT Proteinase K
 - Extraction control and assay control as required by the assay that is used in combination with MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput
 - Binding Bead Mix
 - Silicone oil
- The Tecan™ Fluent™ 1080 Automation Workstation scans the barcodes on sample tubes and sample extraction plates, then registers the information with the SampleManager LIMS™ Software for sample tracking.

Module 1 Required samples, reagents, and consumables

For a complete list of required samples, reagents, and consumables, see the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).

Required samples, reagents, and consumables	Usage (Reload frequency)
Sample input	
Barcoded sample tubes in sample carrier racks	376 samples per run

Required samples, reagents, and consumables	Usage (Reload frequency)
Consumables	
KingFisher™ Deep-Well 96 Plate with Barcode (sample extraction plates)	4 plates per run
1,000 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack	15 racks per 3 runs
200 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack	3 racks per 6 runs
Nunc™ Microplate Lids	12 lids per 3 runs
Axygen™ Multi Well Low Profile Reagent Reservoir (for MagMAX™ MVPII HT Proteinase K/extraction control)	1 reservoir per 6 runs
Axygen™ Single Well High Profile Reagent Reservoir (for Binding Bead Mix)	1 reservoir per 6 runs
Axygen™ Single Well High Profile Reagent Reservoir (for silicone oil)	1 reservoir per 6 runs
Reagents^[1]	
MagMAX™ MVPII HT Binding Beads	1 bottle per 6 runs
MagMAX™ MVPII HT Binding Solution	1 bottle per 6 runs
Extraction control	as recommended by the assay supplier
MagMAX™ MVPII HT Proteinase K	1 bottle per 6 runs
HT Water for Dilution	1 bottle per 6 runs
Silicone oil	1 bottle per 6 runs
Samples and controls	
Positive control and negative control samples	as applicable

^[1] See "In-use reagent stability" on page 4.

Before you begin

Follow the procedure as described in the user guide for the Amplitude™ Platform (Pub. No. MAN0019842), starting with powering the system on through preparing the Tecan™ Fluent™ 1080 Automation Workstation.

Thaw extraction control

Every six runs, thaw the appropriate quantity of control according to the recommendations of the assay supplier.

Prepare the Binding Bead Mix

Every six runs, prepare the Binding Bead Mix.

IMPORTANT! Use the Binding Bead Mix within 24 hours of preparation.

1. Vortex one bottle of MagMAX™ MVPII HT Binding Beads for a minimum of 15 seconds to ensure that the bead mixture is homogeneous.
2. Combine the appropriate volumes of MagMAX™ MVPII HT Binding Beads and MagMAX™ MVPII HT Binding Solution for the required number of runs.
 - For fewer than 6 runs, combine the appropriate volumes in a sterile, secondary mixing container that can be closed.
 - For 6 runs, pour all of the MagMAX™ MVPII HT Binding Beads directly into the bottle of MagMAX™ MVPII HT Binding Solution.

Number of runs	MagMAX™ MVPII HT Binding Beads ^[1]	MagMAX™ MVPII HT Binding Solution ^[2]
1	5.2 mL	133 mL
2	10.3 mL	266 mL
3	15.4 mL	399 mL
4	20.5 mL	532 mL
5	25.6 mL	665 mL
6	30 mL (entire volume)	800 mL (entire volume)

^[1] Fill volume 30 mL.

^[2] Fill volume 800 mL.

IMPORTANT! Keep the bottle of MagMAX™ MVPII HT Binding Beads and the bottle of MagMAX™ MVPII HT Binding Solution to scan when prompted by the Tecan™ Fluent™ 1080 Automation Workstation touchscreen.

3. Mix well by inversion, then store the Binding Bead Mix at room temperature until ready to use.
4. Perform the following procedures as described in the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).
 - a. View the SampleManager Module 1 Load Indicator
 - b. Start the method on the Tecan™ Fluent™ 1080 Automation Workstation

Load the Tecan™ Fluent™ 1080 Automation Workstation deck

IMPORTANT! Start the method on the Tecan™ Fluent™ 1080 Automation Workstation, then load reagents and consumables in the correct deck positions when prompted by the instrument touchscreen. Failure to do so can result in reduced throughput.

The following procedure describes the process for loading consumables and reagents for the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput only. For a complete list of materials that are loaded in the instrument, see the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).

1. Open the Tecan™ Fluent™ 1080 Automation Workstation access door.
2. Follow the touchscreen prompts to fill the empty deck. The consumables and reagents are refilled every 1, 3, and 6 runs as indicated in the following table:

Load the empty deck	Reload frequency		
	Every run	Every 3 runs	Every 6 runs
Add new Binding Bead Mix trough ^[1]			X
Fill Binding Bead Mix trough	X	X	X
Add new silicone oil trough ^[1]			X
Fill silicone oil trough	X	X	X
Add new MagMAX™ MVPII HT Proteinase K/extraction control mixing trough ^[2]			X
Load MagMAX™ MVPII HT Proteinase K in reagent carrier (see Figure 1)			X
Load extraction control × 2 in reagent carrier (see Figure 1)			X
Load KingFisher™ Deep-Well 96 Plates with Barcodes × 4	X	X	X

^[1] Axygen™ Single Well High Profile Reagent Reservoir

^[2] Axygen™ Multi Well Low Profile Reagent Reservoir

- a. **(Every 6 runs)** In the **Load reagents and mixing trough** screen, follow the prompts to replace both the used Binding Bead Mix trough and the silicone oil trough with a new Axygen™ Single Well High Profile Reagent Reservoir.
- b. **(Every 6 runs)** In the **Load reagents and mixing trough** screen, follow the prompts to scan the barcodes on the bottles of MagMAX™ MVPII HT Binding Beads and MagMAX™ MVPII HT Binding Solution that were used to prepare the Binding Bead Mix.
- c. **(Every run)** In the **Load reagents and mixing trough** screen, follow the prompts to **gently** invert the bottle of Binding Bead Mix 10 times to ensure that the mixture is homogenous, then pour the Binding Bead Mix to the trough fill line.



WARNING! Improper or overly vigorous mixing of the Binding Bead Mix can lead to invalid results or failure to inactivate the SARS-CoV-2 virus during the Module 1 process. Minimize foaming during the mixing process.



CAUTION! Ensure that you add the Binding Bead Mix to the correct trough. Adding the reagent to the incorrect trough can lead to invalid results.

- d. **(Every run)** In the **Load reagents and mixing trough** screen, follow the prompts to pour the silicone oil to the trough fill line.



CAUTION! Ensure that you add the silicone oil to the correct trough. Adding the reagent to the incorrect trough can lead to invalid results.

- e. **(Every 6 runs)** Follow the prompts to replace the used MagMAX™ MVPII HT Proteinase K/extraction control mixing trough with a new Axygen™ Multi Well Low Profile Reagent Reservoir.
- f. **(Every 6 runs)** Follow the prompts to scan the reagents, then load the reagent carrier.

Note: Before removing the reagent bottle cap, gently tap the reagent bottle on the bench to ensure the liquid is collected at the bottom of the container.



CAUTION! Only scan, then load new, full bottles of reagents. If a reagent is not at full volume when it is loaded in the system then the reagent may run out mid-run, resulting in lower throughput, inaccurate results, or loss of sample.

Reagent	Amount
MagMAX™ MVPII HT Proteinase K	1 bottle
HT Water for Dilution (for Negative Control)	1 bottle
Extraction control	2 bottles

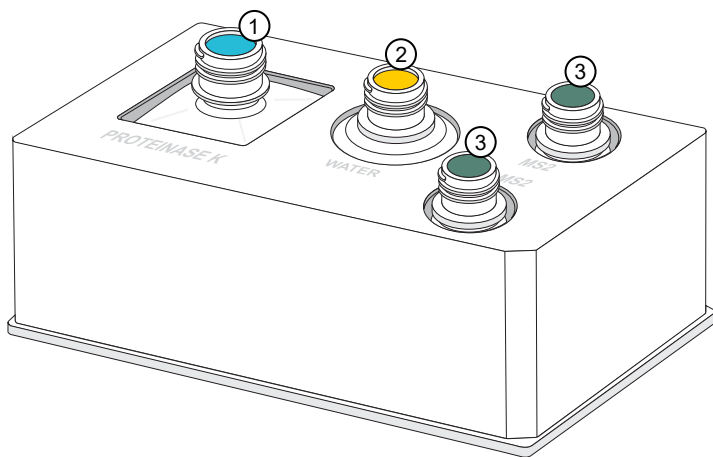


Figure 1 Module 1 reagent carrier positions

- ① MagMAX™ MVP II HT Proteinase K
- ② HT Water for Dilution
- ③ Extraction control × 2

g. (Every run) In the **Load deepwell extraction plates** screen, follow the prompts to load 4 × KingFisher™ Deep-Well 96 Plate with Barcode.

Perform Module 1 run—After all of the reagents and consumables are reloaded, follow the touchscreen prompts to load the tube runners, then complete the remaining procedures for Module 1 as described in the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).

During a Module 1 run, the Tecan™ Fluent™ 1080 Automation Workstation performs the following steps:

1. Picks up equal parts of MagMAX™ MVP II HT Proteinase K and extraction control, then mixes them in the MagMAX™ MVP II HT Proteinase K/extraction control mixing trough.
2. Transfers 200 µL of each sample to a well in a KingFisher™ Deep-Well 96 Plate with Barcode.
3. Transfers 275 µL of Binding Bead Mix and 10 µL of MagMAX™ MVP II HT Proteinase K/extraction control mix to every well in four KingFisher™ Deep-Well 96 Plates with Barcodes.
4. Adds 200 µL of silicone oil to every well in the four KingFisher™ Deep-Well 96 Plates with Barcodes.

Perform a Module 2 run

Module 2 overview

Module 2 operation is controlled via the Momentum™ Workflow Scheduler Software on the Module 2 computer station. For more information, see the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).

During Module 2 operation, the following tasks are performed:

- Technicians transfer extraction plates from Module 1 to Module 2, replenish reagents and consumables, and unload the outgoing nucleic acid elution plates.
- The 4 sample extraction plates are processed, with an output of 4 nucleic acid elution plates that contain 50 µL of purified sample nucleic acid per well.

Module 2 Required sample input, reagents, and consumables

The following tables list the required sample input, reagents, and consumables for automated nucleic acid extraction based on the action being completed in the Momentum™ Software: **Check in**, **Replenish reagents**, or **Replenish consumables**.

Note: The **Check in** process also requires assay-specific reagents and consumables. For more information, see the user guide for the Amplitude™ Platform (Pub. No. MAN0019842)

For a complete list of required samples, reagents, and consumables, see the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).

Table 3 Check in—Required sample input

Required sample input	Usage (Reload frequency)
Hotel Input (Position 1)	
Sample extraction plates from Module 1	4 plates per run

Table 4 Replenish reagents—Required reagents

Required reagents	Usage (Reload frequency)
Multidrop™ Combi Reagent Dispenser × 3 (Positions 6-8)	
MagMAX™ MVPII HT Elution Solution (used with Combi 1)	1 bottle per 18 runs
MagMAX™ MVPII HT Wash Solution (Wash 1, used with Combi 2)	3 bottles per 18 runs
80% Ethanol (Wash 2, used with Combi 3)	2 bottles per 18 runs

Table 5 Replenish consumables—Required consumables

Required consumables	Usage (Reload frequency)
Tecan™ Fluent™ 780 Automation Workstation (Position 2)	
MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode	6 plates per 6 runs
RNA Elution Plate Stackers (Position 3)	
KingFisher™ Deep-Well 96 Plate with Barcode (nucleic acid elution plates)	40 plates per 10 runs
KingFisher™ 96 tip comb for DW magnets (for nucleic acid elution plates)	40 tip combs per 10 runs
Wash Plate Stacker Carousel (Position 5)	
KingFisher™ Deep-Well 96 Plates with Barcodes (wash plates)	80 plates per 10 runs

Before you begin

Follow the procedure as described in the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).

Refill the Multidrop™ Combi Reagent Dispenser reagents

1. Follow the procedure to replenish the Multidrop™ Combi Reagent Dispenser reagents in the Momentum™ Software as described in the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).
2. Refill the reagents.




CAUTION! Ensure that you pour the MagMAX™ MVPII HT Wash Solution (Wash 1) and 80% Ethanol (Wash 2) in the correct carboy.

Reagent	Description
MagMAX™ MVPII HT Elution Solution	Remove the tubing bundle weight from the used MagMAX™ MVPII HT Elution Solution bottle, then place in the new MagMAX™ MVPII HT Elution Solution bottle. Wrap the bottle top with Parafilm™ film to prevent evaporation.
MagMAX™ MVPII HT Wash Solution (Wash 1)	Remove the Wash 1 carboy lid, then pour 3 bottles of MagMAX™ MVPII HT Wash Solution into the Wash 1 carboy. Tightly close the carboy lid.
80% Ethanol (Wash 2)	Remove the Wash 2 carboy lid, then pour 2 bottles of 80% Ethanol into the Wash 2 carboy. Tightly close the carboy lid.

3. On each Multidrop™ Combi Reagent Dispenser keypad, press and hold **PRIME** for the duration listed in the following table.

IMPORTANT! Ensure that you prime each Multidrop™ Combi Reagent Dispenser for the duration listed. Failure to adequately prime the instruments can affect performance.

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ MVPII HT Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	20 seconds
Combi 3 (dispenses Wash 2)	

 **WARNING!** Ensure that the liquid runs steadily from all of the cassette dispensing tips by the end of the recommended prime duration. Failure to do so can affect performance.

Perform Module 2 run—Follow the remaining procedures for Module 2 as described in the user guide for the Amplitude™ Platform (Pub. No. MAN0019842). The workflow processes 200-µL sample input volumes.

During a Module 2 run, instruments perform the following steps:

1. Multidrop™ Combi Reagent Dispenser dispenses Wash 1, Wash 2, and Elution solutions into wash and elution plates.
2. Four KingFisher™ Presto Purification Systems extract RNA from extraction plates, then wash the sample using the Wash 1 and Wash 2 solutions.
3. The sample RNA is eluted in 50 µL of MagMAX™ MVPII HT Elution Solution.
4. The Spinnaker™ Microplate Robot wastes the used wash and extraction plates and conveys the elution plates to instrument systems that carry out the assay. For more information, see the user guide for the Amplitude™ Platform (Pub. No. MAN0019842).


Appendix A Amplitude™ Platform system components

Component	Manufacturer
Instruments	
Tecan™ Fluent™ 1080 Automation Workstation (base unit)	Tecan Switzerland Seestrasse 103 8708 Maennedorf Switzerland
Tecan™ Fluent™ 780 Automation Workstation (base unit)	Tecan Switzerland Seestrasse 103 8708 Maennedorf Switzerland
Thermo Fisher Scientific Spinnaker™ Microplate Robot with BenchTrak	Thermo CRS Ltd. 5250 Mainway Burlington, Ontario L7L 5Z1 Canada
Spinnaker™ Microplate Robot Mini-Hub Control Puck	Thermo CRS Ltd. 5250 Mainway Burlington, Ontario L7L 5Z1 Canada
Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System (x 2)	Life Technologies Holdings Pte Ltd Block 33 Marsiling Industrial Estate Road 3 #07-06, Singapore 739256
Thermo Scientific™ Multidrop™ Combi Reagent Dispenser (x 3)	Life Technologies Holdings Pte Ltd Block 33 Marsiling Industrial Estate Road 3 #07-06, Singapore 739256
ALPS 3000 Automated Microplate Heat Sealer	ABgene™ UK Ltd Units 4-7 Suffolk Drive Fairwood Industrial Park Ashford Kent TN23 4FD UK
Thermo Scientific™ KingFisher™ Presto Purification System (x 4)	Life Technologies Holdings Pte Ltd Block 33 Marsiling Industrial Estate Road 3 #07-06, Singapore 739256
Agilent™ Microplate Centrifuge	Agilent Technologies Singapore (International) Pte Ltd 1 Yishun Avenue 7 Singapore 768923
BioTek® ELx405™ Select Microplate Washer	BioTek Instruments, Inc. 100 Tigan Street Winooski, Vermont 05404 USA
Thermo Scientific™ Arctic™ A25 Refrigerated Circulator (115V or 230V)	Thermo Fisher Scientific (Asheville) LLC 275 Aiken Road Asheville, North Carolina 28804 USA
Lab Automation Robotic Testing Platform	Thermo CRS Ltd. 5250 Mainway Burlington, Ontario L7L 5Z1 Canada

Component	Manufacturer
Software	
Tecan™ FluentControl™ Software v2.8	Tecan Switzerland Seestrasse 103 8708 Maennedorf Switzerland
SampleManager LIMS™ Software Version 12.2 SP1	Thermo Electron Ltd. 1 St. George's Court, Hanover Business Park Altrincham, Cheshire WA14 5TP United Kingdom
Momentum™ Workflow Scheduler Software 6.0.1	Thermo CRS Ltd. 5250 Mainway Burlington, Ontario L7L 5Z1 Canada
COVID-19 Interpretive Software Driver v1.1.0 ^[1]	Life Technologies Corporation 6055 Sunol Blvd Pleasanton, California 94566 USA
BioTek® Liquid Handling Control Software 2.22	BioTek Instruments, Inc. 100 Tigan Street Winooski, Vermont 05404 USA
FILLit™ Software 2.0.1 ^[1]	Thermo Fisher Scientific Oy Ratastie 2 FI-01620 Vantaa Finland
BindIt™ Software 4.0 ^[1]	Life Technologies Holdings Pte Ltd Block 33 Marsiling Industrial Estate Road 3 #07-06, Singapore 739256
QuantStudio™ Real-Time PCR Software v1.7.1	Life Technologies Holdings Pte Ltd Block 33 Marsiling Industrial Estate Road 3 #07-06, Singapore 739256


^[1] The operator does not interact directly with the COVID-19 Interpretive Software Driver, FILLit™ Software, or BindIt™ Software.

Appendix B Safety


 **WARNING! GENERAL SAFETY.** Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, see the “Documentation and Support” section in this document.

Biological hazard safety

 **WARNING! BIOHAZARD.** Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- World Health Organization, *Laboratory Biosafety Manual*, 3rd Edition, WHO/CDS/CSR/LYO/2004.11; found at: www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf
- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 5th Edition, HHS Publication No. (CDC) 21-1112, Revised December 2009; found at: <https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2009-P.pdf>

 **WARNING! Potential Biohazard.** If you use the kit with the automated nucleic extraction workflow, the surface of the KingFisher™ purification system may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.

Chemical safety



WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
 - Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
 - Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with sufficient ventilation (for example, fume hood).
 - Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer cleanup procedures as recommended in the SDS.
 - Handle chemical wastes in a fume hood.
 - Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
 - After emptying a waste container, seal it with the cap provided.
 - Characterize (by analysis if needed) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
 - Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
 - **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.
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Appendix C Documentation and support

Customer and technical support

Visit [thermofisher.com/support](https://www.thermofisher.com/support) for the latest service and support information.

- Worldwide contact telephone numbers
- Product support information
 - Product FAQs
 - Software, patches, and updates
 - Training for many applications and instruments
- Order and web support
- Product documentation
 - User guides, manuals, and protocols
 - Certificates of Analysis
 - Safety Data Sheets (SDSs; also known as MSDSs)

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at www.thermofisher.com/us/en/home/global/terms-and-conditions.html. If you have any questions, please contact Life Technologies at www.thermofisher.com/support.



The customer is responsible for compliance with regulatory requirements that pertain to their procedures and uses of the instrument.

The information in this guide is subject to change without notice.

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Revision history: Pub. No. MAN0019941

Revision	Date	Description
A.0	28 January 2021	New MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, High-Throughput Instructions for Use.

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