

WELCOME TO THE APEX OF CLINICAL SAMPLE PREP



KingFisher Apex Dx instrument

MagMAX Dx Viral/Pathogen NA Isolation Kit

## Diagnostic testing sample preparation solutions for respiratory applications

A dynamic combination designed to propel you to new testing heights

# Respiratory tract infection testing needs continue to evolve

From the start of the COVID-19 pandemic, Thermo Fisher Scientific has enabled almost 700 million tests globally for the detection of SARS-CoV-2. Many labs invested in Thermo Scientific™ KingFisher™ automated sample purification instruments and Applied Biosystems™ MagMAX™ chemistries for their RNA and DNA purified extractions during the pandemic. As the need for testing solely for SARS-CoV-2 declines and the need to differentiate between SARS-CoV-2 and other possible respiratory pathogens increases, the need for more sophisticated testing is paramount. By combining the new Thermo Scientific™ KingFisher™ Apex Dx Purification Instrument with the Applied Biosystems™ MagMAX™ Dx Viral/Pathogen NA Isolation Kit, you can achieve accurate downstream results. This sample preparation combo is designed to be a part of a modular workflow, providing a flexible, scalable, and cost-effective solution.

## Why is molecular respiratory testing needed?

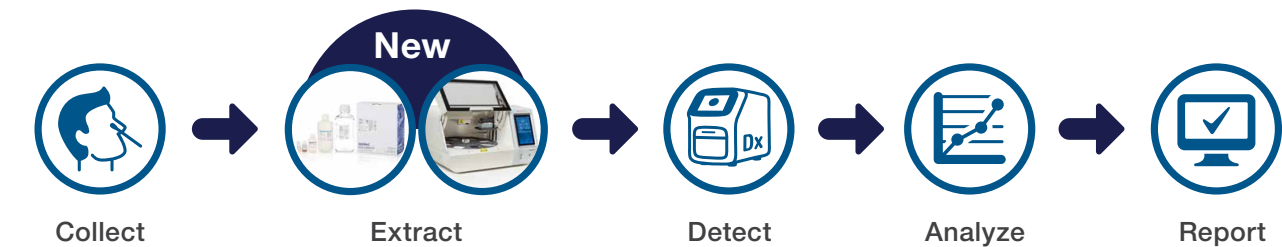
Since respiratory tract infections (RTIs) can be caused by viruses or bacteria, it's important to isolate purified nucleic acids reliably to identify the root cause of the infection. This identification enables healthcare providers to more effectively treat the infection.

- Traditional RTI testing is not as reliable—molecular testing provides the advantage of simultaneous detection of different pathogens
- Molecular testing can differentiate viral and/or bacterial infections, which is essential for selecting the appropriate treatment
- Mistaking a viral infection for bacterial infection and wrongly prescribing antibiotics can cause the patient to develop drug resistance

## Molecular diagnostic sample purification solutions—designed to help guide decisions for treating RTIs

You can choose a CE-IVD-compliant preanalytical solution by combining the KingFisher Apex Dx Purification Instrument with the MagMAX Dx Viral/Pathogen NA Isolation Kit to enable more accurate and reliable downstream results.

### Extract nucleic acid for molecular testing of RTIs with confidence



- ✓ Flexible and scalable
- ✓ Cost-effective
- ✓ Timely and trusted results
- ✓ Options for integrated software for laboratory information management system (LIMS)
- ✓ Recovery of viral and bacterial nucleic acids
- ✓ Intended for *in vitro* diagnostics

# MagMAX Dx Viral/Pathogen NA Isolation Kit

## Easy-to-use, reliable, and accurate for increased confidence

Clinical labs performing testing for RTIs need to generate high-quality results. A workflow that starts with CE-IVD-compliant nucleic acid extraction can give labs increased confidence in their downstream results. The MagMAX Dx Viral/Pathogen NA Isolation Kit helps ensure high-quality, reproducible results by leveraging the advanced formulation from the original Applied Biosystems™ MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, CE-IVD, used predominantly in respiratory research and testing.

The MagMAX Dx Viral/Pathogen NA Isolation Kit uses a magnetic bead-based technology that purifies and isolates viral and bacterial nucleic acid from human respiratory biological specimens for qPCR downstream applications.\*

\* Please refer to the Instructions for Use (IFU) for exact application scope.



### Features and benefits

#### Advanced formulation

Maximizes nucleic acid yield from routinely tested respiratory pathogens

- Improve performance by up to 2.5 C<sub>t</sub> compared to the original formulation when working with some bacterial and viral pathogens
- Little to no bead leftover, enabling precise extraction
- Optimized chemistry to minimize particulate formation and maximize shelf-life and pH stability within a buffer solution

#### Sample-type flexibility

Enable extraction of viral DNA, viral RNA, and bacterial gram-positive and gram-negative nucleic acids from the following sample types\*

-  Nasopharyngeal swab
-  Anterior nasal swab\*\*
-  Saliva
-  Sputum

\* Please refer to the Instructions for Use (IFU) for exact application scope.

\*\* Swabs collected into viral transport medium (VTM).

#### Sustainable design

From design to end of product life, incorporating more sustainable improvements to reduce environmental impacts

- **Paperless documentation**—Instructions for Use (IFU) are available online and are easily accessible via mobile devices\*
- **Less hazardous**—all components are REACH-compliant\*\*
- **Greener surfactant**—biodegradable detergent
- **Responsibly packaged**—compact product packaging sizes

\* [thermofisher.com/mvpxdx-ifu](http://thermofisher.com/mvpxdx-ifu)

\*\* REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals.



#### CE-IVD labeled

Enable trust in your diagnostic respiratory workflow



#### Expansion of testing menu

Compatible with viral and bacterial pathogens



#### Easy to use

Low-viscosity reagent solution for enhanced pipetting efficiency



#### Sustainable packaging

REACH-compliant and biodegradable reagent components

## Product specifications

MagMAX Dx Viral/Pathogen NA Isolation Kit	
Cat. No.	A52735 (up to 2,000 preps/kit)
	A52736 (up to 600 preps/kit)
Shelf life	24 months
Sample input volume	200 µL   scalable to 400 µL
Elution volume	60 µL
Time per run	~30 minutes
Pathogen targets	Viral   bacterial
Sustainability	REACH-compliant   FSC-certified*
Kit components	<ul style="list-style-type: none"><li>• Binding solution</li><li>• Wash solution</li><li>• Binding beads</li><li>• Proteinase K</li><li>• Elution buffer</li></ul>
Kit storage temperature	15°C–25°C

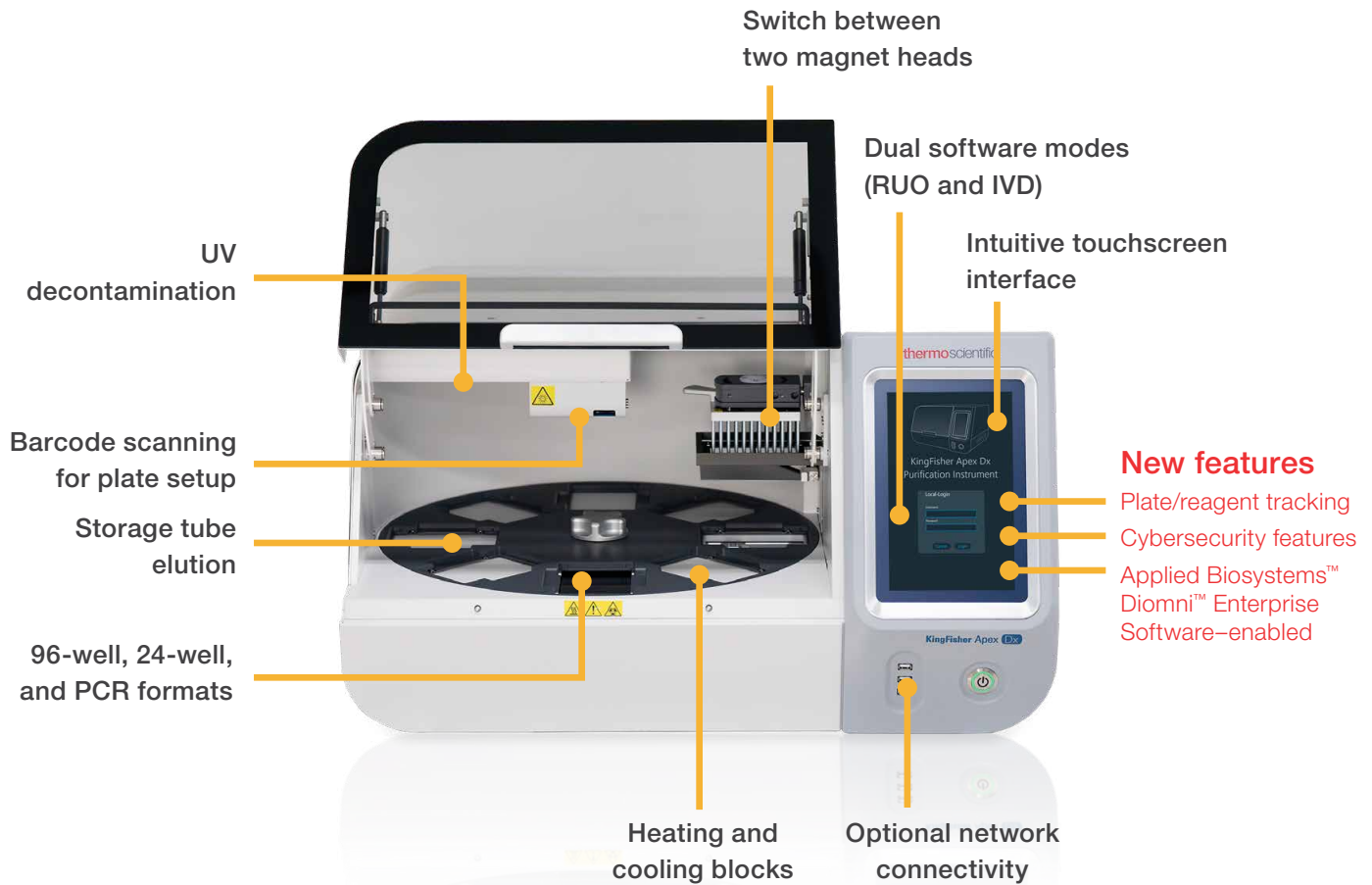
\* Package made from Forest Stewardship Council (FSC)-certified material harvested from responsibly managed forests.



# KingFisher Apex Dx Purification Instrument

## Our most innovative purification system

Clinical labs require the ability to consistently recover high-quality nucleic acids for sensitive downstream applications with maximum reproducibility. The KingFisher Apex Dx system is designed to be part of a streamlined, modular workflow providing precise results, seamless data management, and robust security features per diagnostic regulatory standards.



## Features and benefits



### Minimize risk

Highest standards of quality, safety, and performance with CE-IVD and IVDR compliance



### Improve confidence with enhanced security

Cybersecurity, auditing,\* and e-signature (SAE)\* functionalities



### Choose the software mode that suits your development stage

Seamlessly transition from clinical research to diagnostics with dual RUO and IVD software modes



### Throughput flexibility

24 or 96 deep-well plate options



### Integrate with LIMS/LIS

Diomni Enterprise Software connection to LIMS/LIS\* allows for efficient data management and result tracking



### Sample tracking\*\*

Track sample plate and reagents, in addition to barcoded plastics\*\*



### Maximize lab space

Compact benchtop instrument without the requirement of an attached computer



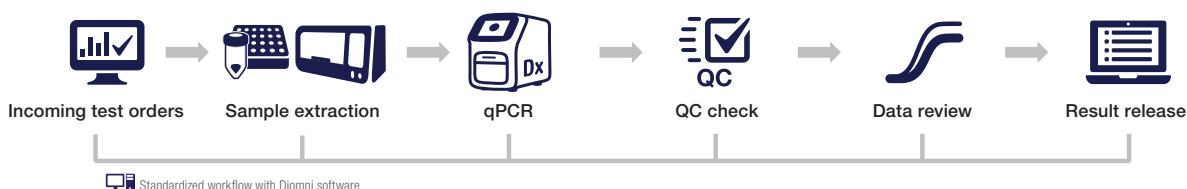
### Comprehensive service and support

Customer Concierge Services, SmartStart Orientation, and a 1-year AB Platinum warranty enhancement at no additional cost

\* Enabled in Diomni Integrated mode.

\*\* Sample tracking capability with barcoded plastics.

## Efficient data management, result tracking, and LIMS integration with optional Diomni Enterprise Software on Applied Biosystems™ QuantStudio™ 5 and 7 Dx systems



### Value for every workflow:



**Reduce errors** with simplified setup

Advanced run templates (ADFs) reduce manual entry and enforce test parameters.



**Shorten time-to-results** with interpretation

Save >2 hours\* of data review time with automated QC and interpretation.



**RUO mode: scale test menu** with flexible, open system

Create personalized workflows and adopt commercial tests.



**Uphold compliance** with connected traceability

Connect directly with LIS to receive test orders and return results.

Track samples and reagents from start to finish.

\* Compared to a manual workflow.

## Features that help you comply with requirements of accrediting bodies, including 21 CFR Part 11 regulations



### Reagent tracking\*

Information about the reagents used with each test run, including lot number and expiration date, has the ability to be stored and archived. Archived files can be retrieved when required to track samples that were tested with a given set of reagents.



### Plate tracking\*

The system enables laboratories to more easily track a particular plate, run date and time, and data files.



### E-signature and data approval\*

SAE software records test events, actions taken, dates, usernames, user roles, and activity performed, for documentation and archiving purposes.



### Cybersecurity

The system has passed penetration testing that fulfills US Food and Drug Administration (FDA) cybersecurity guidance.



### Locked IVD protocols

Improve traceability and accuracy with locked protocols for diagnostic use.

\* Enabled in Diomni Integrated mode.

## Designed with the clinic in mind

### Achieve optimal performance, reduce errors, and increase traceability

#### Plastics specially designed for KingFisher systems.

Specialized tip combs and well design enable lower elution volumes, storage tube elution, and heating and cooling consistency. Lot-specific barcodes confirm proper plate position during loading or may be used for lot tracking and documentation.

### Throughput flexibility

#### Dual mag-head capability

The KingFisher Apex Dx instrument intelligently selects the correct magnetic head based on your protocol needs. Work with small to large volume ranges by choosing from 24-well, 96-well, or other PCR formats with corresponding magnetic heads and plates.

### Simple sample storage

Option to elute in screwcap storage tubes (96- or 24-well format)

### On-deck incubation

Heat blocks recessed below deck until needed to allow precise control of sample temperature



Heating and cooling  
(4°C–100°C)

### Simple, powerful Diomni software

A single, easy-to-use software interface allows users to set up a run, access protocols, control the instrument, and conduct plate analysis.

- Quickly and easily select from a menu of protocols
- Access recent protocols, validated protocol libraries, and other instrument settings
- Rely on guided visuals for easy plate loading, protocol changes, and instrument setup







**Ordering information**

Description	Cat. No.
<b>Instrument</b>	
KingFisher Apex Dx Purification Instrument	B5400900P
KingFisher Apex Dx system with 96 PCR Head, instrument only (package Cat. No.)	A59035 (B5400910)
KingFisher Apex Dx system with 96 Combi Head, instrument only (package Cat. No.)	A59037 (B5400920)
KingFisher Apex Dx system with 96 Deep-Well Head, instrument only (package Cat. No.)	A59038 (B5400930)
KingFisher Apex Dx system with 24 Combi Head, instrument only (package Cat. No.)	A59039 (B5400940)
<b>Components of instrument</b>	
UV lamp	N21447
<b>Heating blocks</b>	
PCR Heating Block	24075910
96 Heating Block	24075920
96 Deep-Well Heating Block	24075930
24 Deep-Well Heating Block	24075940
<b>Magnetic heads</b>	
KingFisher Apex Dx 96 PCR Head	B24079910
KingFisher Apex Dx 96 Combi Head	B24079920
KingFisher Apex Dx 96 Deep-Well Head	B24079930
KingFisher Apex Dx 24 Combi Head	B24079940
<b>Plastics for 96 standard and PCR formats</b>	
KingFisher Apex 96 PCR Tip Comb	97002560
KingFisher 96 Microplate (200 µL), barcoded	97002540B
Armadillo PCR Plate, 96-well, clear, clear wells	AB2396
KingFisher 96 Tip Comb for KingFisher magnets, barcoded	97002524B
Armadillo PCR Plate, 96-well, clear, semi-skirted, low profile, clear wells	AB2496
<b>Isolation kits</b>	
MagMAX Dx Viral/Pathogen NA Isolation Kit, 2,000 preps	A52735
MagMAX Dx Viral/Pathogen NA Isolation Kit, 600 preps	A52736

Learn more at [thermofisher.com/kingfisherapexdx](https://thermofisher.com/kingfisherapexdx)  
 and [thermofisher.com/magmaxdx](https://thermofisher.com/magmaxdx)