

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Life Technologies Corporation
2130 Woodward Street
Austin
Texas
78744
USA

Holds Certificate No:

FM 57081

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The design and development, manufacture and distribution of Biotechnology reagents and kits.

For and on behalf of BSI:



Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2000-12-13

Latest Revision Date: 2017-10-31

Effective Date: 2017-10-31

Expiry Date: 2020-10-30

Page: 1 of 1



...making excellence a habit.™

MagMAX CORE Nucleic Acid Purification Kit

Product No. **A32700**
 Lot No. **1910022**
 Date of Manufacture **08OCT2019**
 Expiration Date **10JUN2020**

TEST	SPECIFICATION	RESULT
PROTEASE K		
< = 30% change in probe relative to control		
Rnase		Pass
Exonuclease		Pass
Endonuclease		Pass
Average unit activity	0.5- 1.0 U/μL	Pass
LYSIS SOLUTION		
pH	7.25 - 7.45 -	Pass
Conductivity	19 - 25 mS/cm	Pass
WASH SOLUTION 1		
Density	0.98 - 1.01 g/mL	Pass
pH	6.57 - 7.07 -	Pass

For Veterinary Use Only.

Manufactured in compliance with our ISO 9001 and ISO 13485 certified quality management system. Site: Austin, TX, USA.

Life Technologies
 5781 Van Allen Way
 Carlsbad, CA, USA 92008
www.thermofisher.com
 For inquiries, contact us at
cofarequests@thermofisher.com

**Quality Assurance
 Issued 11OCT19**

MagMAX CORE Nucleic Acid Purification Kit

Product No. **A32700**
 Lot No. **1910022**
 Date of Manufacture **08OCT2019**
 Expiration Date **10JUN2020**

TEST	SPECIFICATION	RESULT
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MAGNETIC BEADS
 < = 30% change in probe relative to control

Rnase		Pass
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ELUTION SOLUTION
 < = 30% change in probe relative to control

Rnase		Pass
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Exonuclease		Pass
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Endonuclease		Pass
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pH	6.14 - 8.40 -	Pass
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WASH SOLUTION 2
 < = 30% change in probe relative to control

Rnase		Pass
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Exonuclease		Pass
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Endonuclease		Pass
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MagMAX CORE Nucleic Acid Purification Kit

Product No. **A32700**
Lot No. **1910022**
Date of Manufacture **08OCT2019**
Expiration Date **10JUN2020**

TEST	SPECIFICATION	RESULT
Density	0.82 - 0.88 g/mL	Pass
pH	6.79 - 7.67 -	Pass

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MagMAX CORE Nucleic Acid Purification Kit

The last sample extraction method you may ever need

MagMAX CORE Nucleic Acid Purification Kit

The Applied Biosystems™ MagMAX™ CORE Nucleic Acid Purification Kit is a universal sample extraction solution designed to meet your lab's current and future testing needs. This modular technology is optimized to purify nucleic acids from the widest range of veterinary sample matrices of any sample extraction kit on the market. The MagMAX CORE Nucleic Acid Purification Kit helps make your lab more efficient by offering greater convenience and consistent performance, as well as time and cost savings.

Optimize

Labs should work smarter, not harder. The MagMAX CORE Nucleic Acid Purification Kit is optimized to help enable labs to save time and money:

- Reduced plastics significantly minimize waste and extra costs
- Room-temperature reagents improve product handling and help save on storage space and costs
- Complete workflows address 14 unique sample types to provide you with a universal solution
- A single protocol adapted for multiple Thermo Scientific™ KingFisher™ processors enables unification of all workflows regardless of throughput

The MagMAX CORE Nucleic Acid Purification Kit has been validated on the following sample matrices:

• Whole blood	• Feces
• Oral fluids	• Animal, fecal, and environmental swabs
• Tissues/organs	• Milk, mastitic milk
• Hair follicles	• Semen
• Serum	• Ear notches
• Environmental samples	• Biomed Diagnostics InPouch™ TF (<i>Tritrichomonas foetus</i>) culture
• Plasma	• Ear punches

Accelerate

Purification of nucleic acids has to be fast, and has to work the first time so that labs can keep pace with their testing needs. The latest MagMAX CORE workflow offers:

- Highly effective nucleic acid extraction (Figure 1, next page), enabling fewer workflow interruptions and greater sensitivity
- Faster instrument processing times, allowing you to determine diagnostic results more quickly
- Less preparation time because premixed washes don't require the addition of alcohols

Evolve

The diagnostic testing environment is constantly evolving. Labs need a sample extraction method that can grow with them, so the MagMAX CORE kit was designed to meet your lab's current and future testing needs.

- The MagMAX CORE kit chemical formulation is designed to be the last sample extraction method you may ever need to validate
- Flexible modules that couple easily with the "CORE" chemistry, easily introducing new applications without needing to introduce new chemistries
- New formulation and workflow that allow for downstream sequencing applications

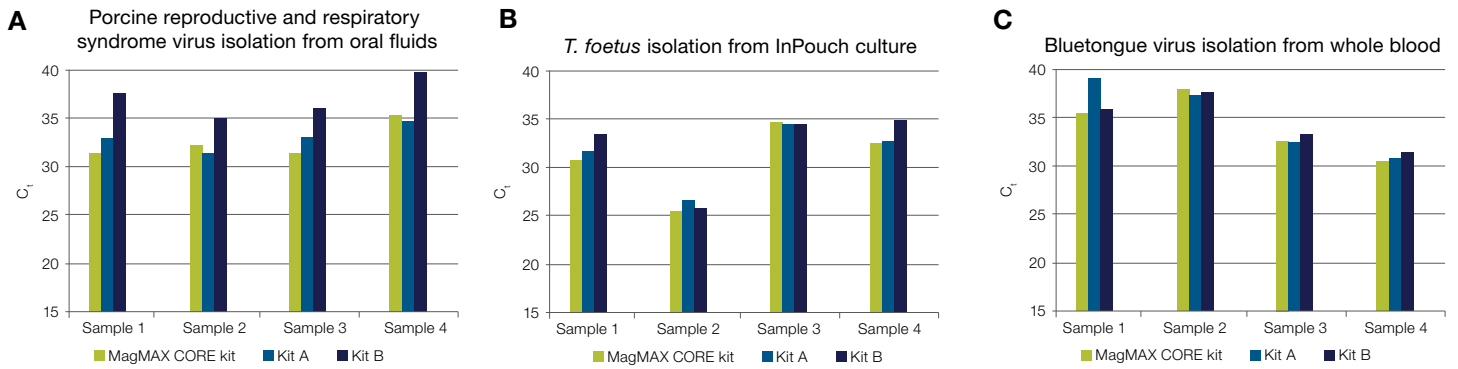


Figure 1. Performance of the MagMAX CORE Nucleic Acid Purification Kit compared to two other suppliers' nucleic acid extraction kits in detecting various pathogens from field samples: (A) oral fluids, (B) InPouch culture, and (C) whole-blood culture.

Recommended workflows for MagMAX CORE Nucleic Acid Purification Kit

Sample matrix	Nucleic acid	Recommended workflow
<ul style="list-style-type: none"> • Ear punch (circular shape, 2–3 mm diameter) in lysis solution 	<ul style="list-style-type: none"> • Viral nucleic acid 	Lysis incubation*
<ul style="list-style-type: none"> • Ear punch (circular shape, 2–3 mm diameter) in PBS • Ear notch (triangular shape, approximately 1 cm width) • Milk • Plasma • Serum 	<ul style="list-style-type: none"> • Viral nucleic acid • Bacterial DNA 	Simple
<ul style="list-style-type: none"> • InPouch TF (<i>T. foetus</i>) culture 	<ul style="list-style-type: none"> • <i>Tritrichomonas foetus</i> DNA 	
<ul style="list-style-type: none"> • Semen • Swabs—animal • Whole blood • Tissue or organ 	<ul style="list-style-type: none"> • Viral nucleic acid 	
<ul style="list-style-type: none"> • Whole blood • Swabs—animal 	<ul style="list-style-type: none"> • Genomic DNA 	Digestion
<ul style="list-style-type: none"> • Tissue or organ • Hair follicles 	<ul style="list-style-type: none"> • Genomic DNA 	
<ul style="list-style-type: none"> • Swabs—animal • Whole blood • Tissue or organ 	<ul style="list-style-type: none"> • Bacterial DNA 	
<ul style="list-style-type: none"> • Environmental samples • Feces • Swabs—environmental or fecal 	<ul style="list-style-type: none"> • Bacterial DNA** 	Complex
<ul style="list-style-type: none"> • Oral fluid 	<ul style="list-style-type: none"> • Viral nucleic acid • Bacterial DNA 	
The following workflows require an additional module:		
<ul style="list-style-type: none"> • Feces • Environmental samples • Milk 	<ul style="list-style-type: none"> • DNA from mycobacteria • DNA from spores 	MagMAX CORE Mechanical Lysis Module
<ul style="list-style-type: none"> • Mastitic milk 	<ul style="list-style-type: none"> • Total bacterial DNA 	MagMAX CORE Mastitis & Panbacteria Module***

* Recommended if overnight incubation is required.

** If concurrent isolation of viral nucleic acid and bacterial DNA is not required, use the digestion workflow.

*** Appropriate for any sample type where the target bacterial DNA is not producing sufficient yield.

MagMAX CORE Mechanical Lysis Module

The Applied Biosystems™ MagMAX™ CORE Mechanical Lysis Module is designed to meet your lab's diagnostic testing needs for *Mycobacterium avium paratuberculosis* (MAP) and other hard-to-lyse pathogens.

- Complete solution using the same MagMAX CORE kit chemistry
- Higher-quality nucleic acids from both small- (0.3 g) and large-volume (2–5 g) sample inputs
- Validated on feces, milk, and environmental samples
- Only purchase what you need

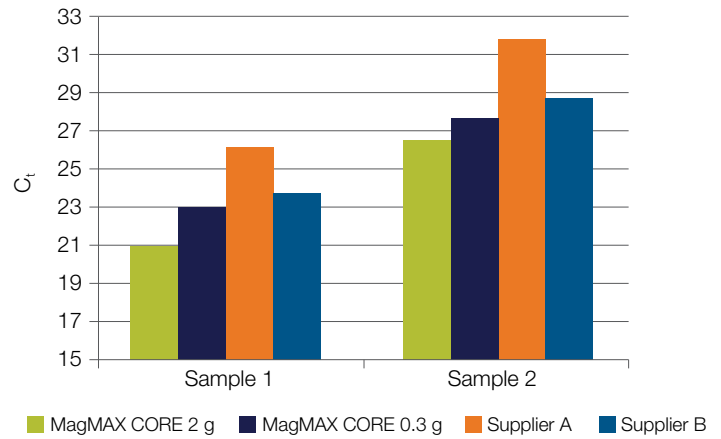


Figure 2. MAP detection from bovine feces.

MagMAX CORE Mastitis & Panbacteria Module

The Applied Biosystems™ MagMAX™ CORE Mastitis & Panbacteria Module is offered in combination with the MagMAX CORE Nucleic Acid Purification Kit to aid in the processing of all bacteria, especially those that are important in the detection of mastitis in cattle and from challenging matrices like mastitic milk.

The MagMAX CORE Mastitis & Panbacteria Module includes a specially optimized lysis solution and an alternative script to improve the recovery of nucleic acid from all bacteria, including gram-positive bacteria.

Features include:

- **Convenient**—a complete solution using the same CORE chemistry
- **Easy**—no centrifugation and no aspiration steps
- **Fast**—less than 1 hour for 96 samples
- **Flexible**—appropriate for fresh, frozen, or preserved milk samples, including samples with high somatic cell count

The MagMAX CORE kit and the MagMAX CORE Mastitis & Panbacteria Module help make your lab more efficient through greater convenience, consistent performance, and time and cost savings.

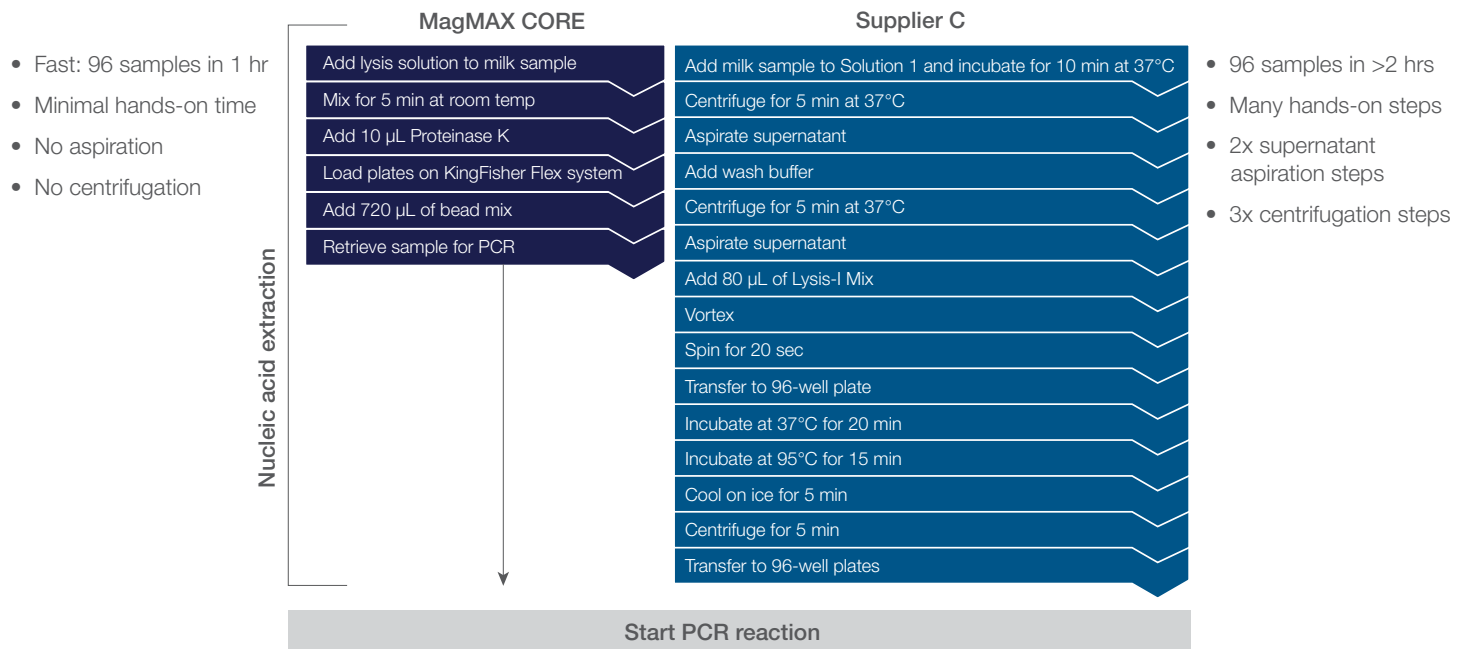
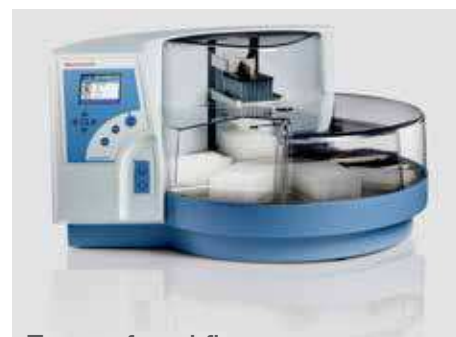


Figure 3. MagMAX CORE nucleic acid extraction kit vs. Supplier C kit.

Automate the processing of virtually any sample from any source

Thermo Scientific™ KingFisher™ magnetic particle processors are ideal for veterinary diagnostic and research labs looking to automate their MagMAX sample preparation system. For decades, our proprietary, industry-leading magnetic separation technology has enabled labs to process virtually any sample from any source. Choose from a wide range of instrument options to fit your specific budgetary, application, and throughput needs.

- **KingFisher™ Flex processor**—two separate magnetic heads provide 96- or 24-well formats, offering high-throughput or large processing volumes (20–5,000 µL)
- **KingFisher™ Duo processor**—advanced functionality, mid-throughput capacity (up to 24 samples), and large processing volumes (up to 5 mL)
- **KingFisher™ mL processor**—provides easy operation for up to 15 samples, including higher processing volumes (50–1,000 µL)



Types of workflows

- **Simple**—liquid sample matrices that require no additional sample processing
- **Digestion**—sample matrices that require Proteinase K digestion
- **Complex**—sample matrices that require a clarification step to remove inhibitors
- **Lysis incubation**—ear punches in lysis solution

Ordering information

Product	Quantity	Cat. No.
MagMAX CORE kit and module		
MagMAX CORE Nucleic Acid Purification Kit	100 reactions	A32700
MagMAX CORE Nucleic Acid Purification Kit	500 reactions	A32702
MagMAX CORE Mechanical Lysis Module	100 reactions	A32836
Combination kits for easy ordering		
MagMAX CORE Nucleic Acid Purification Kit + Mechanical Lysis Module	100 reactions	A37487
MagMAX CORE Nucleic Acid Purification Kit + Mechanical Lysis Module + Glass Microbeads	100 reactions	A37488
MagMAX CORE Nucleic Acid Purification Kit + Mastitis & Panbacteria Module	100 reactions	A40289
Additional products for specific workflows		
MagMAX CORE Glass Microbeads	100 reactions	A37489
MagMAX CORE Lysis Solution	100 reactions	A32837
PK Buffer for MagMAX-96 DNA Multi-Sample Kit	100 reactions	4489111

Find out more at thermofisher.com/animalhealth

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