

# Bioprocessing solutions

Rapid analytical solutions for  
in-process and lot-release testing

Analytics | Automation | Cell culture | Cell therapy | Purification | Single-use technologies | Supply chain logistics

# Applied Biosystems SEQ Rapid Analytical Methods

Applied Biosystems™ SEQ analytical testing products are rapid molecular methods designed for pharmaceutical manufacturing to help ensure quality and safety of your pharmaceutical products. Our rapid analytical methods offer fully integrated solutions, utilizing highly sensitive molecular technologies. These methods detect viral and microbial contaminants, identify bacterial and fungal species, quantitate process- and product-related impurities. Sensitivity, accuracy, specificity, and time to results are critical in the detection of contaminants and quantitation of impurities. As a leader in rapid molecular identification, we offer:

- Rapid molecular methods, with same-day, actionable results, typically in less than five hours
- Regulatory accepted analytical solutions for lot-release testing
- Broad use of our products in the majority of top pharma companies
- Experienced, comprehensive technical support



# Qualify with confidence and implement with success

Compliance with government and international standards requires documented verification that your systems are installed and functioning according to operational specifications. The process can be complex, time-consuming, and costly. Internal development and optimization of in-house–developed testing methods requires investment, including procurement and qualification of reagents from multiple vendors, development of SOPs, and preparation of standards and controls.

When you use our complete analytical solutions, you leverage our experience gained from solving sample preparation and testing challenges around the world.

Our knowledgeable field applications scientists can help minimize the need for internal specialized training programs and improve implementation of rapid methods. Our Installation Qualification and Operational Qualification (IQ/OQ) Service verifies and records the system’s ability to meet standard functional criteria after installation or reinstallation.

The IQ/OQ process involves a comprehensive set of tests to ensure data is acquired, processed, and retains integrity according to designed and configured specifications. Our Implementation Program assists in lab design, setup, and technician training.

No one understands your systems better than the people who design, develop, and support them. Trust our trained and certified specialists to help you through your IQ/OQ as part of your overall system validation.



## Warrington, UK facility

Certification status: ISO 9001, ISO 13485, OHSAS18001, AFNOR, ISO 18385

### • Key capabilities

- Multi-scale clean (DNA-free) formulation and manufacturing
- Real-time PCR
- Automated, human contact–free manufacturing
- Cell line and plasmid growth and manipulation
- Human identification products (STR kits and associated sample prep and DNA quantification kits; allelic ladders)
- Pharma analytics (microbial DNA extraction and real-time PCR target identification, including mycoplasma detection)
- Food and environmental safety (food pathogen detection, GMO detection, flu virus detection, sample preparation)
- PCR reagents (*Taq* polymerase, master mixes, size standards)
- Oligo products
- Protein sequencing reagents

# Impurity testing

## resDNASEQ Host Cell Residual DNA Quantitation System

### Host cell residual DNA quantitation

The removal of host cell impurities is a critical step in the purification of biopharmaceutical products. A major challenge is the accurate and sensitive quantitation of host cell DNA impurities in both in-process and drug substance samples.

The hallmark of a great system is not that it makes one aspect better, but that it makes everything better—in this case, highly efficient process characterization. The Applied Biosystems™ resDNASEQ™ Host Cell Residual DNA Quantitation System enables greatly reduced retesting, lower sample cost compared to outsourcing, and reduced unit operation costs. In summary, you can enjoy greater productivity and utilization of your valuable time, effort, and resources.

The resDNASEQ Host Cell Residual DNA Quantitation System is the first and only fully integrated real-time qPCR system for quantitation of residual host cell DNA, including a highly characterized DNA reference standard. This system is an established industry-leading solution with wide adoption for routine use at major biopharma companies.



### The resDNASEQ Host Cell Residual DNA Quantitation System offers:

- **Assays for commonly used cell lines**—CHO, HEK293, human, *E. coli*, Vero, MDCK, *Pichia pastoris*, and NSO
- **Rapid testing and streamlined workflow**—time-to-results typically under 5 hours
- **Ultrahigh sensitivity and specificity**—no cross-reactivity to unrelated DNA
- **Reliable performance**—consistent performance kit to kit, lot to lot, year to year
- **Optimized sample prep**—quantitative DNA recovery with high precision
- **Comprehensive product solution**—all-inclusive kits with standards and all reagents
- **Worldwide support network**—expert training, technical support, validation, and regulatory guidance

Find out more at

[thermofisher.com/resdnaseq](https://www.thermofisher.com/resdnaseq)

# resDNASEQ Host Cell Residual DNA Quantitation System



## Ordering information

Description	Cat. No.
resDNASEQ Quantitative CHO DNA Kit	4402085
resDNASEQ Quantitative CHO DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit	4413713
resDNASEQ Quantitative HEK293 DNA Kit	A46014
resDNASEQ Quantitative HEK293 DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit	A46565
resDNASEQ Human Residual DNA Quantitation Kit	A26366
resDNASEQ Human Residual DNA Quantitation Kit with PrepSEQ Residual DNA Sample Preparation Kit	A27335
resDNASEQ Quantitative <i>E. coli</i> DNA Kit	4458435
resDNASEQ Quantitative <i>E. coli</i> DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit	4460366
resDNASEQ Quantitative Vero DNA Kit	4458444
resDNASEQ Quantitative Vero DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit	4460367
resDNASEQ Quantitative NS0 DNA Kit	4458441
resDNASEQ Quantitative NS0 DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit	4460364
resDNASEQ Quantitative <i>Pichia pastoris</i> DNA Kit	4464336
resDNASEQ Quantitative <i>Pichia pastoris</i> DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit	4464340
resDNASEQ Quantitative MDCK DNA Kit	4464335
resDNASEQ Quantitative MDCK DNA Kit with PrepSEQ Residual DNA Sample Preparation Kit	4464339
PrepSEQ Residual DNA Sample Preparation Kit (sample prep only)	4413686

Note: Each resDNASEQ kit includes 100 reactions.



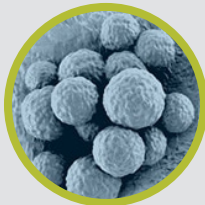
# Contaminant testing

## MicroSEQ Microbial Identification System

### Microbial identification

Bacterial and fungal contamination of raw materials and production facilities negatively impact product quality and safety. The use of a genetic approach for microbial detection based on the 16S rDNA gene for bacteria or a specific genomic region of the large-subunit rDNA gene for fungi can help prevent delayed product releases, back orders, and even recalls.

Identify thousands of bacterial and fungal species typically in under 5 hours with the Applied Biosystems™ MicroSEQ™ Microbial Identification System.



#### Validated

We conduct a rigorous validation process for accurate taxonomic information of new and existing bacterial and fungal species. From sequence information entry and genus- and species-level validation to revalidation of existing MicroSEQ library entries—all done by trained personnel—the process is designed to offer the most comprehensive, accurate, reliable libraries available for your pharma QC testing.



#### Curated

We closely evaluate our libraries and curate for what really matters to our pharma QC customers—quality and accuracy. We have increased the number of *Candida*, *Cladosporium*, *Aspergillus* species, and added species for 223 new genera for our fungal database. We partner with the Westerdijk Fungal Biodiversity Institute, part of the Royal Netherlands Academy of Arts and Sciences, for the latest and reliable sequence information for mycological identification and classification.



#### Updated

Increasing the power of this database, We regularly update the MicroSEQ ID Software Library. This helps ensure that your MicroSEQ ID database is always up to date by providing periodic updates of quality-checked and validated bacterial and fungal sequences.

### Ordering information

Description	Cat. No.
MicroSEQ Rapid Microbial ID System II with 3500 Genetic Analyzer	Contact sales rep
MicroSEQ Rapid Microbial ID System II with 3500xL Genetic Analyzer	Contact sales rep
Fast MicroSEQ 500 16S rDNA PCR Kit	4370489
MicroSEQ 500 16S rDNA PCR Kit	4348228
MicroSEQ 500 16S rDNA Sequencing Kit	4346480
MicroSEQ Full Gene 16S rDNA PCR Kit	4349155
MicroSEQ Full Gene 16S rDNA Sequencing Kit	4347484
Fast MicroSEQ D2 rDNA Fungal PCR Kit	4382397
MicroSEQ D2 rDNA Fungal PCR Kit	4349153
MicroSEQ D2 Fungal rDNA Sequencing Kit	4347481
MSID V3.1.3 SW + Library Bundle (excluding supplemental library)	A46364
MSID V3.1.3 LITE SW + Library Bundle (excluding supplemental library)	A46530
MSID 16s rDNA 500 Supplemental Library v2019	A47133

Find out more at

[thermofisher.com/microseq](http://thermofisher.com/microseq)

# Contaminant testing

## MycoSEQ *Mycoplasma* Detection System

### **Mycoplasma species detection**

Mycoplasmas, the smallest known free-living organisms, are relatively common bacterial contaminants of mammalian cell cultures. Detection of *Mycoplasma* species is difficult, sometimes impossible, when using traditional microbiological techniques such as the 28-day culture test. Regulatory guidance requires that all products derived from mammalian cell culture be tested for the presence of mycoplasmas. In 2007, the European Pharmacopoeia began recommending the use of nucleic acid tests, including real-time PCR, as an alternative method for traditional mycoplasma detection after proper method validation.

The Applied Biosystems™ MycoSEQ™ *Mycoplasma* Detection Kit is a fully integrated solution for real-time PCR-based mycoplasma detection. Used throughout the bioproduction workflow, the MycoSEQ method is an alternative to costly, time-consuming culture-based tests often done externally by contract labs, which can take up to 28 days. Following validation, regulatory review, and acceptance, the MycoSEQ assay and method are now used by many global manufacturers of different biotherapeutics modalities. Thermo Fisher holds two patents from the US Patent and Trademark Office for its MycoSEQ real-time PCR-based mycoplasma detection assay. These patents cover the assay's proprietary multiplexed PCR primer approach and the discriminatory positive/extraction control, which are new innovations to real-time PCR that enable this rapid test for mycoplasmas to meet the rigorous requirements of regulatory authorities and manufacturers.



- **Rapid testing and streamlined workflow**—time-to-results typically in under 5 hours
- **Comprehensive solution**—detection of more than 90 *Mycoplasma* species
- **Demonstrated sensitivity**—detects less than 10 copies/reaction
- **Proven specificity**—no cross-reactivity with non-mycoplasma DNA
- **Proven technology**—PrepSEQ sample preparation reagents enable high-efficiency DNA recovery
- **Discriminatory positive/extraction control**—minimize risk of false-positive results
- **Dependable and efficient**—rapid analysis of results and automatic presence/absence call (based on acceptance criteria) with Applied Biosystems™ AccuSEQ™ Real-Time PCR Detection Software

Find out more at

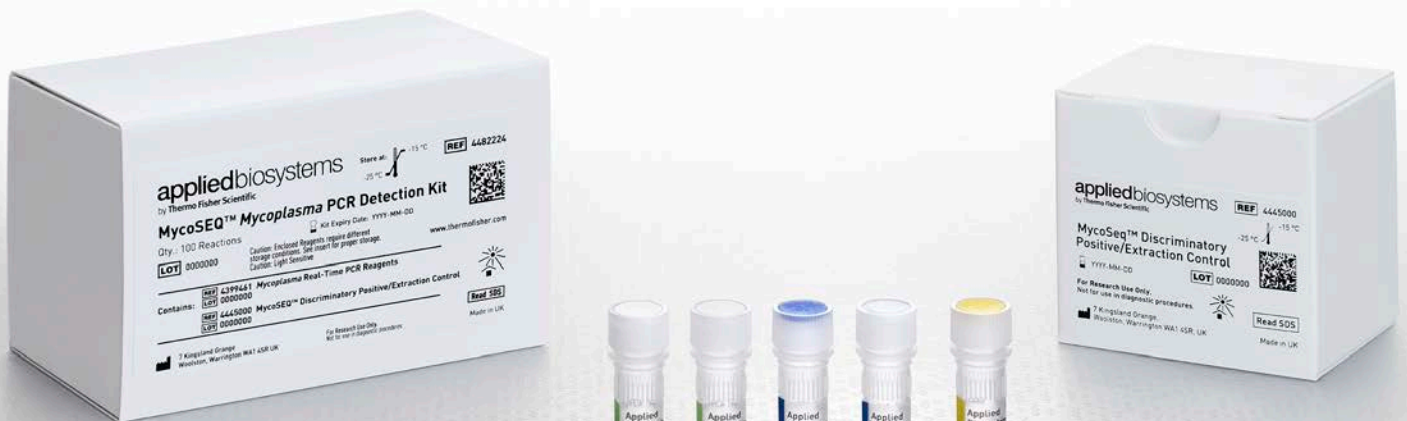
[thermofisher.com/mycoseq](https://thermofisher.com/mycoseq)

# Mycoseq *Mycoplasma* Detection System



## Ordering information

Description	Cat. No.
Mycoseq <i>Mycoplasma</i> Detection Kit, with Discriminatory Positive Control	4460623
Mycoseq <i>Mycoplasma</i> Detection Kit, with Discriminatory Positive Control (sample prep included)	4460626





# Contaminant testing

## ViralSEQ Detection System

### Adventitious virus testing

Mouse minute virus (MMV) and vesivirus contamination are potential threats to mammalian cell culture manufacturing processes. Multiple cell culture manufacturing facilities have been negatively impacted following contamination with these viruses. The Applied Biosystems™ ViralSEQ™ Detection System is an integrated DNA purification and real-time PCR-based test designed for rapid and sensitive detection of MMV and vesivirus from a wide range of sample types.

- **Comprehensive workflow solution**—kit includes assay, sample prep, instrument, and analysis
- **Proven TaqMan technology**—highly sensitive detection down to 10 genome copies per reaction (viral particles equivalent to 0.002 TCID50)
- **Highly specific**—no cross-reactivity with unrelated DNA
- **Rapid time to results**—see results typically in under 5 hours
- **Assays for most common CHO cell culture contaminants**—MMV, vesivirus
- **Discriminatory positive/extraction control**—Minimized risk of false-positive results from accidental cross-contamination with control DNA
- **Reliable performance**—consistent performance kit to kit, lot to lot, year to year
- **Worldwide support network**—expert training, technical support, validation, and regulatory guidance



### Ordering information

Description	Cat. No.
ViralSEQ Mouse Minute Virus (MMV) Detection System	4444415
ViralSEQ Vesivirus Detection Kit	4448398C

Find out more at

[thermofisher.com/viralseq](https://thermofisher.com/viralseq)

# Instruments and analysis software

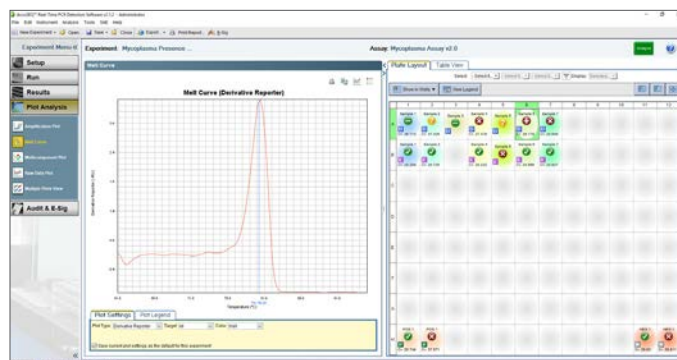
## Real-time PCR systems and AccuSEQ software

### Real-time PCR detection software

Applied Biosystems™ AccuSEQ™ Real-Time PCR Detection Software supports the unique needs of analytical testing of contaminants and impurities during the biopharmaceutical manufacturing process, as well as routine qPCR assays. AccuSEQ software is part of the integrated workflow for mycoplasma detection, residual host cell protein (HCP) quantitation, residual Protein A quantitation, and residual DNA quantitation. Advanced algorithms built in to the AccuSEQ real-time PCR software automate the analysis of presence/absence calls for the MycoSEQ *Mycoplasma* Detection Assay based on the melting temperature ( $T_m$ ), cycle at threshold (Ct), and the derivative value (Dv) of the test sample and inhibition control, according to user specifications. Nonlinear curve fitting enables rapid analysis of ProteinSEQ Protein Quantitation System data. Next-generation algorithms is designed to deliver accurate quantitation data for the resDNASEQ Host Cell Residual DNA Quantitation System with automatic calculation of dilution adjusted quantity, % recovery, and % CV.

### Key features

- **Streamlined workflow**—integrates with Applied Biosystems™ QuantStudio™ 5 and 7500 Fast real-time PCR instruments
- **High efficiency and ease of use**—single software platform for multiple SEQ real-time PCR assays
- **Proven technology**—supported and fully tested for Windows 10 operating system
- **Worldwide support network**—helps enable 21 CFR Part 11 compliance
- **Comprehensive solution**—features ensure full traceability



### Ordering information

Description	Cat. No.
AccuSEQ 2.1.1 Real-Time PCR Detection Software	4443420
7500 Fast Real-Time PCR System, with Dell Tower	4365464
Pharmaceutical Analytics QuantStudio 5 Real-Time PCR System	A31670

Find out more at

[thermofisher.com/accuseq](https://www.thermofisher.com/accuseq)

# Sample preparation products

## PrepSEQ Nucleic Acid Extraction Kits

### Sample preparation kits

Applied Biosystems™ PrepSEQ™ chemistry enables universal sample preparation for contaminant and impurity testing used in multiple applications, including residual host cell DNA quantitation, *Mycoplasma* detection, and viral detection. It offers performance for quantitative recovery, high reproducibility, and consistent performance across a broad range of complex matrices.

- **Multi-assay, time-saving, cost-effective**—DNA extraction for *Mycoplasma*, MMV, vesivirus, and residual host cell DNA
- **Highly efficient, reproducible recovery** of DNA from complex samples
- **Superior performance**—enable consistent performance with complex matrices
- **Universal sample prep for nucleic acid extraction**—residual host cell DNA, *Mycoplasma*, MMV, vesivirus
- **Flexible throughput and workflow options**—manual and automated workflows



### Ordering information

Description	Cat. No.
PrepSEQ 1-2-3 Nucleic Acid Extraction Kit	4452222
PrepSEQ Residual DNA Sample Preparation Kit	4413686
PrepSEQ Express Nucleic Acid Extraction Kit	4466351

Find out more at

[thermofisher.com/prepseq](https://thermofisher.com/prepseq)

# Sample prep automation systems

## Automated nucleic acid extraction

### Automation systems

Boost lab productivity by reducing hands-on sample preparation time, increasing throughput, reducing costs, and improving the quality of sample extractions. Intuitive to operate and pre-loaded with protocols, our automated sample preparation instruments help meet your throughput needs.

- **Applied Biosystems™ AutoMate™ Express™ Nucleic Acid Extraction System**—ideal for in-process testing of contaminants and impurities, that easily integrates into existing workflows and lab configurations, this closed system offers out-of-the-box automation with prefilled, well-established Applied Biosystems™ PrepSEQ™ Express cartridges to minimize the risk of cross-contamination.
- **Thermo Scientific™ KingFisher™ Flex 96 Deep-Well Magnetic Particle Processor**—a premier automated platform designed to meet your high-throughput needs, this system seamlessly incorporates the rapid, reliable, and cost-effective magnetic bead-based extraction of nucleic acids in a 96-well automation system, providing excellent reproducibility and quality.

Whatever your throughput or automation requirements, we can help you find the right solution.



### Ordering information

Description	Cat. No.
AutoMate <i>Express</i> Nucleic Acid Extraction System	4467754
Pharma KingFisher Flex 96 Deep-Well Magnetic Particle Processor	A31508



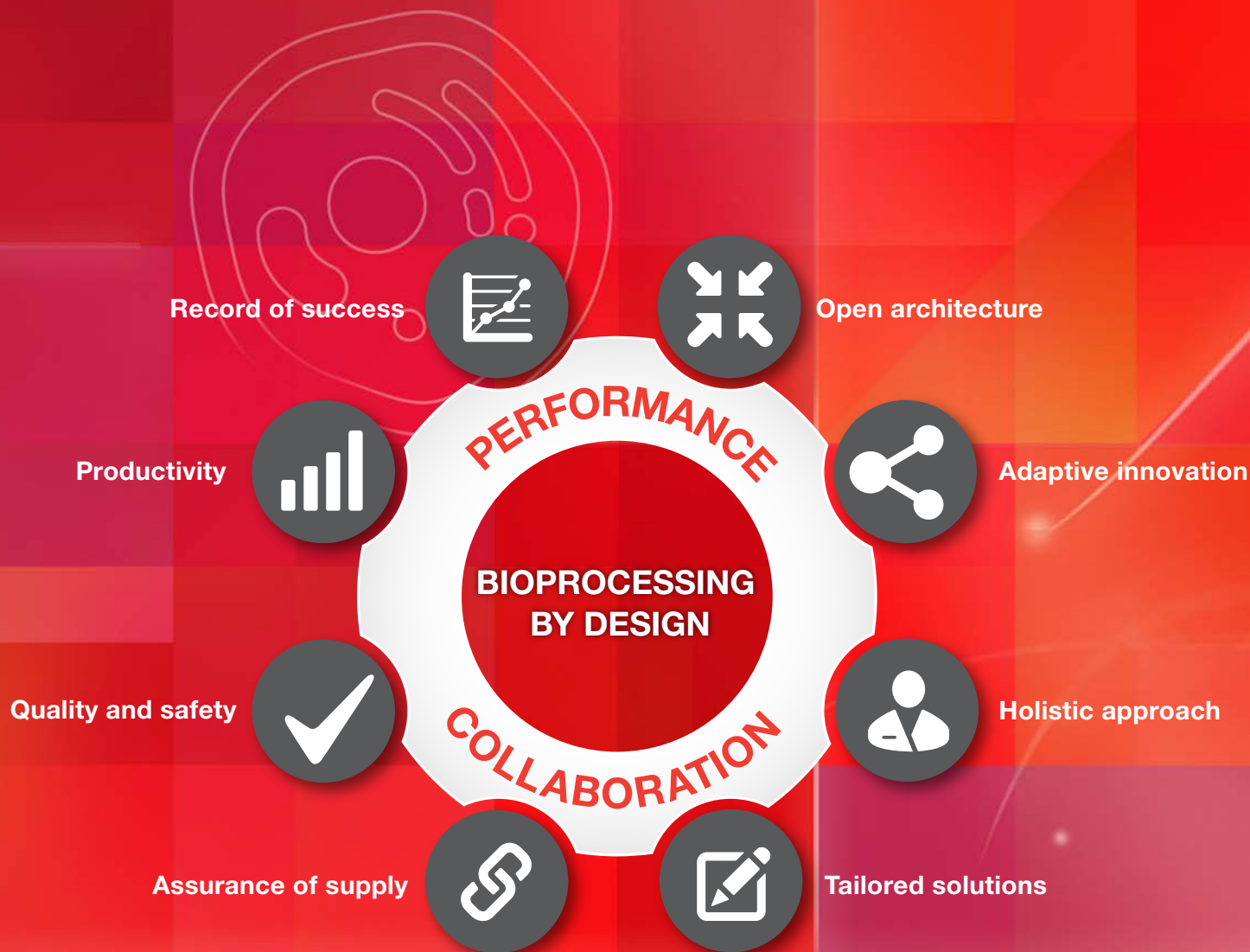
AutoMate *Express* Nucleic Acid Extraction System



KingFisher Flex 96 Deep-Well Magnetic Particle Processor

Find out more at  
[thermofisher.com/automate](http://thermofisher.com/automate)





Find out more at [thermofisher.com/bioprocessing](https://thermofisher.com/bioprocessing)

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SCIENTIFIC

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