

Pharmaceutical analytics for monoclonal antibody (mAb) therapeutic development

Help ensure the safety, purity, and efficacy of your mAb therapeutic while driving efficiency in your production process

During therapeutic antibody production, regulatory requirements help ensure that final products are safe, effective, and of high quality. These requirements, guided by global regulatory agencies, pharmacopoeias, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and other bodies such as the World Health Organization (WHO), involve comprehensive tests and analyses throughout the development and manufacturing processes.

Thermo Fisher Scientific offers an extensive portfolio of analytical testing solutions to support the therapeutic antibody manufacturing workflow. Based on rapid molecular methods like real-time PCR (qPCR), digital PCR (dPCR), and DNA sequencing, Applied Biosystems™ SEQ analytical testing solutions enable high sensitivity, fast results, and increased throughput—including optional automated sample preparation processes to improve efficiency when testing hundreds to thousands of samples during process characterization and validation. SEQ analytical testing solutions play a vital role in helping efficiently develop and control manufacturing processes while helping meet regulatory requirements for lot-release testing.

Product safety:

- Mycoplasma testing
- Adventitious virus testing
- Sterility testing

Product quality:

- Residual host cell DNA quantitation

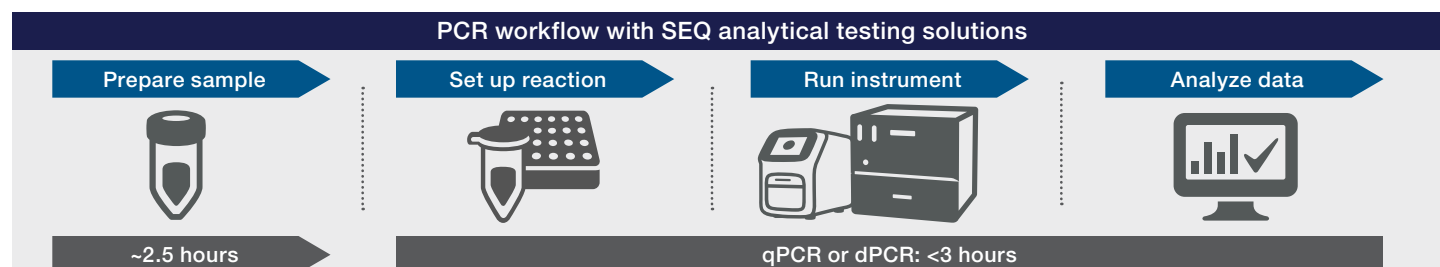
Environmental monitoring:

- Microbial detection and identification
- Sterility testing

Benefits

- Analyze your product throughout the development process to help ensure safety and quality
- Leverage a fully integrated solution, including kits, instruments, and analysis software, to save time, free up development resources, and obtain more consistent results to help therapies get released more quickly
- Enable the design and execution of comprehensive host cell DNA clearance studies, thereby enhancing the therapeutic development and validation of the purification process and helping meet regulatory requirements

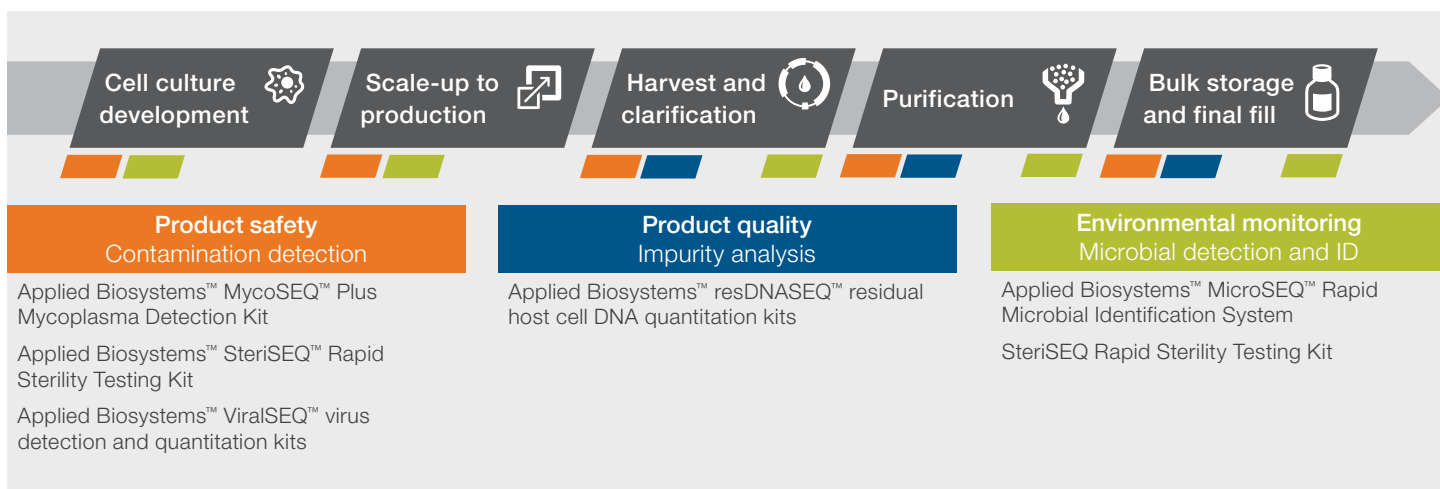
Simple PCR-based workflow*



* Microbial identification solutions employ an endpoint PCR to sequencing workflow.

Analytical solutions for your mAb production workflow

SEQ analytical testing solutions provide integrated, internally validated solutions for upstream and downstream process testing. Known for their sensitivity, reliability, and fast time-to-results, SEQ analytical testing solutions enable simple, easy-to-implement workflows and are backed by a world-class service and support team that can help you from evaluation through validation.



Featured products

MycoSEQ Plus Mycoplasma Detection Kit

- **Fast**—qPCR-based workflow delivers actionable results in less than 5 hours
- **Sensitive**—meets or exceeds the recommended regulatory guidance of 10 colony-forming units per mL (CFU/mL) or 10 genome copies per mL (GC/mL) for a variety of *Mycoplasma* species
- **Comprehensive**—multiplex assay enables simultaneous screening of >200 *Mycoplasma* species, including all key species listed in the US, European, and Japanese pharmacopeias (USP, EP, and JP)



Applied Biosystems™ resDNASEQ™ Quantitative CHO DNA Kit

- **Simple**—easy-to-use with actionable results in less than 5 hours
- **Sensitive**—limit of quantitation as low as 1.5 pg/mL for CHO DNA in your sample extract ion; 10x more sensitive than the CHO assay recommended by the USP
- **Specific**—designed using extensive bioinformatics to detect CHO DNA with no cross reactivity to unrelated DNA
- **Versatile**—solutions available for both qPCR and dPCR



Applied Biosystems™ kits, libraries, and software ordering information

Description	Cat. No.	
	qPCR	dPCR
MycoSEQ kit		
MycoSEQ Plus Mycoplasma Detection Kit	A55124	
SteriSEQ kit		
SteriSEQ Rapid Sterility Testing Kit	A57185	
resDNASEQ kits		
resDNASEQ Quantitative/dPCR CHO DNA Kit	4402085	A59366
resDNASEQ Quantitative/dPCR <i>E. coli</i> DNA Kit	4458435	A57017
resDNASEQ Human Residual DNA Quantitation Kit	A26366	
resDNASEQ Quantitative/dPCR NS0 DNA Kit	4460364	
resDNASEQ Quantitative/dPCR HEK293 DNA Kit	A46565	A59365
resDNASEQ Quantitative/dPCR E1A DNA Fragment Length Kit	A51970	A55852
MicroSEQ PCR kits		
Fast MicroSEQ 500 16S rDNA PCR Kit, with protocol and quick reference card	4370489	
MicroSEQ Full Gene 16S rDNA PCR Kit, with protocol and quick reference card	4349155	
Fast MicroSEQ D2 LSU rDNA Fungal PCR Kit, with protocol and quick reference card	4382397	
MicroSEQ sequencing kits		
MicroSEQ 500 16S rDNA Sequencing Kit, with protocol and quick reference card	4346480	
MicroSEQ Full Gene 16S rDNA Sequencing Kit, with protocol and quick reference card	4347484	
MicroSEQ D2 rDNA Fungal Sequencing Kit, with protocol and quick reference card	4347481	
MicroSEQ libraries and software		
MicroSEQ ID 16S rDNA 500 Microbial Library, v2019	A47134	
MicroSEQ ID 16S rDNA Full Gene Library v2.0	4371295	
MicroSEQ ID Fungal Gene Library, v2018	A47135	
MicroSEQ ID 16S rDNA 500 Supplemental Library, v2019	–	