

Count on connections

Enable 21 CFR Part 11 compliance

Biotech

Regulatory compliance to 21 CFR Part 11 is critical to helping ensure a scalable process from discovery to commercialization. Part 11 of the 21 CFR (Code of Federal Regulations Title 21—Food and Drugs) is a document issued by the United States Food and Drug Administration (FDA) that outlines the criteria for accepting electronic records and signatures, defining the requirements for use of electronic documents in place of paper documents.

Compliance with this rule provides an opportunity to use electronic records and signatures during the manufacturing process, removing the burdensome process of physical document control. In addition, it may help increase operational efficiency, improve system security, and decrease the number of records with defects. Discover our portfolio of equipment and products that can enable compliance for your process at scale.

Instruments that support 21 CFR Part 11 compliance

Cell therapy development

- Gibco™ CTS™ Rotea™ Counterflow Centrifugation System
- Gibco™ CTS™ Xenon™ Electroporation System
- Thermo Scientific™ CryoMed™ Controlled-Rate Freezers with OPC UA

Cell analysis

- Invitrogen™ Countess™ 3 and Countess™ 3 FL Automated Cell Counters
- Invitrogen™ Attune™ CytPix™ Flow Cytometer
- Thermo Scientific™ microplate readers

Protein analysis

- Invitrogen™ Luminex® instruments
- Invitrogen™ iBright™ imaging systems

Sample analysis

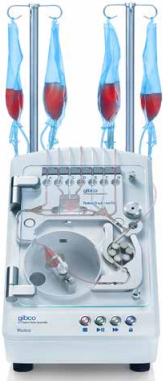
- Thermo Scientific™ NanoDrop™ One and NanoDrop™ One^c UV-Vis spectrophotometers
- Thermo Scientific™ NanoDrop™ Eight UV-Vis Spectrophotometer

Genetic analysis

- Applied Biosystems™ SeqStudio™ Flex Genetic Analyzers
- Ion Torrent™ Genexus™ System
- Applied Biosystems™ QuantStudio™ IVD real-time PCR systems



Cell therapy development



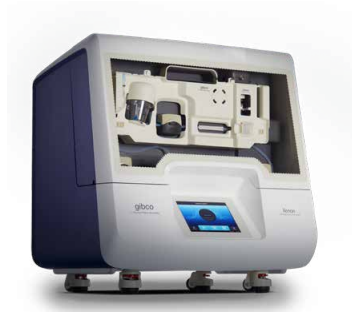
CTS Rotea Counterflow Centrifugation System

Closed cell-processing system

- **Process flexibility**—user programmable software enables you to create and optimize a broad range of protocols for cell separation, washing, and concentration
- **High cell recovery and viability**—gentle processing enables >95% cell recovery while maintaining cell viability
- **Low output volumes**—proprietary technology can deliver as little as 5 mL of concentrate
- **Research through commercial manufacturing**—the closed single-use kit enables sterile processing, and an Open Platform Communications Unified Architecture (OPC UA) interface enables connectivity to a 21 CFR Part 11-compliant system

Find out more at

thermofisher.com/rotea



CTS Xenon Electroporation System

Closed, scalable electroporation system

- **High speed and large volume**—transfect up to 2.5×10^9 T cells/25 mL in less than 25 minutes
- **Scalable, proven performance and viability**—up to 90% gene knockout and 80% cell viability when used with Gibco™ CTS™ TrueCut™ Cas9 Protein
- **Process flexibility**—user-programmable system enables you to create and optimize electroporation protocols for various cell types and payloads, from process development through commercial manufacturing
- **Efficient nonviral transfection**—can be used to deliver DNA, RNA, and protein payloads
- **Closed-system processing**—CTS™ Xenon™ MultiShot™ Electroporation Cartridge helps enable sterile welding to PVC or C-Flex™ tubing

Find out more at

thermofisher.com/xenon



CryoMed Controlled-Rate Freezers with OPC UA

Freeze and protect your cells with reliability and data traceability

- Onboard OPC UA server—Ethernet only
- UI logs usage and events, supporting compliance with 21 CFR Part 11 requirements
- User security—three levels of user accessibility
- USB data export of PDF file run logs supports 21 CFR Part 11 compliance
- FDA-listed Class II medical device, 510(k) exempt (US version only)
- Real-time run monitoring for sample protection
- Reliable temperature performance for high-throughput usage

Find out more at

thermofisher.com/cryomed



Countess 3 and Countess 3 FL Automated Cell Counters

Automate your cell counting

- **Accurate**—developed with a deep-learning neural network algorithm that can count clumpy cells, cells with debris, and peripheral blood mononuclear cells
- **Fast**—counts live and dead cells, measures viability, reports average cell size, and saves data with a single touch, in about 20 seconds
- **Convenient**—requires no cleaning or routine maintenance; high-resolution capacitive touchscreen and simple user interface provide quick start-up and requires minimal training

Find out more at

thermofisher.com/countess



Attune CytPix Flow Cytometer

Efficient, flexible, and transformative flow cytometer with up to 14 colors

- **High sensitivity at all sample rates**—maintains precise alignment due to the acoustic focusing, even at sample rates of up to 1,000 $\mu\text{L}/\text{min}$
- **Save time**—10x faster than traditional hydrodynamic focusing systems with no loss in data quality
- **Clog-resistant**—easily handles larger, clumpy cell samples that other flow cytometers can't process
- **Less work**—a flow cytometry analyzer with brightfield imaging capabilities to confirm cell morphology and gating strategy
- **Rapid time-to-results**—obtain images while maintaining standard acquisition speeds for flow cytometry

Find out more at

thermofisher.com/attune



Thermo Scientific microplate readers

Flexibility, performance, and ease of use for a variety of microplate assays

- **Thermo Scientific™ Varioskan™ LUX Multimode Microplate Reader**
- **Thermo Scientific™ Multiskan™ FC Microplate Photometer and SkyHigh Microplate Spectrophotometer**
- **Thermo Scientific™ Fluoroskan™ FL Microplate Fluorometer and Luminometer**
- **Thermo Scientific™ Luminoskan™ Microplate Luminometer**

For fluorescence, absorbance, luminescence, time-resolved fluorescence (TRF), or AlphaScreen™ assays, Thermo Scientific microplate readers have features to help you save time and maximize productivity, including:

- Autocalibration
- Easy export to Microsoft™ Excel™ format
- Automation readiness with robot compatibility
- No limit to the number of computers on which you can install our intuitive Thermo Scientific™ SkanIt™ Software
- Ready-to-use protocols available in an extensive online protocol library

Find out more at

thermofisher.com/platereaders

Protein analysis



Luminex instruments

Protein and gene expression analysis on the Luminex platform

- Invitrogen™ Luminex® 200™ Instrument System
- Invitrogen™ Luminex® FLEXMAP 3D® Instrument System
- Invitrogen™ Luminex® xMAP® INTELLIFLEX™ instruments

The Luminex xMAP technology of the instruments combines advanced fluidics, optics, and digital signal processing with fluorescently dyed microspheres, which enables the quantitation of multiple nucleic acid or protein targets from a single sample with Invitrogen™ ProcartaPlex™ and QuantiGene™ Plex assays.

Find out more at

thermofisher.com/luminex

Sample analysis



NanoDrop UV-Vis spectrophotometers

Rapid microvolume analysis of DNA, RNA, and protein samples

- NanoDrop One and NanoDrop One^c UV-Vis spectrophotometers
- NanoDrop Eight UV-Vis Spectrophotometer

Innovative Thermo Scientific™ Acclaro™ Sample Intelligence technology is built into the instruments for improved measurement accuracy and contaminant identification. Quantify and qualify DNA, RNA, and protein samples in seconds with only 1–2 µL. Analyze up to eight samples at once with the NanoDrop Eight UV-Vis Spectrophotometer.

Find out more at

thermofisher.com/nanodrop



iBright imaging systems

Stunningly easy western blot and gel imaging

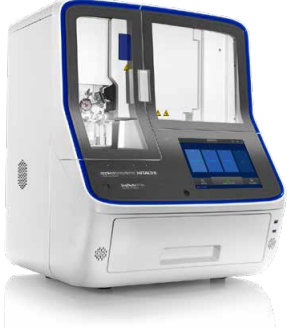
- **Powerful imaging**—Smart Exposure™ technology for rapid determination of optimal exposure time, combined with a sensitive, 9.1 MP camera
- **Load and go**—logical interface, and automatic zoom, focus, and sample rotation* simplify the image capture workflow
- **Data analysis in seconds**—overlay molecular weight markers, perform densitometry analysis, and normalize data using housekeeping proteins or total lane protein
- **Bring your blots to life**—multiplex with the five fluorescence channels of the Invitrogen™ iBright™ FL1500 Imaging System; capture signal from up to four proteins at once to measure protein(s) of interest against loading controls to better discriminate two or more proteins of similar molecular weight, or to use western blotting as an analytical tool for complex protein pathways

* Automatic rotation available only on the iBright FL1500 Imaging System and the Invitrogen™ iBright™ CL1500 Imaging System.

Find out more at

thermofisher.com/ibright

Genetic analysis



SeqStudio Flex Genetic Analyzers

Flexibility, usability, connectivity, and serviceability in a mid-throughput genetic analyzer

SeqStudio Flex Genetic Analyzers deliver the high level of Sanger sequencing and fragment analysis data quality and reliable performance that scientists need, while leveraging design improvements and technological advances for increased flexibility, easier operation, enhanced connectivity, and remote serviceability.

Find out more at

thermofisher.com/seqstudioflex



Genexus System

An end-to-end next-generation sequencing (NGS) platform to automate your NGS workflow

- **NGS results in less than a day**—two touchpoints, 20 minutes hands-on time
- **Simple workflow**—load and go, from nucleic acid extraction to report
- **Consumables to minimize manual steps**—ready to load, and helps save time and reduce user errors
- **Intuitive software**—one ecosystem
- **Simplified NGS data reporting**—customizable reports and deeper insights

Find out more at

thermofisher.com/genexus

Genetic analysis (for *in vitro* diagnostics)



QuantStudio IVD real-time PCR systems

Innovative real-time PCR (qPCR) solutions for molecular diagnostics

- Applied Biosystems™ QuantStudio™ 5 Dx Real-Time PCR System
- Applied Biosystems™ QuantStudio™ 7 Pro Dx Real-Time PCR System

The QuantStudio IVD qPCR instruments allow you to choose from a range of high-quality systems with small footprints, simple workflows and software, and comprehensive service and support plans.

Find out more at

thermofisher.com/quantstudio-molecular-diagnostics

For *in vitro* diagnostic use only.



 Connect with us at thermofisher.com/biotech

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