Agilent

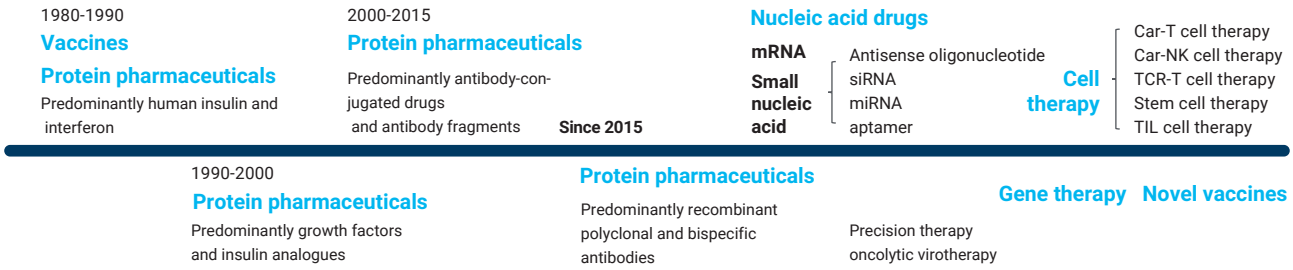
Trusted Answers

Biopharmaceutical Agilent Overall Solutions

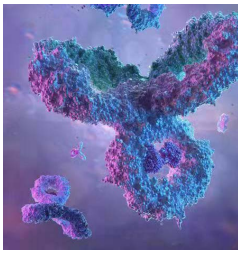
Agilent Biopharmaceutical Overall Solutions

Medicines derived from cells or organisms through cutting-edge technologies are generally referred to as biopharmaceuticals. Often employing genetic, protein/enzyme, and cellular engineering, biopharmaceuticals offer new pathways to drugs that are difficult to obtain by traditional chemical synthesis technologies. Advances in science and technology and demands for improved public health have promoted the continuous development of biopharmaceutical technology, making this field one of the most active and rapidly developing fields today.

Development of new drugs is not only costly but also difficult. As information from basic and applied research in biotechnology is turned into knowledge, more and more targets associated with human diseases will be identified. Agilent provides a variety of solutions for all stages of discovery, development, and manufacturing quality control. Agilent products that support the biopharmaceutical industry include chemical analysis instrumentation such liquid and gas, mass spectrometry, and infrared and Raman spectroscopy. Agilent also supports cell-based and genomics applications that employ electrophoresis, flow cytometry, microplate readers, gene editing, next-generation sequencing high-throughput sample processing, and multifunctional imaging along with automation and powerful data analysis software. Agilent is committed to providing technical support for a new generation of therapies and technologies (novel antibodies, mRNA technology, cell and gene therapy, novel vaccines, etc.) to provide reliable solutions for the biopharmaceutical industry.

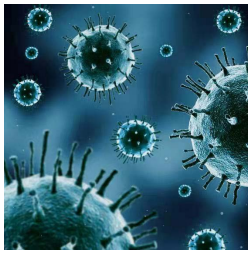


Development of biopharmaceuticals



Protein Pharmaceuticals

Drug Discovery
Drug Screening
Pharmacodynamic Studies
Structural Characterization and Quality Studies



Vaccines

Virus Infestation Studies
Strain Identification
Vaccine Component Analysis
Vaccine Efficacy Assessment

Nucleic Acid Drugs

Nucleic Acid Analysis
Nucleic Acid Preparation
Lipid Nanoparticle Analysis
Efficacy and Safety Assessments

General Technology and Services

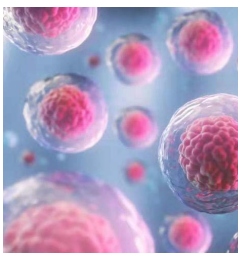
High Throughput and Automation

Residue Analysis and Safety Testing

Analysis of Raw Materials and Excipients and Packaging Materials

Intelligent Laboratory Informatization Management

Services and Consultation



Cell and Gene Therapy

Gene Editing
Plasmid Analysis
Viral Vector Analysis
Cell Therapy Development
Efficacy and Safety Assessments

Protein Pharmaceuticals

Protein pharmaceuticals have gradually developed from insulin, interferon, and growth factors, through monoclonal antibodies and antibody-conjugated drugs, to innovative novel antibodies. Whether small or large molecules, each drug or universal therapy should follow the basic process of new drug development.

Drug Discovery

Drug discovery is the construction of biological models, lead generation and optimization, and validation of the efficacy of candidate drugs affinity and avidity towards the proposed biological target.

Discovery and Validation of Targets

Gene Level
Next-generation sequencing technology
Microarray chips

Metabolic Level
Mass spectrometry-based metabolomics study

Protein Level
Mass spectrometry-based proteomics study
Molecular-Molecular interaction analysis

Cell Level
Cellular energy metabolism analysis
Flow cytometry
Molecular-Molecular interaction analysis
High content analysis

NGS Sample Preparation

Library Preparation

SureSelect XT HS2 DNA
SureSelect XT HS2 RNA

Capture panels

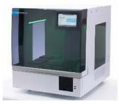
Human All Exon V8

Customized SureSelect

Automation

Bravo NGS

Magnis



Quality Control

TapeStation 4150 & 4200

5200/5300 Fragment Analyzer

2100 Bioanalyzer

Agilent's Mass Spectrometry System for Omics Studies

Bravo Automation Platform

Cytation C10 Confocal Imaging Reader

SynergyNeo2 Microplate Reader

Seahorse XF Analyzers

NovoCyte Flow Cytometer

xCELLigence Real-Time Cell Analysis

CBM Fully Automated Live Cell Workstation

Biological Model Construction

Biological model systems include cell models and animal models of human diseases. Among them, organoid models represent a major technological breakthrough and are currently recognized as important biological research tools. New organoid platforms are continually developed, such as breast cancer organoid sample banks and brain structural organoids that highly mimic the human body. In vitro organoid models are used to study the pathogenic mechanism of diseases and related signaling pathways due to their corresponding functions of the original organs.

Organoid Models
- Cytation C10 Confocal Imaging Reader
- MultiFlo FX MultiMode Dispenser
- CBM Fully Automated Live Cell Workstation

Cell Models
- Seahorse XF Analyzers
- NovoCyte Flow Cytometer

Drug Screening

Drug screening evaluates biological activity, druggability, and the medicinal value of candidate drugs using appropriate chemical and biological methods. From hit to lead to candidate, tens of thousands of molecules are continuously optimized and screened, and finally one is identified as the putative drug.

Assay

Cary 3500 UV-Vis Spectrophotometer

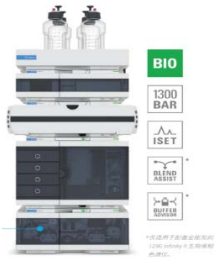
Epoch Microplate Reader

2100 Bioanalyzer

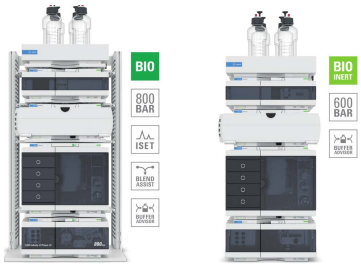
Physicochemical Analysis

6545XT LC/Q-TOF LC/MS

1290 Infinity II Bio LC System



1260 Infinity II Bio-inert LC System



7100 Capillary Electrophoresis System

Cary Eclipse Fluorescence Spectrometer

Protein purification and preparation

Preparative LC

Automation of Sample Pre-treatment

Assay MAP Bravo Platform

Bioassay

Bioassays determine active ingredients, content, potency, and provide quality control of a putative drug.

xCELLigence Real-Time Cell Analysis

Focus Applications

- Detection of cell health, cell morphology, and cell-substrate attachment in antibody-dependent cell-mediated cell killing (ADCC)
- Evaluating whether antibodies improve the killing effect of immune cells on solid and hematological tumors

NovoCyte Flow Cytometer

Focus Applications

- Quantification and identification of specific immune cell subsets, cell surface biomarkers, and signaling proteins in mixed cell samples
- Direct monitoring of cytokine production and intracellular protein concentration

EL406 Washer/Dispenser

Cytation Series Imaging Multimode Readers

Focus Applications

- Detection of binding of receptors to ligands, protein-protein interactions, and other molecular interactions
- Antibody internalization monitoring, antibody cell binding capacity evaluation
- High content imaging analysis
- Automated imaging and analysis of ELISpot using Cytation
- Automated imaging of co-cultures for cell-mediated cytotoxicity

Synergy Series Microplate Readers

Focus Applications

- Detection of binding of receptors to ligands, protein-protein interactions, and other molecular interactions
- ELISA
- Antibody Fc fragment bioassays, such as ADCC, CDC

Pharmacodynamic Studies

Drug-organism interactions, biological pathways, and mechanisms of action, are determined through pharmacokinetic and pharmacodynamic studies. In addition to efficacy studies, pharmacotoxicology studies and immunogenicity studies are essential to assess the safety of the proposed drug.

Drug Metabolism and Pharmacokinetics

Plasma Concentration Monitoring
6495 LC-QQQ LC/MS
Synergy series microplate readers

Metabolite Identification
6530 LC/Q-TOF

Sample Pre-treatment
RapidFire 400 MS Sample Pre-treatment System

Pharmacodynamics

Pharmacodynamic index testing
NovoCyte Flow Cytometer

In Vitro Cell Level Efficacy Evaluation
Cytation series imaging multimode readers
xCELLigence Real-Time Cell Analysis
Seahorse XF Analyzers
NovoCyte Flow Cytometer

Drug Interactions
6495 LC-QQQ LC/MS

Pharmacotoxicology

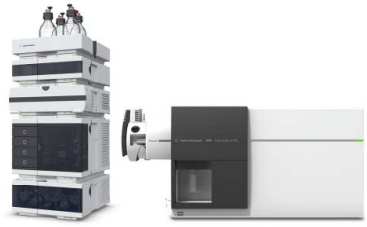
In Vitro Cytotoxicity Evaluation
Cytation series imaging multimode readers
Synergy series microplate readers
Seahorse XF Analyzers

Cytology testing
NovoCyte Flow Cytometer
Histopathology of Animals
Cytation series imaging multimode readers
Toxicokinetics
6530 LC/Q-TOF

Immunogenicity

NovoCyte Flow Cytometer
Synergy series multimode microplate readers

6495 LC-QQQ LC/MS



6530 LC/Q-TOF LC/MS

RapidFire 400 MS Sample Pre-treatment System

Synergy Series Microplate Readers

NovoCyte Flow Cytometer

Cytation Series Imaging Multimode Readers

Focus Applications

- Detection of binding of receptors to ligands, protein-protein interactions, and other molecular interactions
- ELISA
- Antibody Fc fragment bioassays, such as ADCC, CDC

Focus Applications

- Pharmacodynamic studies to assess receptor occupancy
- Analysis of cell death and cellular damage to assess safety
- Immune response/immune cell function analysis, such as lymphocyte activation and intracellular cytokine/phosphoprotein expression
- Immunogenicity and immunotoxicity studies

Focus Applications

- Detection of binding of receptors to ligands, protein-protein interactions, and other molecular interactions
- ELISA, ELISpot analysis for T cell responses
- High content imaging analysis
- Automated imaging and analysis of ELISpot using Cytation
- Automated imaging of co-cultures for cell-mediated cytotoxic

xCELLigence Real-Time Cell Analysis

Seahorse XF Analyzers

EL406 Washer/Dispenser

Focus Applications

- Studies from basic cellular pharmacotoxicology to drug safety in cardiomyocytes

Focus Applications

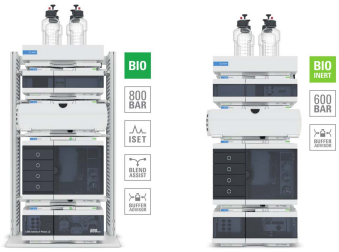
- Studies for mechanism of action of drugs
- Preclinical safety testing for mitochondrial and cardiotoxicity

Structural Characterization and Quality Studies

Structural characterization and quality studies are critical for drug manufacturing. Chemical and biological analytical testing is required through every stage of drug discovery, development, and manufacturing. Additionally, quality analysis and studies such as method development and validation, stability studies, and impurity studies are required during process development and scale-up.

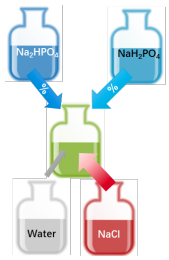
6545XT LC/Q-TOF LC/MS

1260 Infinity II Bio-inert LC System

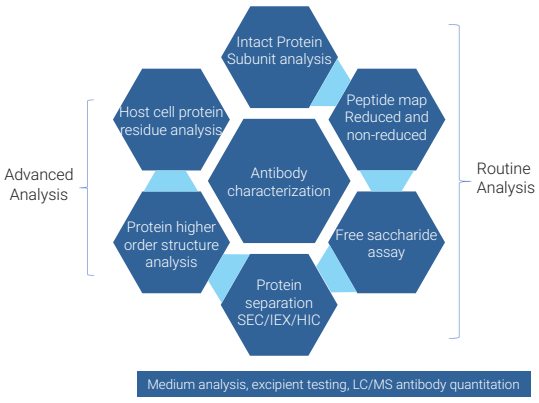


1290 Infinity II Bio LC System

Buffer Advisor



BioConfirm software and ADC DAR value calculation



2D-LC System

Sialic Acid Kit

Polysaccharide assay kit

Cary 630 FTIR Spectrometer

7100 Capillary Electrophoresis System

Agilent Biomolecular Column Product Line

For nucleic acid				For protein				
Plasmid supercoiling ratio	5' capping	poly-A tail	Aggregate analysis	Aggregate analysis	Intact protein and subunit assays	Peptide mapping and PTM assays	Charge variant assay	Polysaccharide assay
		PLRP-S 1000Å 5 µm PEEK-lined		AdvanceBio SEC 1.9 µm PEEK-lined	PLRP-S 1000Å 5 µm PEEK-lined	AdvanceBio EC-C18 PEEK-lined	Bio MAb (WCX)	
Bio-Monolith DEAE	AdvanceBio oligonucleotide	AdvanceBio oligonucleotide	Bio SEC-5	AdvanceBio SEC 1.9 µm	PLRP-S	AdvanceBio Peptide Mapping	Bio IEX (SAX, WAX, SCX, WCX)	AdvanceBio Glycan Mapping
				AdvanceBio SEC 2.7 µm	AdvanceBio RP mAb 450Å	AdvanceBio Peptide Plus	PL SCX, SAX	
				Bio SEC-5	ZORBAX RRHD 300 Å, 1.8 µm	ZORBAX RRHD 300 Å, 1.8 µm		
				Bio SEC-3	ZORBAX 300SB 3.5, 5 & 7 µm			
					Poroshell 300 5 µm			

Stainless steel (SS) tubing

PEEK/PEEK tubing

Solutions of high-throughput and automation, residue analysis and safety testing as well as analysis of raw materials and excipients and packaging materials are described in the "General Technology" section.

Nucleic Acid Drugs

Nucleic acid drugs include mRNA drugs and small nucleic acid drugs (antisense oligonucleotides, siRNAs, miRNAs, and nucleic acid aptamers, etc.). Small nucleic acid drugs are short chain oligonucleotide molecules with multiple mechanisms of therapeutic action, such as gene silencing or inhibition of preprogrammed protein expression. For mRNA therapies, mRNA sequences encoding specific antigens are designed and synthesized in vitro, then delivered to human cells in a specific manner after steps such as sequence optimization, chemical modification, and purification.

Nucleic Acid Analyses

Nucleic Acid Quantification
Epoch Microplate Reader
SynergyLX Microplate Reader
Cary 3500 UV-Vis Spectrophotometer

Nucleic Acid Fragment and Purity
5200/5300 Fragment Analyzer
1260/1290 Infinity II Bio LC System
Oligo Pro II System

Nucleic Acid Melting Temperature
Cary 3500 UV-Vis Spectrophotometer

mRNA Capping Rate Detection and PolyA Tail Analysis

mRNA therapies have made great progress in vaccine development, cancer immunotherapy, and rare genetic diseases. In vitro transcription to synthesize mRNA and delivery systems are critical for the maturation of this technology.
In mRNA therapy techniques, synthesized mRNAs need to be translated in vivo, and capping and tailing are essential to prevent mRNA degradation and promote mRNA translation in cells. However, the 5' end capping rate and 3' end PolyA sequence detection of mRNA require specialized analytical techniques. Agilent 6545XT LC/Q-TOF is designed specifically for biological macromolecules and provides a reliable, stable solution for capping and tailing analysis.

6545XT LC/Q-TOF LC/MS

BioConfirm software

Plasmid Analysis

The mRNA production process requires plasmid purification and DNA linearization, followed by in vitro transcription. Analysis of plasmids plays an important role in process development and monitoring.

Plasmid Content and Purity
Epoch Microplate Reader
Synergy series microplate readers
Cary 3500 UV-Vis Spectrophotometer
1260/1290 Infinity II Bio LC System

Restriction Map of Plasmid
2100 Bioanalyzer
5200/5300 Fragment Analyzer

Plasmid Topology
1260/1290 Infinity II Bio LC System

Spectroscopy

Cary 3500 UV-Vis Spectrophotometer

Epoch Microplate Reader

SynergyLX Microplate Reader

Chromatography

1260 Infinity II Bio-inert LC System

1290 Infinity II Bio LC System

Biocolumns

Electrophoresis

2100 Bioanalyzer

5200/5300 Fragment Analyzer

Oligo Pro II System

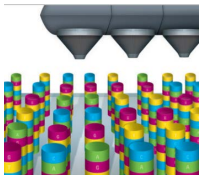
Nucleic Acid Preparation

	Analytical scale		Semipreparative	Preparative
Productivity Range	Micrograms	Milligrams		Grams
Agilent 1220/1260/1290 Infinity II Analytical-Scale LC Purification System	0.01–10 mL/min			
Agilent 1260 Infinity II Autoscale Preparative LC System		1–50 mL/min		
Agilent 1290 Infinity II Autoscale Preparative LC System		1–50 mL/min		5–200 mL/min
Column ID	4.6 mm	10 mm (½ inch)	20–25 mm (1 inch)	30 mm	50 mm (2 inch)
Typical flow rate (mL/min)				

Flow range extensions made possible by exchangeable pump heads

Preparative LC

DNA/RNA Oligo Synthesis Services



DNA/RNA Oligo synthesis provides a solution from research to GMP

Together with Agilent, researchers benefit from our industry-leading nucleic acid solutions to effectively advance the process from development to obtaining candidate oligonucleotides for clinical research and marketing. Agilent materials from research grade to GMP grade supporting the whole-process from early research through clinical development to commercialization.

Lipid Nanoparticle Analysis

Lipid nanoparticles (LNP) can transport hydrophobic or hydrophilic molecules (including small molecules, proteins, and nucleic acids) and are an extremely versatile nanomedicine delivery platform. With the application of mRNA technology, LNP has rapidly become one of the most potential drug delivery platform technologies. It is difficult to detect these components using conventional analytical techniques. Agilent has successfully developed analytical methods suitable for this complex application by introducing a combined high performance liquid chromatography-evaporative light scattering (HPLC-ELSD) technique.

Liquid Chromatography-Evaporative Light Scattering Detector

Efficacy and Safety Assessments

xCELLigence Real-Time Cell Analysis

Focus Applications

- Detection of cell health, morphology, and attachment
- High-throughput screening of neutralizing antibody therapies, as well as assessment of the toxicity of the drug itself
- Studies from basic cellular pharmacotoxicology to drug safety in cardiomyocytes

Seahorse XF Analyzers

Focus Applications

- Studies for mechanism of action of drugs
- Preclinical safety testing for mitochondrial and cardiotoxicity

Synergy Series Microplate Readers

Focus Applications

- Detection of binding of receptors to ligands, protein-protein interactions, and other molecular interactions
- ELISA

Cytation Series Imaging Multimode Readers

Focus Applications

- Detection of binding of receptors to ligands, protein-protein interactions, and other molecular interactions
- ELISA, ELISpot analysis for T cell responses
- High content imaging analysis
- Automated imaging and analysis of ELISpot using Cytation
- Automated imaging of co-cultures for cell-mediated cytotoxic

NovoCyte Flow Cytometer

Focus Applications

- Quantification and identification of specific immune cell subsets, cell surface biomarkers, and signaling proteins in mixed cell samples to determine efficacy
- Direct monitoring of cytokine production and intracellular protein concentration
- Analysis of cell death and cellular damage to assess safety
- Immune response/immune cell function analysis, such as lymphocyte activation and intracellular cytokine/phosphoprotein expression
- Immunogenicity and immunotoxicity studies

EL406 Washer/Dispenser

Solutions of high-throughput and automation, residue analysis and safety testing as well as analysis of drug substance and excipients and packaging materials are described in the "General Technology" section.

Cell and Gene Therapy

Cell therapy can be divided into non-genetically modified and genetically modified cell products. Genetically modified cell products introduce exogenous genes into target cells and expressing the genetically modified cells into the body. Gene therapy is performed by in vivo transfection using vectors such as viruses to complete gene delivery or gene editing.

Gene Editing

Gene editing technology is widely used in life science research and biopharmaceuticals, and has a pivotal role in cell therapy and gene therapy.

Gene Editing by CRISPR

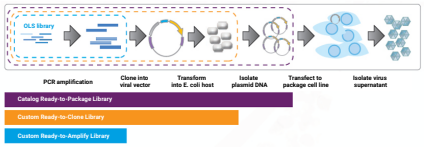
CRISPR-Cas9 is one of the most efficient and simple gene editing technologies and is currently the most mainstream gene editing system. In the CRISPR-Cas9 system, sgRNAs pair to recognize corresponding DNA sites in the genome and cleave DNA through the DNA endonuclease activity of Cas9.

SureGuide CRISPR Libraries

The Agilent SureGuide CRISPR libraries are available in three formats.

- Ready to package libraries contain predefined licensing content, and genome-wide knockout libraries or GeCKO libraries target all exons in the human or mouse genome
- Ready-to-clone libraries provide great flexibility for designing custom guide sequences and are available in the form of linear DNA amplification libraries
- Ready-to-amplify libraries provide the greatest customized flexibility to completely design every aspect of CRISPR protocols, such as using other vector systems, cloning methods or targeting any organism selected

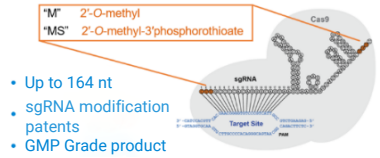
SureGuide CRISPR DNA Libraries



SureGuide CRISPR sgRNA Synthesis

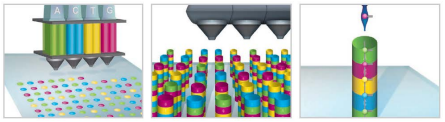
- Patented "TC-RNA" synthesis technology is able to synthesize highly active sgRNAs up to 164 nt
- Patented CRISPR sgRNA modification, licensed in several countries and regions worldwide, including China
- GMP grade sgRNAs are available, with experience in the commercialization of oligonucleotide drugs to provide customers with a complete solution from R&D to commercialization

SureGuide CRISPR sgRNA (Chemical synthesis)



SureGuide CRISPR DNA Libraries

SureGuide CRISPR DNA Libraries



- Whole genome libraries that are ready to package viruses
- Custom Ready-to-Clone Library
- Oligo DNA custom libraries
- Gene knockout
- Gene activation/interference

Quality Control Protocol for Gene Editing Process

Multiple automated electrophoresis devices meet the quality control needs of nucleic acid and protein

2100 Bioanalyzer

TapeStation 4150 & 4200

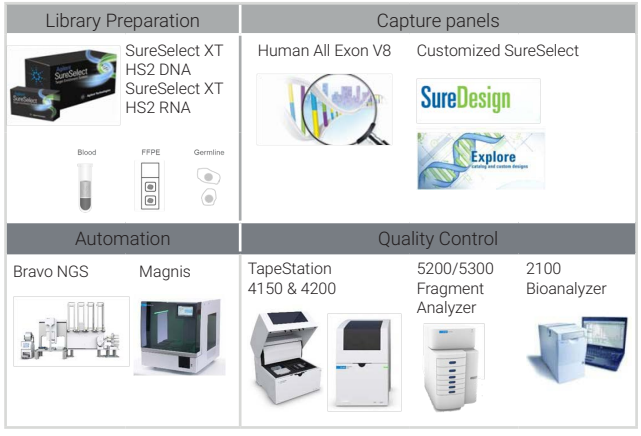
5200/5300 Fragment Analyzer

Editing Efficiency Test

After the gene is introduced into the cell for gene editing, the efficacy or off-target needs to be determined. Parallel testing is usually performed at the gene and protein levels. Gene level detection technologies include next-generation sequencing and qPCR. Protein level detection technologies include molecular-molecular interaction analysis and flow cytometry.

Gene Level Detection

NGS Sample Preparation



Protein Level Detection

NovoCyte Flow Cytometer

Cytation Series Imaging Multimode Readers

Synergy Series Microplate Readers

Plasmid Analysis

Refer to "Plasmid Analysis" in Section "Nucleic Acid Drug".

Viral Vector Analysis

Adenovirus-associated virus (AAV) is widely applied because of its excellent safety record and low immunogenicity. The virus coat is analyzed by similar analytical methods as protein analysis for its identification and purity determination.

Virus Titer Testing

Synergy Series Microplate Readers

Cytation7 Cell Imaging Multimode Reader

AriaMx Real Time PCR System

Capsid protein molecular mass

Capsid protein peptide mapping

Capsid protein purity analysis

Virus aggregation analysis

Virus vector empty shell rate

1260 Infinity II Bio-inert LC System

1290 Infinity II Bio LC System

6545XT LC/Q-TOF LC/MS

Cell Therapy Development

Seahorse XF Analyzers

Focus Applications
- Provides critical information to optimize immune cell selection and engineering design to select and design engineered immune cells with excellent metabolic properties to achieve excellent tumor killing ability
- Used to optimize immune cell components and growth conditions in therapeutic cell production
- Immunotherapy target identification/validation, cell therapy engineering design (e.g. CAR-T, cell fate, function, adaptability, etc.)
- QC of transplant, adaptability, and potency of T Cells

xCELLigence Real-Time Cell Analysis

Focus Applications
- Measure cell health, morphology, and attachment to determine the potency of immune cell-mediated killing with low E:T in real time
- Rapid, high-throughput in vitro target screening and potency assessment of candidate cell therapies (e.g., CAR-T, TCR-T, CAR-NK, etc.)
- Assessment of cell killing of solid and hematological tumors by cell therapy

Cytation Series Imaging Multimode Readers

Focus Applications
- 2D or 3D cell model-based real-time T cell & NK cell killing imaging
- Stem cell differentiation ability test
- Cytokine detection, T cell activation detection, etc.
- In vitro cell model culture and optimization: dynamic monitoring of cell growth curve, 3D cell culture sphere-forming monitoring of stem cells, etc.
- Cell viability assay: imaging counting
- Detection of residual cytokine: ELISA or HTRF
- Bead residue detection: High throughput imaging
- Cytotoxicity detection, including cell viability detection, cell growth curve determination, 2D and 3D cell model detection such as cytotoxicity/apoptosis, tumorigenicity detection, HE staining of animal tissues and immunohistochemical imaging, and other automatic ELISpot analysis for T cell response

- Cell health and viability
- cellular metabolism
- Cell migration and invasion
- Apoptosis and necrosis
- Cell proliferation
- Cell migration associated with cancer cell physiology and cell necrosis
- Scratch assay and tissue regeneration physiology
- Cell migration
- NK cell-mediated cytotoxicity

EL406 Washer/Dispenser

CBM Fully Automated Live Cell Workstation

NovoCyte Flow Cytometer

Focus Applications
- Quality study of cell products, such as cell number (viable cell number, functional cell number, etc.), cell survival rate, identification, homogeneity and purity testing, purity and impurity analysis
- CAR expression level detection, CAR-T cell subset detection (Th, Tc, naïve/memory T, etc.), T cell proliferation
- Biological potency testing (cytokines)
- Analysis of cell death and cellular damage to assess safety
- Immune response/immune cell function analysis, such as lymphocyte activation and intracellular cytokine/phosphoprotein expression
- Immunogenicity and immunotoxicity studies

Efficacy and Safety Assessments

Refer to "Efficacy and Safety Assessments" in Section "Nucleic Acid Drug".

Solutions for high-throughput and automation, residue analysis and safety testing as well as analysis of drug substance, excipients, and packaging materials are described in the "General Technology" section.

Vaccines

Vaccines are biological formulations for the prevention of disease. From the technical perspective, vaccines can be divided into viral vector vaccines, DNA vaccines, RNA vaccines, attenuated and inactivated viral vaccines (intact virus type), protein vaccines, and polysaccharide and polyglycoprotein conjugate vaccines.

Virus Infestation Studies

Cytation Series Imaging Multimode Readers

Focus Applications

- Fluorescent labeling of intracellular virus, calculating infection rate, automated imaging and analysis
- Identification of cellular predisposition to viral infection and use host cell biomarkers to identify the type of viral infection
- Host response, altered expression of cell surface receptors, intracellular cytokine staining
- TCID50 assay, plaque assay, imaging and quantification

Seahorse XF Analyzers

Focus Applications

- Host cell and metabolism responses to pathogen infection
- Comparative study of how pathogens hijack host metabolism
- Immune checkpoints and regulation during infection

EL406 Washer/Dispenser

Synergy Series Microplate Readers

Focus Applications

- Fluorescent labeling of intracellular virus, calculating infection rate
- Identification of cellular predisposition to viral infection and use host cell biomarkers to identify the type of viral infection
- Host response, altered expression of cell surface receptors, intracellular cytokine staining
- TCID50 assay, plaque assay

NovoCyte Flow Cytometer

Focus Applications

- Quantification and identification of specific immune cell subsets, cell surface biomarkers, and signaling proteins in mixed cell samples to determine efficacy
- Direct monitoring of cytokine production and intracellular protein concentration
- Understanding the mechanism of action of drugs and the impact on specific cell types due to virus and/or drug interactions

xCELLigence Real-Time Cell Analysis

Focus Applications

- Rapid detection of cell health, morphology, and attachment, and real-time understanding of the entire viral life cycle, viral titer, and cytopathic effects
- Characterize viral adaptation to assess viral activity e.g. attachment, penetration, replication

6495 LC-QQQ LC/MS

6530 LC/Q-TOF LC/MS

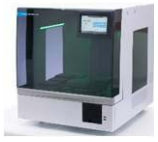
Focus Applications

- Characterize protein and lipid composition of pathogens
- Identify changes in host metabolism after infection

Strain Identification

NGS Sample Preparation

Library Preparation	Capture panels
SureSelect XT HS2 DNA SureSelect XT HS2 RNA	Human All Exon V8
	
Customized SureSelect	
	

Automation		Quality Control		
Bravo NGS	Magnis	TapeStation 4150 & 4200	5200/5300 Fragment Analyzer	2100 Bioanalyzer
				

AriaMx Real-Time PCR System

Vaccine Component Analysis

Assay

Cary 60 UV-Vis Spectrophotometer

Cary 3500 UV-Vis Spectrophotometer

2100 Bioanalyzer

Epoch Microplate Reader

Physicochemical Analysis

6545XT LC/Q-TOF LC/MS

1290 Infinity II Bio LC System

1260 Infinity II Bio-inert LC System

7100 Capillary Electrophoresis System

Virus Titer Testing

Synergy Series Microplate Readers

Cytation7 Cell Imaging Multimode Reader

AriaMx Real Time PCR System

Vaccine Excipients and Adjuvant Testing

Item to be tested	Specific ingredient	Main technique
Process residue	Medium defoamng agent	ICP-OES
Process residue	Inactivators like formaldehyde, glutaraldehyde, etc.	UV-Vis / LC / GC
Adjuvant	Aluminum adjuvant	ICP-MS
Excipients	Cholesterol	HPLC-ELSD
Excipients	Sucrose	HPLC-RID
Delivery vehicle	Lipid nanoparticle	HPLC-ELSD

Nucleic Acid Fragment and Purity

5200/5300 Fragment Analyzer

Oligo Pro II System

Vaccine Efficacy Assessment

NovoCyte Flow Cytometer

Focus Applications

- Quantification and identification of specific immune cell subsets, cell surface biomarkers, and signaling proteins in mixed cell samples to determine efficacy
- Direct monitoring of cytokine production and intracellular protein concentration
- Understanding the mechanism of action of drugs and the impact on specific cell types due to virus and/or drug interactions

xCELLigence Real-Time Cell Analysis

Focus Applications

- Rapid detection of cell health, morphology, and attachment, and real-time understanding of the entire viral life cycle, viral titer, and cytopathic effects
- High-throughput screening of neutralizing antibody therapies to assess the ability of the vaccine to neutralize the virus, as well as assessment of the toxicity of the vaccine itself

Cytation Series Imaging Multimode Readers

Focus Applications

- Evaluation of mRNA vaccine transfection efficiency in vitro
- Evaluation of mRNA vaccine antigen expression
- Vaccine humoral immunity evaluation: fully automated high-throughput neutralizing antibody analysis
- Vaccine cellular immunity evaluation: ELISpot assay
- Animal tissue section imaging

Solutions of high-throughput and automation, residue analysis and safety testing as well as analysis of drug substance and excipients and packaging materials are described in the "General Technology" section.

General Technology and Services

High Throughput and Automation

Automated Liquid Handling Platform

Bravo Automation Platform

Assay MAP Bravo Platform

NGS Workstations

Bravo NGS Workstation

Magnis NGS Prep System

Cell Automation Workstation

EL406 Washer/Dispenser

BioSpa8 Automated Incubator

CBM Fully Automated Live Cell Workstation

BioStack Microplate Stacker

High-Throughput Automation Components

RapidFire 400 MS Sample Pre-treatment System

BenchCel Workstation

Microplate Centrifuge

PlateLoc Thermal Microplate Sealer

Microplate Barcode Labeler

Labware MiniHub Microplate Management

Agilent Microplates

Agilent microplate technology has accumulated more than 35 years of experience, with rich and diverse microplate products, including cell culture and imaging microplates, storage/assay microplates, reservoir microplates, and filter microplates, which can meet almost all the needs of the entire workflow.

Storage & Assay Microplates

Reservoir Microplates

Filter Microplates

Cell Culture & Imaging Microplates

Residue Analysis

Residue analyses are performed on intermediates and finished drug products throughout the entire drug discovery, development, and manufacturing processes. Safety testing must be tightly controlled. The presence of bacterial endotoxins, mycoplasmas, viruses, and other substances not only affect the efficacy of drugs, but are harmful to human health.

Residue	Main technique	Agilent solutions	Application examples
Protein residues	ELISA	Epoch Microplate Reader Synergy Multimode Reader	1. Protein pharmaceuticals - host cell protein residues and protein A residues 2. mRNA nucleic acid drug - plasmid host cell protein residues and nuclease residues 3. Cell and gene therapy - protein residues in viral vectors, bovine serum albumin BSA residues in viral culture
	Electrophoresis	2100 Bioanalyzer	
	LC/MS 6545XT	LC/Q-TOF LC/MS	
Nucleic acid residues	qPCR	AriaMx Real-Time PCR	1. Protein pharmaceuticals - host nucleic acid residues 2. mRNA nucleic acid drug - nucleic acid residue such as template 3. Vaccines - nucleic acid residues
	Electrophoresis	2100 Bioanalyzer 5200/5300 Fragment Analyzer	
Bead residues	High-throughput imaging	Cytation series imaging multimode readers	Cell Therapy - bead residue detection
Antibiotic residues	HPLC	1260/1290 Infinity II LC System	Cell and gene therapy - antibiotic residues during plasmid preparation
Reagent residues	HPLC-ELSD	1260/1290 HPLC-ELSD	Gene therapy - Tween 20 Triton X-100 transfection agent polyethylenimine PEIpro
	UV-Vis / LC / GC	Cary3500 UV-VIS Spectrophotometer 1260/1290 Infinity II LC System 8890 GC System	Inactivated or attenuated vaccines - inactivators formaldehyde, glutaraldehyde, etc.
Medium defoamng agent	ICP-OES	5800 ICP-OES	1. Cell and gene therapy - plasmid and virus preparation 2. Vaccines

Safety Testing

Substance to be tested	Main technique	Agilent solutions
Endotoxin detection	LAL reagent method, rFC method	Epoch Microplate Reader Synergy Multimode Reader EL406 Washer/Dispenser
Mycoplasma Detection	Enzymatic luminescence detection	
Replicative virus testing	Cytopathic detection or antigen detection by RCL bioassay (ELISA)	

Raw materials and reactive intermediate analyses is an excellent area for GC and GC/MS applications

Pharmaceutical excipients are an important part of pharmaceutical formulations. Pharmaceutical excipients not only have the function of shaping and filling carriers, but also have the important functions of solubilizing, assisting dissolution, and improving stability. Pharmaceutical excipients may also influence the quality, safety, and efficacy of the drug product. In order to ensure the safety of pharmaceutical excipients, pharmacopeias of various countries clearly specify the qualitative and quantitative methods for excipients.

Agilent HPLC-ELSD Technology

Agilent HPLC-ELSD technology uses a special photomultiplier tube and laser device of the new 1290 Infinity II ELSD, which improves the sensitivity while increasing the dynamic range by 90 times, and the unique high-precision glass nozzle design provides assurance for peak area reproducibility.

Liquid Chromatography-Evaporative Light Scattering Detector

In the field of pharmaceutical and biopharmaceutical excipient analysis, many compounds to be tested lack significant UV absorbing moieties. The 1290 Infinity II ELSD is well suited for reproducible and highly sensitive detection of semi-volatile and non-volatile compounds that cannot be analyzed by UV detection, particularly for pharmaceutical excipients that lack UV absorbing moieties and are not volatile.

Application Solution Based on HPLC-ELSD

Application area	Drug product excipients	Process residue
Protein pharmaceuticals	Surfactant Tween 80/ 20 Stabilizer Poloxamer (P188) Lyoprotectant saccharides Amino acids in drug product	Analysis of defoaming agents
Gene therapy	Stabilizer Poloxamer (P188)	Tween 20 Triton X-100 Transfection agent polyethylenimine PEIpro
Nucleic acid drugs Novel vaccines	Lipid nanoparticle delivery vehicle	–

Media, buffers, amino acids, surfactants, and inorganic salts are widely used in biopharmaceuticals. It is of great significance to realize 100% identification of raw materials and excipients using the minimum packaging of samples, so as to maintain the aseptic state of samples, avoid cross-contamination, accelerate the release speed, and improve the operating efficiency of enterprises.

Raman Spectrometer

RapID Raw Material ID Verification System

Vaya HandHeld Raman Spectrometer

Agilent RapID mobile Raman system and Vaya HandHeld Raman Spectrometer use patented spatially offset Raman spectroscopy (SORS) technology, which can directly identify the ingredients through the common packaging of raw materials and excipients in biopharmaceuticals, such as opaque plastic bottles, dark glass bottles, kraft paper bags, woven bags, etc., and escort the safe production and efficient operation of enterprises.

- Effective tool for identification (test with packaging) of raw materials and excipients
- Patented spatially offset Raman spectroscopy (SORS) technology for identification of raw materials and excipients with packaging
- Accurate identification of similar components using R^2 and LMC double criteria
- 830 nm laser effectively avoids fluorescence interference from material
- Meets 21 CFR Part 11

ICP-MS

8890-5977 GC-SQ

8890 GC

Intelligent semiquantitative technology in Agilent ICP-MS can rapidly screen elemental impurities analysis for compatibility of packaging materials for antibodies and vaccines. It is suitable for the analysis of inorganic elements of raw materials and excipients in the culture medium, has ultra-high sensitivity detection ability, can quantitatively monitor trace elements in the cell culture process, and ensure accurate information for the culture medium feeding link.

Agilent ICP-OES is effective in tracking residual defoaming agents used during cell culture.

Metal element detection
- ICP-MS
- ICP-OES

Volatile substances testing
- GC
- GC-MS

Non-Volatile substances testing
- LC
- LC-MS

Detection of substances with infrared absorbing groups
- Cary 630 FTIR

ICP-OES

1260 Infinity II LC System

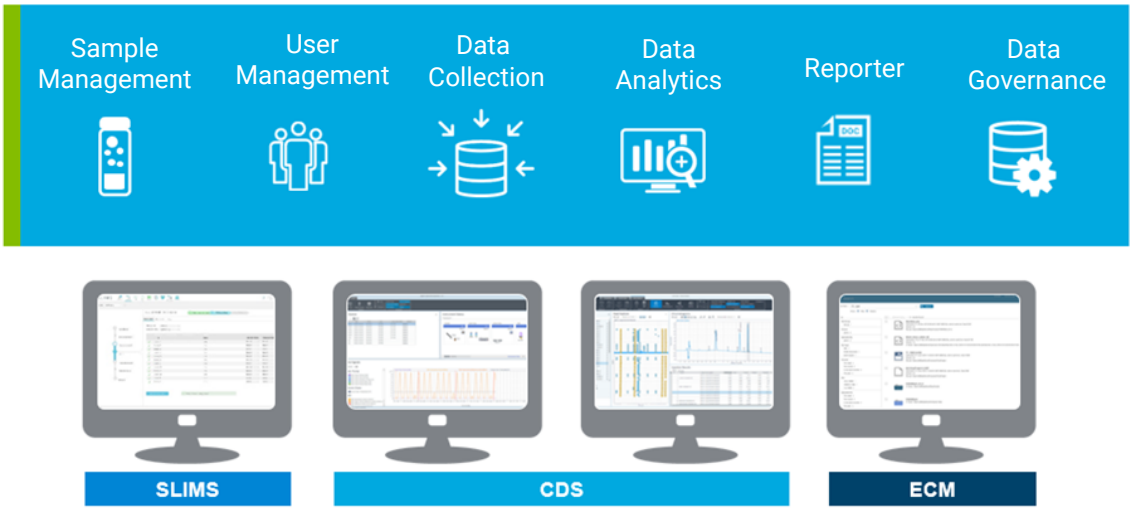
LC-SQ/LC-QQQ

Cary 630 FTIR

Intelligent Laboratory Informatization Management

As a leader in the life sciences, diagnostics and applied chemistry market, Agilent is also a laboratory informatization software supplier that fully integrates SDMS (Scientific Data Management System), CDS (Chromatographic Data System), and LIMS (Laboratory Information Management System).

- Meet the latest regulatory requirements and significantly reduce the cost of laboratory data reliability inspection
- Strong alliance between chromatographic data system (OpenLab CDS) and scientific data management system (ECM) to realize unified management of laboratory instruments
- SLIMS solution provides biological laboratory sample process management, reagents, consumables, inventory management, laboratory original record management



Services and Consultation

Agilent provides comprehensive post-sales service to the biopharmaceutical industry and customizes professional solutions for laboratories as needed.

Advantage Services Plan

Service contracts and annual maintenance plans to meet your needs for instrument status and response times

Training and Consulting

Basic and customized training, as well as application consulting services help solve difficult problems such as instrument operation, and application development

Specific Maintenance Services

Specific multiple instrument maintenance services are available to adjust instrument optimal conditions, reduce downtime, and delay instrument life cycle

Finance Lease

Comprehensive financial solutions, such as instrument leasing, financing purchases, and Agilent refurbished instruments, mitigate short-term funding problems

Laboratory Operations

Support customers to integrate resources according to scientific and business objectives and help customers build global management laboratories

Directed Refurbishment and Overall Relocation

Provide a variety of services such as relocation of the laboratory, refurbishment of old instruments, digital laboratories, etc.

Compliance Verification and Regulatory Certification

Compliance verification and regulatory certification services to ensure necessary validation of computers and analytical equipment

Compliance Verification and Regulatory Certification

Computerized System Validation

- Agilent Software Standards IQOQ Certification
- CSV validation for all software systems in the laboratory (including chromatography and non-chromatography systems, Agilent or other brand's systems)
- System data backup and restore validation and disaster recovery solutions
- GMP pre-audit - data integrity gap analysis

Analytical Instrument Equipment Regulatory Certification

- Agilent Instrument Standards IQOQ Certification
- Customized EQPs and RQs for post repair qualification
- Network distributed ACE (NDA) Certification
- Enterprise regulatory certification services for entire laboratory - instruments and equipment of Agilent and other manufacturers
- USP1058 AIQ regulatory consulting services - in development

Helping users move toward operational excellence in the laboratory is Agilent's greatest mission for services.

Find a local Agilent customer center
in your country:
www.agilent.com/chem/contactus

U.S. and Canada
1-800-227-9770
agilent_inquiries@agilent.com

Europe
info_agilent@agilent.com

Asia Pacific
inquiry_lsca@agilent.com

www.agilent.com

Published in the USA
February 11, 2022
5994-4595EN