

Agilent Solutions for Biologic Characterization

High-productivity  
**workflow  
solutions**  
for biopharmaceutical analysis

Our measure is your success.

products | **applications** | software | services



**Agilent Technologies**

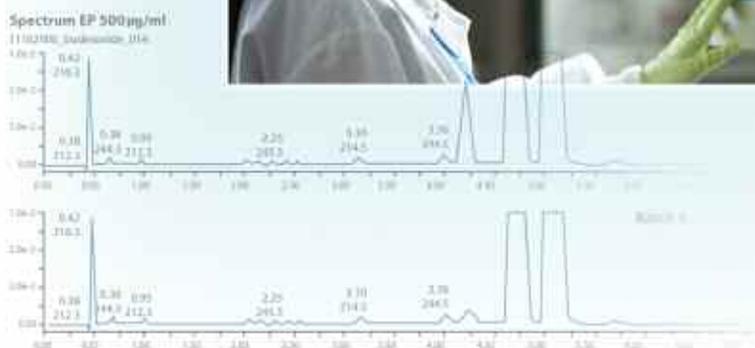
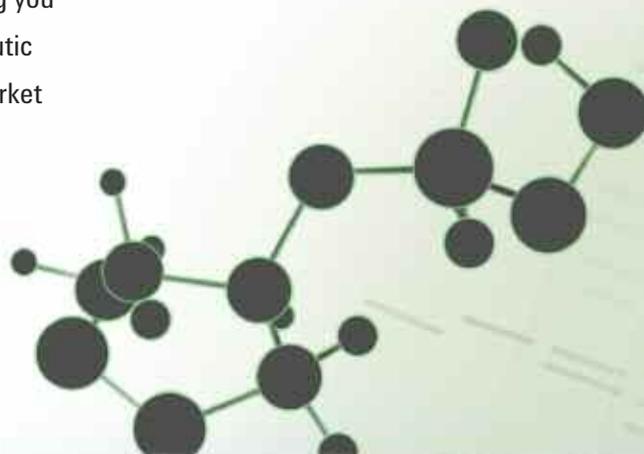
## Agilent Solutions for Biopharmaceutical Analysis

# The tools and technologies you need to bring your biologic to market.

As the leading provider of analytical solutions to the biopharmaceutical industry, Agilent is helping you provide safe, high-quality, high-efficacy therapeutic products. And we're helping you get them to market faster and more cost-effectively.

We offer an extensive portfolio of end-to-end, workflow-driven solutions across key process development, scale-up, manufacturing and QA/QC applications, including:

- Physicochemical characterization
  - Intact NBE analysis
  - Glycosylation and phosphoprotein analysis
  - Amino acid analysis
  - Peptide mapping
- Product-related impurity analysis
- Process-related contamination testing
- Protein and antibody QA/QC
- Stability and dosage form testing



We understand the complexity and the depth of the technical challenges you're facing. We address concerns with protein aggregates and fragmentation, and we provide robust analytical solutions for host cell DNA, viruses, leachables, extractables, cell culture media and components, as well as the purified reagents and chemicals needed to ensure highest confidence in your results. Agilent's broad technology portfolio includes:

- Liquid chromatography
- LC/MS
- Capillary electrophoresis
- Ion analysis (CE and HPLC)
- Isoelectric focusing
- Evaporative light scattering
- Gas chromatography
- GC/MS
- qPCR
- LC column technology (reversed phase, ion exchange and size exclusion)
- Protein standards and protein processing kits
- Lab-on-a-Chip



*Across the entire biopharmaceutical pipeline, Agilent-reliable, integrated solutions deliver superior sensitivity, selectivity, speed and ease of use and real world performance that can measurably improve your company's productivity.*



### **Services and software that support the regulated lab**

With a comprehensive compliance portfolio that includes IQ and OQ for a single instrument, multiple labs or global, multi-vendor implementations, Agilent is ready to help you optimize, automate and streamline compliance procedures. We can improve the consistency and accuracy of your validation initiatives, while freeing up staff time, minimizing risk and reducing costs.

Agilent software solutions also support GLP/GMP and 21 CFR Part 11 compliance with features such as built-in audit trails, multi-user login security, configurable user permissions and electronic signatures.

## Physicochemical Characterization | Purity Monitoring and Stability

**CE • CE/MS • LC • LC/MS • GC • GC/MS • ICP-MS**

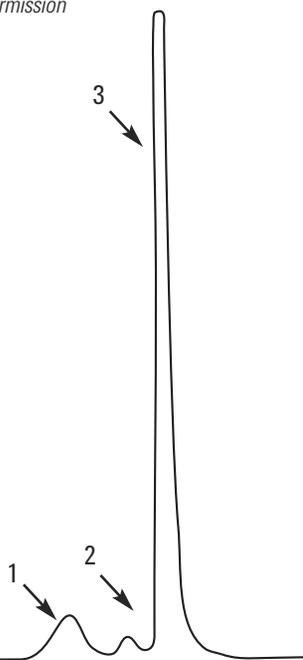
From the most advanced R&D to routine QA/QC, Agilent offers a broad range of solutions for determining integrity, purity and molecular weight of proteins and oligonucleotides. Complementary separation tools, like the OFFGEL System and Bio-monolith LC columns, enable highest resolution and fastest separation of intact proteins. OFFGEL can also be used to diagnose peaks found in CIEF (capillary isoelectric focusing) separations.

Our 6200 and 6500 Series LC/MS systems deliver industry-leading performance, reliability and value. Agilent CE and CE/MS systems extend your analytical options. Our 1200 Series LC systems with ELSD detector allow both size exclusion and light scattering techniques to be applied to aggregate issues.

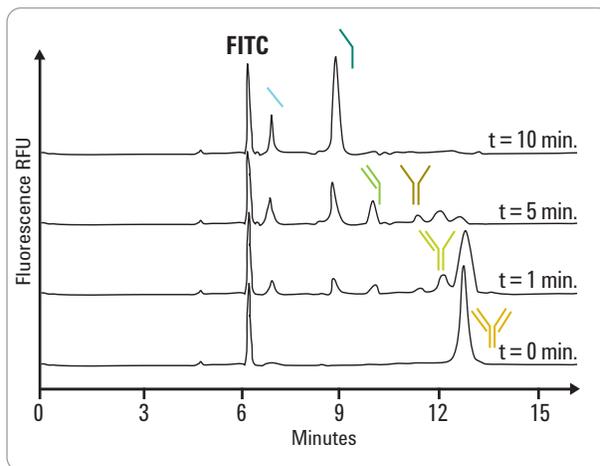
DeLeenheer, A.P. *et al.* (1991) *J. Pharm Sci.* 80: 11.

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1. Aggregate
2. Albumin dimer
3. Albumin



**Size Exclusion separation of Albumin Monomer, Dimer and Aggregate** using the ZORBAX GF-250/450 columns. Particles are specially treated to reduce protein sticking and to increase long column lifetimes.



**Capillary electrophoresis using Laser-Induced Fluorescence** allows high sensitivity protein profiling. Monoclonal antibody stability was monitored at different incubation times with mercaptoethanol. Data courtesy of Picometrics.



**Agilent's 1200 Series LC** provides exceptional precision, resolution, reproducibility and spectral quality at all flow rates, over a wide range of mobile phases.

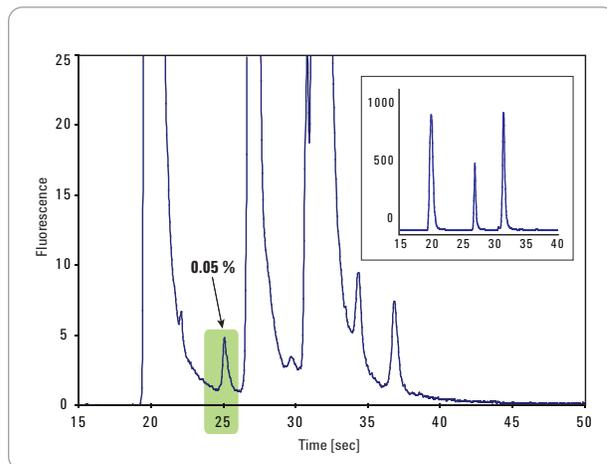
# Physiochemical Characterization | Integrity & Molecular Weight Analysis

LC/MS • LC-ELSD • CE • CE/MS • 2100 Bioanalyzer

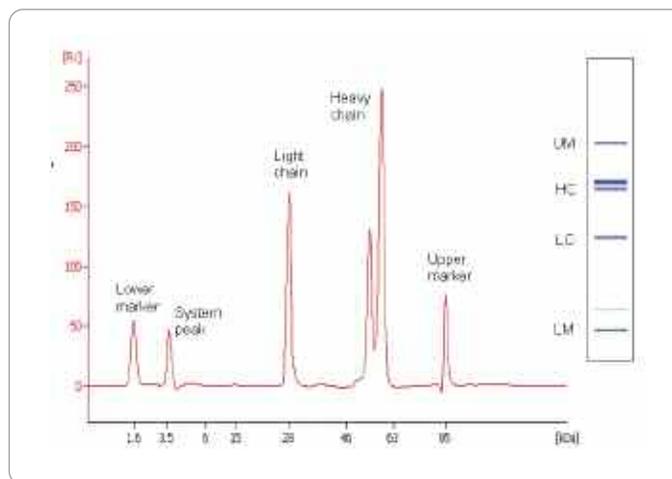
Convenient molecular weight determination on the Agilent 2100 Bioanalyzer allows rapid, one-step methodology for your antibodies and other biologics.



**The Agilent 2100 Bioanalyzer** lets you trade messy gels for convenient, cost-effective LabChip assays—a convenient and cost-efficient solution for testing and monitoring protein and antibody products.



**Highly sensitive protein analysis.** The High Sensitivity Protein 250 kit for the Agilent 2100 Bioanalyzer offers four orders of magnitude in linear dynamic range and automatically detects and quantifies protein impurities down to 0.05%.

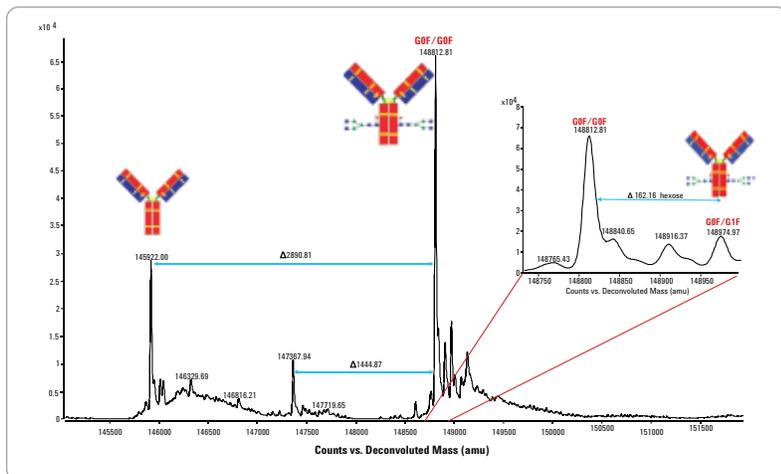


**PAGE-less protein and antibody QC testing.** In one simple step, you get details on protein size, stability, purity and concentration. Using pre-developed methods with a convenient reagent kit, the easily validated system analyzes 10 samples in less than an hour.

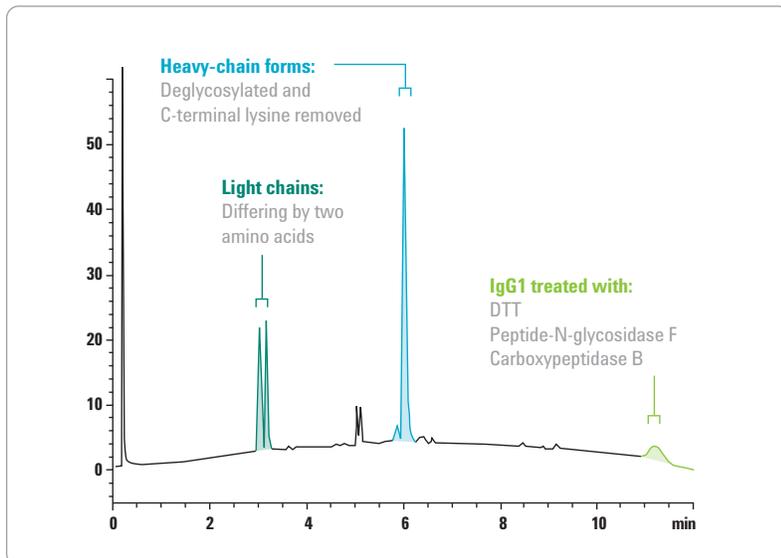
# Physiochemical Characterization | Identity

LC • LC/MS • CE • CE/MS • Peptide Mapping • Amino Acid Analysis

Agilent's CE and CE/MS high resolution capability enables thorough, confident characterization of proteins, oligonucleotides and glycans. Our LC and LC/MS solutions are also widely used for identity confirmation via peptide mapping and amino acid analysis.



**High-confidence antibody characterization.** Agilent's Ultra High Definition (UHD) mass spectrometers provide clarity needed to fully characterize intact antibodies. In the example above, the differing glycoforms can be clearly seen. MassHunter BioConfirm software (in this example showing the deconvoluted spectrum of an intact mAb) uses sophisticated algorithms for automated confirmation and characterization of recombinant proteins or synthetic peptides.



**High resolution separations of antibodies.** The Agilent Poroshell 300SB-C8 columns enhance peak shape and recovery through simplified interaction with the bonded phase. The Poroshell 300 column provides clear separation between heavy and light antibody chains of a monoclonal antibody treated with DTT, peptide-N-glycosidase F and carboxypeptidase B.

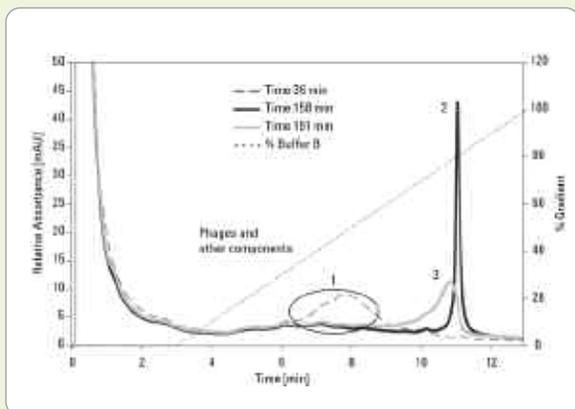


## Impurity Testing | Product-Related Impurities

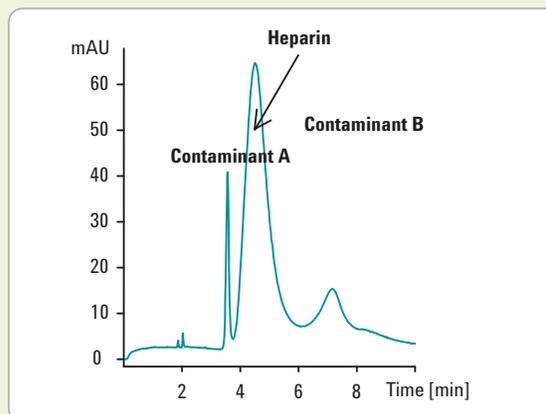
LC • LC/MS • CE • CE/MS • GC • GC/MS • ICP-MS

With the industry's most complete—and most reliable—portfolio of instruments, columns and software, we deliver the assurance you need to safeguard the quality of your therapeutic products.

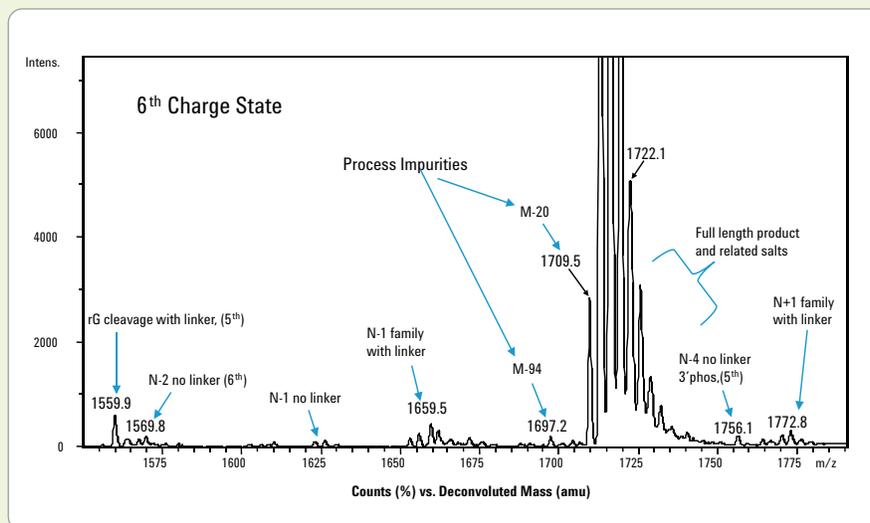
Avoiding protein aggregates and fragmentation is a particular concern—and can be challenging. Agilent can help with LC, LC/MS, microfluidic electrophoresis devices and size exclusion HPLC systems to determine these product-related impurities.



**The Agilent Bio-Monolith DEAE column provides a rapid and accurate solution for monitoring fermentation-related impurities. Host genomic DNA (peak 2) was monitored throughout a phage proliferation. This analysis provides the optimal time to stop the bioreactor before the DNA begins to degrade (peak 3), which cannot be removed through purification.**



**High-speed, high-resolution CE separation of heparin. Agilent's extended light path capillaries provide a significant sensitivity advantage for the detection of heparin-related impurities in this rapid, robust QA method.**

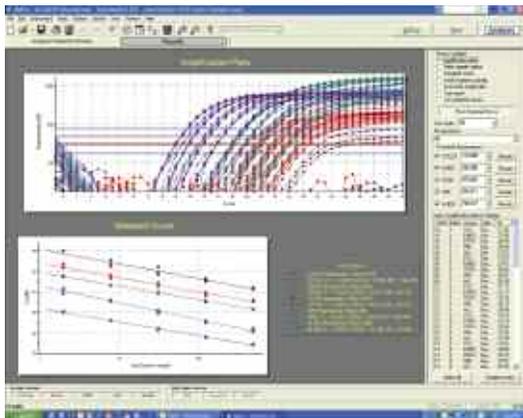


**Oligonucleotide analysis. In this LC/MS analysis of a synthesized 30-mer RNA aptamer, an expanded view of the 6th charge state reveals a variety of process impurities.**

## Impurity Testing | Host Cell DNA, Viruses

### Stratagene Quantitative PCR

With the addition of Stratagene real-time PCR, Agilent is able to offer complete workflow solutions to address contamination of host cell DNA and viruses—a critical step in ensuring the purity of your biological organisms expressing your product. Stratagene Brilliant II QPCR reagents offer superior sensitivity of detection and accommodate rapid cycling for fast, reliable results.



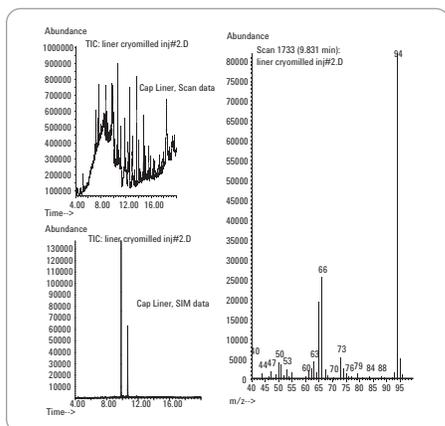
*The Stratagene Mx3005P QPCR system offers unmatched flexibility and capability to support the widest range of real-time QPCR applications and chemistries.*

## Impurity Testing | Column/Vessel Leachables and Extractables

### LC • GC • GC/MS

With a 40-year history of leadership, Agilent offers the industry's most trusted GC and GC/MS solutions. Our systems are widely used to detect and identify residual solvents in cleaning processes, as well as volatile leachables from packaging and other sources.

The Agilent 1200 Series LC continues to set the standard for analysis of non-volatile process- and packaging-related contaminants, such as cell culture media components.



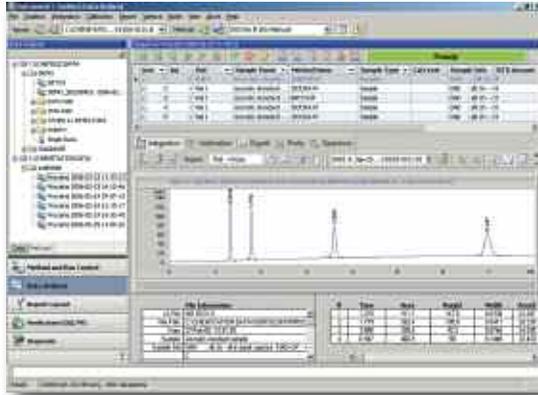
*GC/MS headspace analysis of leachables. The SIM and scan data clearly show the presence of phenol in a linear polymer material. Compound confirmation was made by comparison with a hazardous chemicals library.*



*The Agilent 7000B Triple Quadrupole GC/MS delivers femtogram-level detection of target compounds—along with maximum day-after-day productivity.*

# Integrated software solutions for R&D, scale-up, QA/QC—and the enterprise.

From instrument control to enterprise content management, Agilent recognizes the critical role software plays in bringing your company's products to market. Our software and informatics team is working towards a single goal: To help you reduce the time, effort and cost to get from raw data to final insight.



## Agilent ChemStation software

- Industry-standard chromatography data system for Agilent instrumentation
- Robust, scalable CDS ideally suited for biopharmaceutical applications from early product development to quality control



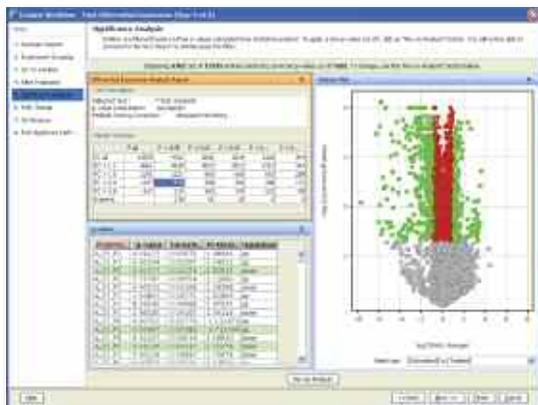
## Agilent MassHunter Workstation software

- Perfectly complements the best-in-class performance of Agilent's mass spectrometry solutions
- Single, easy-to-use interface handles basic qualitative and quantitative tasks for all Agilent MS platforms
- Seamlessly integrates with application modules such as Mass Profiler Professional and MassHunter BioConfirm software



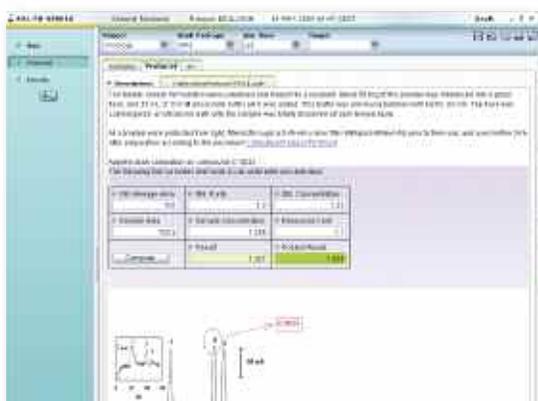
## MassHunter BioConfirm software

- Combines powerful data processing algorithms with sophisticated sequence and database matching tools for fast, accurate identification of intact proteins, peptides and their variants
- Includes a Large Molecule Feature Extractor (LMFE) specifically designed for analyzing complex mixtures of intact proteins or large oligonucleotides



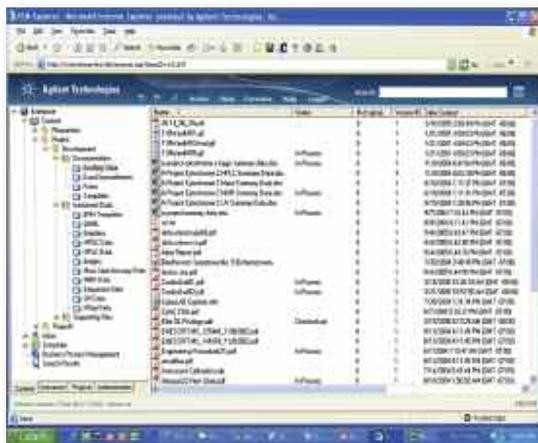
### Mass Profiler Professional

- The only chemometrics software package designed specifically for mass spectrometry data
- Lets you easily import, normalize, compare and display microarray and MS data, including GC/MS, LC/MS, CE/MS and ICP-MS
- Lets you analyze different experiment types in a single project



### Kalabie ELN lets you spend less time on paperwork and more time on science.

- Scalable, integrated platform for cross-team collaboration
- Simplifies and accelerates the R&D process and streamlines data management
- Provides a robust IP protection framework



### Agilent OpenLAB Enterprise Content Manager (ECM)

- Brings all your lab's information resources together in a scalable Web-based environment
- Provides comprehensive search functions and fast, easy accessibility

## Agilent Services keep your lab running at peak productivity.

Agilent Advantage Service not only protects your investment in Agilent instruments—it connects you with our global network of experienced service professionals dedicated to helping you get the highest levels of speed, resolution and performance from every system in your laboratory. Count on us to provide the services you need across all stages of your instrument's life cycle, from installation and upgrade to maintenance, qualification and repair.

You can also trust Agilent to deliver proven instrument qualification and calibration services in support of GMP and GLP guidelines. In fact, Agilent has been ranked #1 in compliance by independent survey since 1997. With over 100,000 successful qualification deliveries, industry-leading quality development processes and over a decade of practical compliance experience, Agilent Compliance Services helps assure confidence in your analytical results.

## The Agilent Value Promise— 10 years of guaranteed value.

In addition to continually evolving products, we offer something else unique to the industry—our 10-year value guarantee. The Agilent Value Promise guarantees you at least 10 years of instrument use from your date of purchase, or we will credit you with the residual value of that system toward an upgraded model. Not only does Agilent ensure a safe purchase now, we help ensure your investment is as valuable to you in the long run.



### The Agilent Service Guarantee

Should your Agilent instrument require service while covered by an Agilent service agreement, we guarantee repair, or we will replace your instrument for free. No other manufacturer or service provider offers this level of commitment to keeping your laboratory running at maximum productivity.

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