

Agilent Molecular Spectroscopy Solutions

For the pharmaceutical and biopharmaceutical industries



Analytical Workflows for Drug Discovery, Drug Development, and Drug Manufacturing

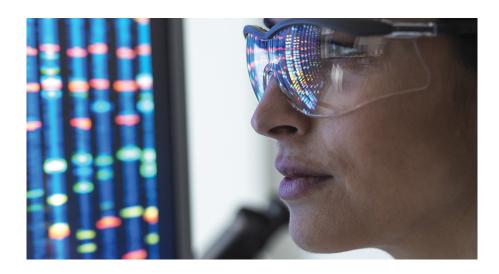
Agilent's innovative molecular spectroscopy products are designed to meet the application requirements that are critical for pharmaceutical and biopharmaceutical laboratories.

Our range of molecular spectroscopy products includes:

- Ultraviolet visible spectrophotometers (UV-Vis)
- Fluorescence spectrometers (FLR)
- Fourier transform infrared spectrometers (FTIR)
- Laser direct infrared chemical imaging systems (LDIR)
- Transmission Raman spectroscopy (TRS)
- Spatially offset Raman spectroscopy (SORS)

These analytical instruments can be used for basic research, drug discovery, and drug development, and most have the necessary features to be used in manufacturing environments.

Agilent also has an extensive range of other instrumentation, including chromatography, mass spectrometry, and atomic spectroscopy instruments. All instruments are designed and manufactured according to a quality management system certified to ISO 9001. We also offer a wide range of support services to help with instrument qualification, maintenance and repair, and operator training.





Basic research/drug discovery

•	
Instruments	Applications
• • •	Lead compound discovery and optimization
• • •	Structure confirmation
• • •	Ligand binding interaction
• • •	Reaction monitoring
• • •	DNA and protein quantification
• • •	Drug receptor binding studies



Drug development

Instruments	Applications
• • •	Structure elucidation and confirmation
• • •	Purity analysis
• • •	Organic impurity analysis
•	Formulation development
•	API stability and degradation analysis
•	Polymorph screening

Content uniformity and assay

Tablet dissolution studies



Drug manufacturing

Instruments	Applications
•	Raw material analysis
•	Packaging material identification
• •	Raw material verification/identification
• •	Batch release testing—identification
• •	Batch release testing—content uniformity and assay





Cary 60 UV-Vis Spectrophotometer

The flexible UV-Vis for wide ranging applications

The wide range of accessories available for the Cary 60 make it suitable for many applications. From measuring sample volumes of less than 4 μ L, to dilute samples in long pathlength cells, through to solid samples or those remote from the instrument.

The Cary 60:

- Is ideal for routine pharma QA/QC workflows and R&D applications
- Accepts low-volume and long-pathlength cuvettes
- Offers fiber-optic probe capability for fast measurements without pipetting or cuvettes
- Collects data fast, giving you high sample throughput

Applications include:

- Characterization and quantification of unknown or newly synthesized compounds
- Monitoring kinetics of chemical or biological reactions that occur at sub-second rates
- Nucleotide and protein quantification
- Measuring cold biological samples immediately after removal from the refrigerator
- Analyzing small amounts of precious sample (< 4 μL)
- Measuring low concentration samples with a range of long pathlength cells

Learn more: www.agilent.com/chem/cary60



As well as being a standalone instrument for routine UV-Vis measurements, the Cary 60 is also a powerful component of application-specific systems. This includes the Agilent 708-DS dissolution apparatus (shown here).



The Cary 60 fiber-optic probe removes the need for expensive cuvettes. It can measure cold, hot, and odd-shaped samples. Samples can be measured straight out of the fridge, without condensation causing problems.



The Cary 60 has a highly focused beam, ideal for use with small volume cuvettes.

Cary 3500 UV-Vis Spectrophotometer

Multiply your experimental possibilities and amplify confidence in your results

The Cary 3500 has an integrated, permanently aligned multicell holder with no moving parts—removing the risk of misalignment and incorrect results.

All eight cuvettes can be measured at the same time—with the cuvettes grouped into one, two or four temperature zones, each at any temperature between 0 and 110 °C. You can run reaction kinetics or temperature stability studies in parallel, slashing data collection from days to minutes. Having eight cuvette positions means you can measure your standards and sample concentrations at the same time, under the same conditions.

The Cary 3500 is ideal for liquid sample measurements, such as:

- Biological samples: nucleic acids and proteins for thermal analysis
- Chemicals: concentration and characterization
- Enzymes, other catalysts: kinetics and time-based measurements

The Cary 3500 UV-Vis spectrophotometer is compatible with the Agilent OpenLab software suite of products.

Learn more: www.agilent.com/chem/cary3500uv-vis





The Cary3500 Multizone UV-Vis has no moving parts and allows up to four temperature zones to be configured. Each pair of cuvettes can be held at a different temperature.



A single zone instrument configuration is also available, with temperature ramping supported.



In-cuvette temperature probes accurately control experimental temperature via feedback from within the sample itself. The instrument's light beam is tightly focused, making it ideal for small volume samples.

TRS100 Quantitative Pharmaceutical Analysis System

Content uniformity, drug product assay, and identity for oral solid dosages

Completing quality control to release your products after manufacture can be a significant bottleneck. Traditional wet chemistry techniques take skill, resources, and much time spent preparing samples. The Agilent transmission Raman technology (TRS) can reduce the bottleneck by analyzing oral solid dosages (OSD) directly in manufactured form, without dissolving. Sample preparation involves putting the tablets in a tray. Content uniformity, product assay, and ID can all be done in around 15 minutes per batch.

R&D applications in formulation development and polymorph quantification

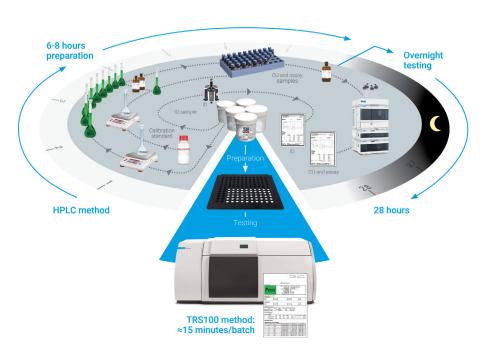
The TRS100 is used in R&D and formulation development applications for both qualitative and quantitative analysis of a variety of sample types; tablets and capsules, powders, creams, gels or liquids.

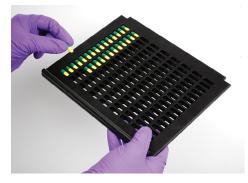
The versatile sample tray can accommodate all these sample types to allow fast, non destructive, high throughput screening.

For polymorph and crystallization analysis, the Agilent TRS100 can be used to quantify the amount of crystalline material in whole, intact tablets. This is useful for stability studies where the same sample is required to be measured multiple times over a long period of time. The instrument has limits of detection as low as 1%w/w.

Learn more: www.agilent.com/chem/raman-trs100

TRS100 FAQs: www.agilent.com/chem/trs-faq





1. Place tablets or capsules on a tray.



2. Place the tray in the instrument for analysis. No sample preparation is required.

Cary 630 FTIR Spectrometer

Multifunction FTIR with a tiny footprint

The small footprint Cary 630 can be fitted with a range of easy-to-swap sampling modules. Common measurement types include variable pathlength transmission measurements (DialPath accessory) and standard diamond/ZnSe/Ge ATR.

The Cary 630 meets the performance specifications of global pharmacopoeia such as the European, U.S., Indian, and Japanese pharmacopoeia.

Analyzing polymers used in pharmaceutical packaging

The Cary 630 is ideal for:

- Detecting pharmaceutical counterfeits with packaging analysis
- Testing of plastic materials used to package pharmaceutical products in accordance with regulations such as USP Chapter <661.1>
- Identifying packaging materials when investigating product quality issues

Verifying the identity and quality of raw materials, in-process materials and final products

The Cary 630 reliably identifies materials, using spectral-matching, generally without sample preparation. Spectral libraries can be created from reference materials and new spectra can be easily added to a library. Alternatively, Agilent offers application-specific spectral libraries. The instrument's MicroLab software has logic-setting capabilities that allow it to easily distinguish between different material qualities.

Quantifying small and large molecules

The Cary 630 can be used to quantify multiple components with a single measurement. Typical routine quantification applications include:

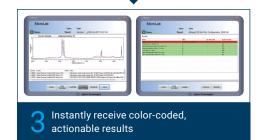
- APIs in tablets
- Antibiotics in formulations
- Immunoglobins in plasma
- Assays of final products (according to pharmacopeial methods)

Learn more: www.agilent.com/chem/cary630





2 Follow the picture-driven software guidance and load the sample



The Agilent MicroLab software uses step-by-step guidance with pictures. The easy workflow interface means less training and fewer mistakes.



The Agilent Cary 630 FTIR spectrometer with a DialPath sampling module eliminates the need for fragile and error-prone liquid cells.

Cary Eclipse Fluorescence Spectrophotometer

Multifunctional fluorescence measurements for pharmaceutical research and development

The Cary Eclipse is a general-purpose fluorescence instrument with a wide range of optional accessories, making it suitable for many applications. Its Xenon lamp is guaranteed for 10 years and enables immunity to room light. You can run your samples in many configurations, including outside the sample compartment, using a fiber-optic probe. The lamp also minimizes photobleaching effects in sensitive samples.

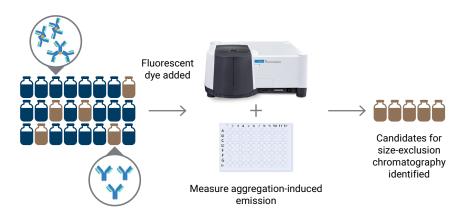
The instrument has accessories for precise sample temperature control, a rapid-mix accessory for ultrafast kinetics studies, and automated polarizers with a wavelength range that allows proteins to be analyzed. The microplate reader is ideal for biopharma applications.

The Cary Eclipse operates in fluorescence, phosphorescence, chemiluminescence, bioluminescence, and time-resolved collection modes.

The Cary Eclipse is ideal for:

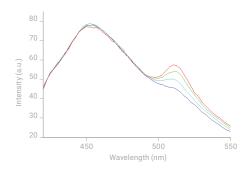
- Qualitative and quantitative fluorescence, phosphorescence, chemiluminescence, or bioluminescence measurements
- Protein quantification and structural studies
- Protein-protein interactions
- Membrane studies
- Enzyme kinetics with fluorescent substrate
- Fluorescent protein expression
- Drug receptor binding studies
- High throughput mAb aggregation prescreening

Learn more: www.agilent.com/chem/cary-eclipse





The wide range of accessories available for the Cary Eclipse includes a microplate reader, ideal for biopharma applications.



Emission spectra of a fusion protein (blue fluorescent protein and green fluorescent protein) following 360 nm excitation.

Green fluorescent protein emission (~510 nm) is seen upon specific excitation of blue fluorescent protein alone (360 nm). This emission is indicative of fluorescence resonance energy transfer.

Using a Cary Eclipse fluorescence spectrometer and a PEPBOPS dye as a fluorescent probe, you can prescreen samples for size exclusion chromatography (SEC), or other higher resolution techniques.

mAbs samples containing aggregates and monomers

RapID and Vaya Portable Raman Spectrometers

Through-container raw material verification

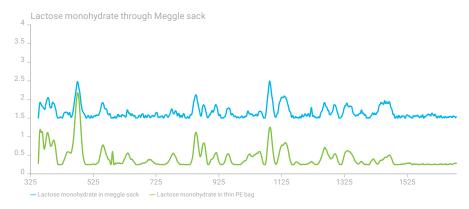
The portable RapID and the handheld Vaya instruments use Spatially Offset Raman Spectroscopy (SORS) technology to identify solid and liquid materials inside their containers. They are designed for high-throughput identification testing of incoming raw materials. They work through opaque packaging, such as paper sacks, FIBC, thick plastic containers, and amber glass bottles, with a single 5 to 30 second measurement. Both instruments can verify the identity of most active APIs, and common excipients and be used in a cGMP warehouse for ID at receipt. They can replace existing Raman, NIR and FTIR spectroscopy instruments being used for this purpose.

Identifying materials through the packaging allows you to:

- Avoid sampling booth, sampling booth costs, and quarantine delays
- Reduce QC lab turnaround times and expensive outsourced testing
- Maintain sterility, prevent cross-contamination
- Preserve shelf life of unopened products
- Avoid worker exposure to high potency APIs

Learn more: www.agilent.com/chem/raman-vaya

FAQs about Vaya handheld instruments: www.agilent.com/chem/vaya-faq

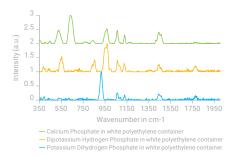


The overlaid spectra of lactose monohydrate inside a Meggle sack and inside a polyethylene liner show good agreement. By producing a spectrum of the raw material, free of container interferences, the Agilent Vaya instrument can easily verify the identity of a raw material through multilayer paper bags. Study: Rapid Identification of Raw Materials Inside Packaging





The Vaya and RapID instruments can measure the Raman spectra of solid and liquid materials without opening containers.



The overlaid Raman spectra of L-Alanine, L-Phenylalanine, and Glycine amino acids. These three amino acids can easily be distinguished by their specific spectral markers. Study: <u>Differentiating Biopharmaceutical</u> <u>Raw Materials Using Spatially Offset Raman</u> <u>Spectroscopy</u>

GMP Compliance



21 CFR Part 11/Annex 11 compliance support

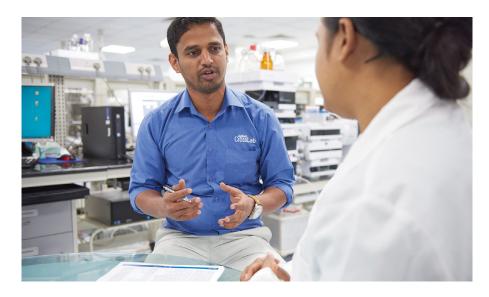
Agilent offers software tools to help meet the requirements of electronic records regulations, as indicated in the table following:

Instrument	Instrument software	Software tools to support 21 CFR Part 11 compliance
Cary 60 UV-Vis	Cary WinUV	Yes ¹
Cary 3500 UV-Vis	Cary UV Workstation	Yes¹ Agilent OpenLab compatible
Cary Eclipse Fluorescence	Cary WinFLR	No
Cary 630 FTIR	MicroLab	Yes ¹
TRS100 TRS	ContentQC	Yes ²
RapID SORS	RapID	Yes
Vaya	Vaya software	Yes

^{1.} Optional

 $^{2.\} Does\ not\ support\ the\ requirements\ of\ subpart\ C,\ electronic\ signatures,\ of\ US\ FDA\ CFR\ 21\ Part\ 11.$

Set Up Your Lab for Success





Maximize instrument performance with Agilent CrossLab services. Our industry-leading services—tailored to meet your needs—can help your lab extend uptime, produce reliable data, stay compliant, and have predictable service costs. And because a skilled team is a key driver of lab success, we also offer comprehensive learning opportunities from beginner to expert.

Compliance services

Labs are increasingly outsourcing their compliance tasks to save time and maximize efficiency. Agilent CrossLab compliance services—including operational and repair qualification—give you confidence that your equipment and processes conform.

Rely on our Network Distributed ACE platform to simplify deployment and preserve data integrity, while enabling paperless electronic reports and signatures. Most importantly, you'll also be confident that you are audit ready.

Financial solutions

Acquire the latest innovations through flexible installment plans—without a large down payment.

CrossLab service plans

Maintain instrument performance with Agilent CrossLab service plans. Choose Enhanced Extended Warranty for added peace of mind with annual preventive maintenance after your first year.

Agilent University

Gain insights for boosting efficiency and minimizing downtime with flexible training options—including in person, virtual, and on-demand online.

CrossLab start up

Prepare your site, familiarize yourself with operations, and maximize accuracy from the start with installation, introduction, and First Run Assist.

Method & applications services

Overcome application problems and reduce the time it takes to deploy new methods—by partnering with our global team of application experts.

Learn more: www.agilent.com/en/service/laboratory-services/compliance-services

Agilent CrossLab: Real insight, real outcomes

CrossLab goes beyond instrumentation to bring you services, consumables, and lab-wide resource management. So your lab can improve efficiency, optimize operations, increase instrument uptime, develop user skill, and more.



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