

# Optimizing LCs During a Pandemic

Agilent InfinityLab LC Solutions



Agilent  
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Trusted Answers

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## Preface

# The World Expects a Lot from You

Almost 20 years ago, in my first “real job,” I was running LC tests on a therapeutic candidate to treat lupus nephritis—a terrible disease where the human body attacks itself using its own immune system. The honor and responsibility I felt working to find a treatment to prevent these horrible effects was very real to my 23-year-old brain, and I was devastated when the clinical trial results were not as we had hoped. I have since moved on to work for LC and LC/MS vendors, and I have felt immense satisfaction for 14 years now from being a part of creating and implementing novel technologies that assist all of you in your work developing and manufacturing not just one potential treatment, but thousands of them. Informed by these experiences, I know the demands on you in the pharmaceutical industry have never been higher, given the COVID-19 pandemic. The global community expects vaccines to be readily available in mere months, when the shortest development time previously observed was four years.

At the same time, (bio-)pharmaceutical laboratory efficiencies have been severely hampered by split schedules, social distancing and formal virtual meetings replacing those wonderfully spontaneous hallway discussions that always seemed to make collaboration and planning easier. While each of us is worrying about our families and friends and exhausted from the fatigue of constant decision making (Should I go to the grocery store today? Should I send my child to school?), people worldwide continue to suffer from cancer and other illnesses, millions of people in all geographies continue to require medicine to manage their existing conditions like diabetes and heart disease (among others), and low- to middle-income countries continue to need vaccinations against other deadly diseases like tuberculosis.

It is therefore more important than ever for each of us to use every capability possible to get the most out of those precious minutes where access to the laboratory is feasible. That is what this eBook is really about—there are many unique and elegant technologies embedded in the Agilent InfinityLab LCs that are designed to free up experts for more challenging tasks and to provide versatility while delivering excellent results in a robust way. We understand from our users that these valuable features are often underutilized and we know they can make a difference, especially now. We therefore felt compelled to compile this special set of application notes, user testimonials, and educational content in one place to do our part in supporting you in your efforts to improve the human condition.

Thank you for all you do for me and my loved ones in providing new and existing treatment options. I wish all of you safety, good health, and success in these unprecedented times.

– **Jade C. Byrd**

Director of Industry Marketing,  
Agilent Technologies, Inc.



Jade has worked with laboratory-driven organizations implementing LC and LC/MS solutions for 14 years, first as an applications chemist and then as a product manager. Prior to working for LC vendors, Jade worked in the pharmaceutical space doing routine analysis and software-assisted chromatographic method development and validation. Today, Jade works to ensure that Agilent InfinityLab LC Solutions meet both the technical and business needs of her user communities, which include the (bio-) pharmaceutical, environmental, research, food, chemical, and energy markets and she is passionate about LC and LC/MS.

Chapter 1

Ensuring a Safe  
**and Content**  
Lab Environment



Ensuring a safe and content lab environment

## Safety First

Clearly, the safest choice for your staff is to telecommute. However, for (bio-)pharmaceutical organizations, operations are largely laboratory driven and require work that can only be achieved with access to the laboratory.

In addition to the “big three” (washing hands, wearing a mask, and keeping distance), instituting shifts, relocating data analysis stations, and dedicating instruments to certain shifts or staff members (instead of dedicating instruments to methods) can allow for continuation of lab operations while still ensuring the safety of lab personnel.<sup>1</sup> Indeed, LCs can be quickly upgraded to run multiple different methods (similar to the [Agilent 1290 Infinity II Multimethod System](#)).



Agilent 1290 Infinity II  
Multimethod System

Switching from a 2 mL vial to 364-well plate sample format can enable up to 4 days of continuous unattended run times (at a UHPLC scale of ~1 minute run time per injection) using the Agilent InfinityLab multisamplers. With four Agilent InfinityLab multicolumn thermostats, two external solvent selection valves, and eight temperature zones, as in the [Agilent 1290 Infinity II Method Development System](#), up to 5,400 different chromatographic methods can be explored.

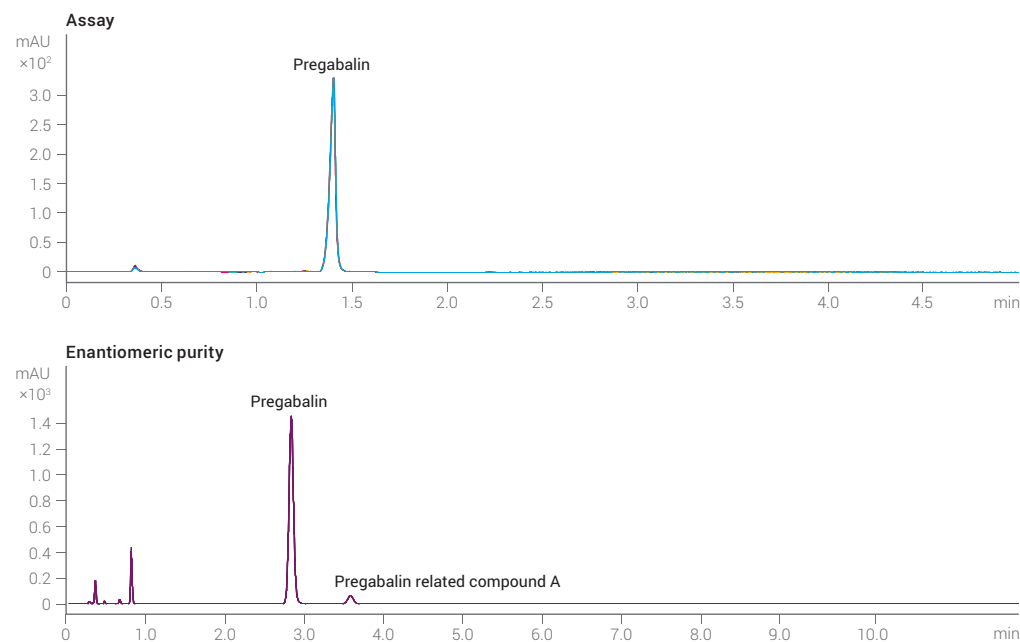


[Agilent 1290 Infinity II  
Method Development System](#)

*"Method development is not easy. We bought the 1290 Infinity II LC because of its good integration with ChromSword."*

– **Keiko Yamane,**  
Researcher,  
Taiho Pharmaceutical Co, Ltd.

If your lab is not able to quickly change autosamplers or sample containers, the simple addition of a column selection valve can ensure that many samples and methods can be queued up to run overnight (see Figure 1).



**Figure 1.** The two USP methods required for the analysis of pregabalin—assay and enantiomeric purity—are run on a single Agilent 1260 Infinity II Prime LC instrument, which contains technology from the Agilent 1290 Infinity II LC System. The methods use different columns, so a column selection valve was employed so that no manual method switchover of the LC was required.



#### Download application note

Learn how the 1260 Infinity II Prime LC can run two USP methods on one system.



#### Mind behind the science

*“Thinking about the multisampler, what I am most proud of is that 6,144 samples can be run unattended within the same spatial geometry as what previously could only handle two well plates of 384 samples each. It is purely very astonishing and is very unique in the marketplace.”*

– **Matthias Wetzel**,  
Senior Engineering Director,  
Agilent Technologies, Inc.

Ensuring a safe and content lab environment

## Precious Moments in the Lab

A published global 2019 survey showed that 20% of chemists today feel their job does not fully utilize their skills.<sup>2</sup> In addition to ensuring the laboratory staff feels their time is valued and well spent, access to glassware, waste disposal services, fume hoods, and instrumentation is currently at a premium, so it is critical now more than ever to automate any task that does not require expert skill and knowledge.

There are many sample and mobile phase solutions that can be automatically created for analysis using the LC—**calibration curves and high/low sample concentrations can be programmed directly in the injector control panel** and **varying concentrations of mobile phase components can be programmed using elegant software called BlendAssist**.

Few scientists will appreciate having to waste both their time and that of potentially absent or furloughed glasswashers to unnecessarily make buffer and test solutions manually.



### Download technical overview

Learn how the injector program of the Agilent 1290 Infinity II Vialsampler and Multisampler can be used to prepare calibration solutions.

### Download technical overview

Discover how solvent composition can be rapidly optimized with BlendAssist.

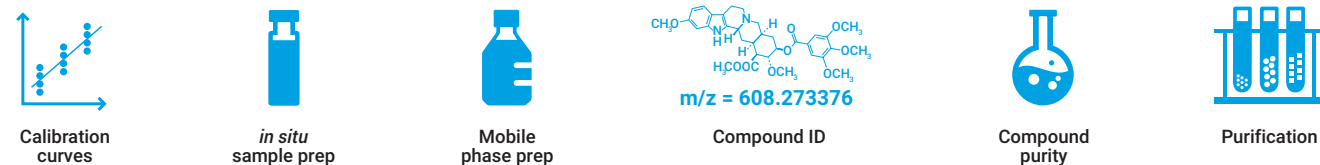


### Mind behind the science

*“Thinking about the 1290 Infinity pump technology, one of our significant enhancements in the design is our approach to the metering of eluent using sophisticated algorithms of piston motion control and mixing the mobile phase components to a precise gradient by using a Jet Weaver mixer, which is based on metal microfluidics technology. These innovations enable better control of the solvent mixing and are more efficient, providing more precise flow and better composition performance with lower additional delay volume in the system compared to traditional mixing devices—for example, ball mixers.”*

— **Konstantin Shoykhet, PhD**,  
Principal Scientist, Liquid Phase R&D,  
Agilent Technologies, Inc.

Automation of the **identification of a chemical formula, assessing compound purity, and purification by fraction collection** can also be performed unattended.



**Figure 2.** Lean on your LC—six ways the LC can do the work for your staff: creation of calibration curves, in-situ sample dilution, mobile phase preparation, compound chemical identification, assessment of compound purity, and purification by preparative-scale fractionation are all possible with little to no oversight of laboratory personnel.

*“I was most interested in the new Automated Purification Software. I am normally a skeptical guy and I doubted that the software could magically create the ideal gradient, but this software actually works.”*

— Laszlo Varady, PhD,  
President and CEO,  
Rilas Technologies



#### [Download application note](#)

Read more about using an Agilent single quadrupole LC/MS system to accurately identify a chemical formula.

#### [Download application note](#)

Learn how the Agilent 1260 Infinity II LC, coupled with the Agilent LC/MSD XT, enables easy purity analysis.

#### [Download technical overview](#)

See how the Agilent 1290 Infinity II Preparative LC/MSD System can be used to purify a sample under low- and high-pH conditions.

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## Communication in the Socially Distanced Lab

High-tech options will certainly be on the rise, but sometimes it is best to use the simplest approach for the communication of a split shift's status, a request of assistance, or labeling an instrument that is down for maintenance.<sup>3</sup> Some, including some regulatory bodies, have stated that the pandemic has simplified decision making and publishing guidance documents<sup>4</sup> and some scientists feel more connected than ever.<sup>5</sup>

Whatever your lab is experiencing, capabilities in the newly released [Agilent InfinityLab Companion](#) can alleviate any LC-related miscommunications by allowing chemists to dial directly into their LC and see the instrument status for themselves.

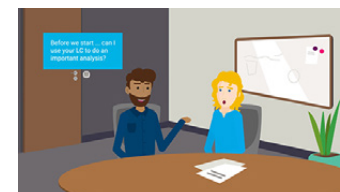
*"We find the instruments from Agilent more flexible; I think we can do more with them."*

– **Keiko Yamane,**  
Researcher,  
Taiho Pharmaceutical Co., Ltd.



**Watch three short videos**

to discover the benefits of the InfinityLab Companion.



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## Eliminating Human Errors

The emotional toll of worrying about family members<sup>6</sup> and making constant decisions<sup>7</sup> has exhausted the workforce in ways not previously observed. Whether the team is working from home or in the laboratory, it is vital to provide training (see page 18) and software that is efficient, easy to use, and error tolerant.

Agilent InfinityLab LC Solutions offer many configuration options to provide the possibility of multipurpose instruments and therefore require elegant software to display what is installed in the instrument and the instrument's current status.

*"The Agilent 1290 Infinity II LC is extremely useful because even nonanalytical researchers can easily perform measurement tasks."*

– **Kazuaki Kanai, PhD,**  
President and CEO of  
JITSUBO

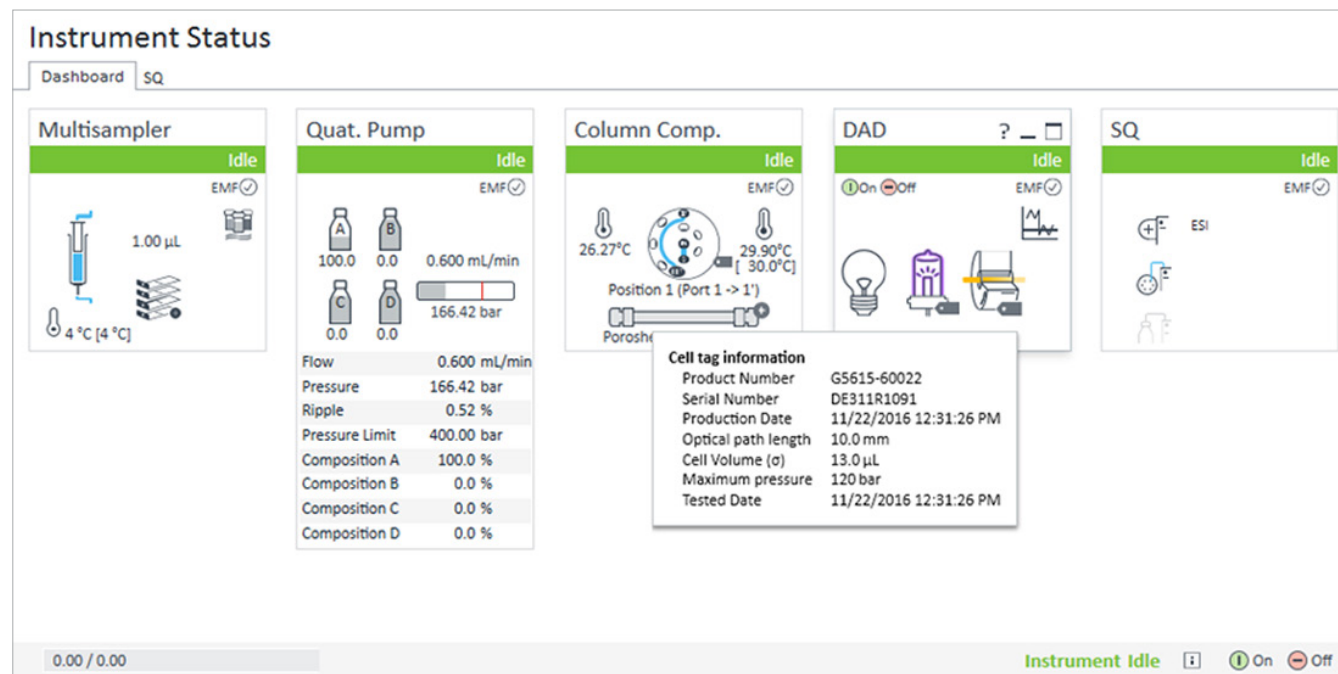


**Agilent 1290 Infinity II  
Multi-Method System**

See Figure 3 and Figure 4 for an example of this user-centric approach, which is harmonized across Agilent and multivendor data systems in the robust [Agilent Instrument Control Framework](#).



Agilent Instrument  
Control Framework




**Figure 3.** The instrument dashboard within the instrument console clearly shows which type of flow cell is installed. This view is the same in a non-Agilent data system as in an Agilent data system.

Column Assignment

Plumbing

Valve Position	Location
1	Left 1
2	Left 2
3	Left 3
4	Left 4

Visualization



Valve Type: 4-pos/10-port bio-inert valve 600 bar (5067-4134)

Column Tag Information

	Location	Color Code	Description	Length [mm]	Diameter [mm]	Particle Size [µm]	Max. Pressure [bar]	Injections
▶	Left 1	Red	Poroshell 120 EC-C18	100	0.01	2.7	600	21
	Left 2	Blue	Poroshell 120 EC-C18	150	3.0	2.7	600	21
	Left 3	Green	Poroshell 120 EC-C18	50	3.0	2.7	600	43
	Left 4	Yellow	Poroshell 120 EC-C18	100	4.6	2.7	600	17
	Right 1	None		0	0.0	0.0	0	0
	Right 2	None		0	0.0	0.0	0	0
	Right 3	None		0	0.0	0.0	0	0
	Right 4	None		0	0.0	0.0	0	0

Refresh Table   Ok/Write Tag   Cancel   Help

**Figure 4.** Color-coded references of the installed columns in the instrument control software make it easy to understand what is installed and configured in the instrument.



### Mind behind the science

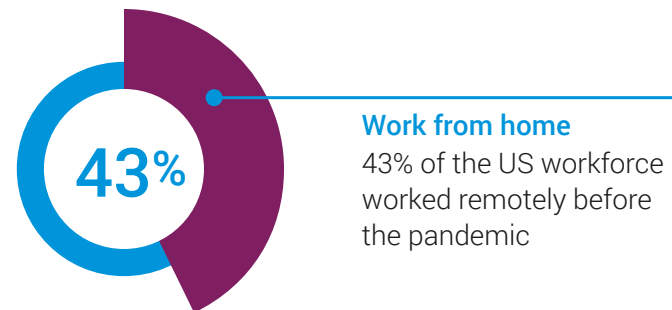
*“The one thing that I’m most proud of, considering our instrument control strategy, is that with the advent of the RC.NET interface and Instrument Control Framework (ICF) and the generalization that we made there, we are now able to quickly deliver a new product or an enhancement to a new product with its complete functionality to multiple data systems at the same time... Our users who are in non-Agilent data systems can enjoy the power of the Agilent LC systems as we intend them to; we can take care that whatever experience a user is having, either in our data system or from someone else, the experience is at the quality standards that we set, as Agilent.”*

– **Peter Nill, PhD,**  
Product Manager,  
LC Instrument Control,  
Agilent Technologies, Inc.

Ensuring a safe and content lab environment

## Leading in Uncertain Times

The etiquette for online meetings has certainly evolved since the early days of the pandemic, where initially it was expected that children or pets would be disruptive—but for some, the charm of these interruptions has waned.<sup>8</sup> Whatever the culture in your organization, it is vital to demonstrate empathy<sup>9</sup> and patience with staff working from home and to continue to engage in meaningful ways.<sup>10</sup> One key aspect of keeping the team motivated is to continue to connect their individual work to the company's mission statement or core values.<sup>11</sup> Setting realistic expectations—both for yourself and for your team—is also critically important as the dynamics of the day-to-day situation change.<sup>12</sup>



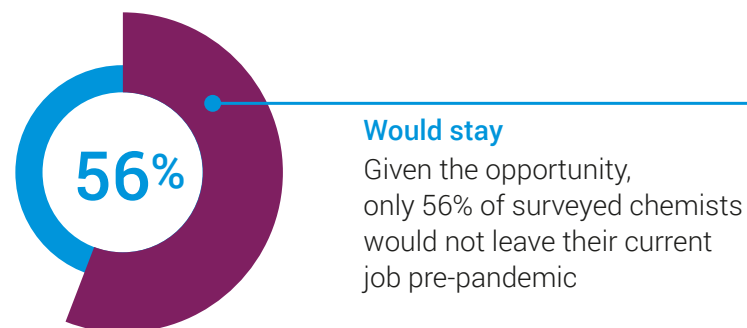
**Figure 5.** Pre-pandemic, 43% of the U.S. workforce was working remotely, but this was a rarity for laboratory personnel.<sup>10</sup> The pandemic has required those for whom working remotely was largely unknown to adapt, chemists and lab managers alike.

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## A Pandemic's Effect on Employee Engagement

A global 2019 survey shows that 44% of chemists would consider leaving their current position<sup>2</sup> and, while the pandemic may slow a staff's willingness to leave a stable job, many are still willing.<sup>13</sup> Employee satisfaction will continue to—and potentially increasingly—affect the efficiency of the laboratory, the quality of results, and the adherence to compliant behaviors.

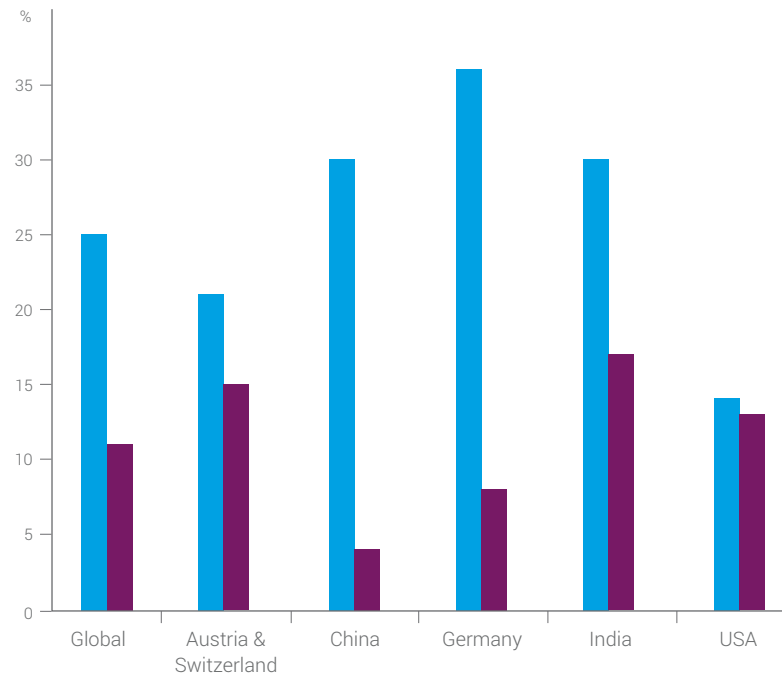
The mental and emotional demands on laboratory teammates have soared since the start of the pandemic, many requiring more careful coordination and the use of new tools to schedule experiments, plan socially distanced use of equipment, and maintain social relationships.<sup>14</sup>



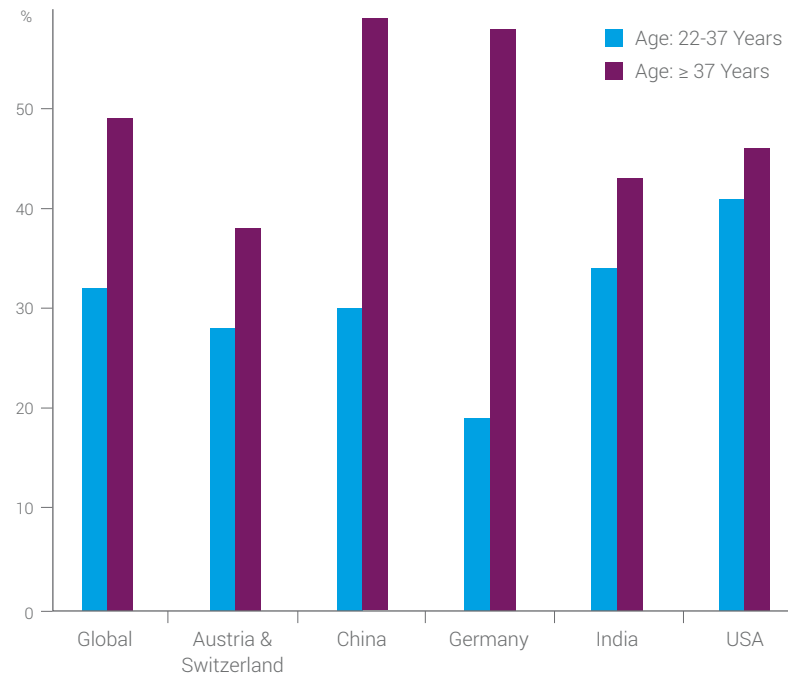
**Figure 6.** How likely is your staff to leave their job? A pre-pandemic 2019 survey showed only 56% of chemists would not leave given the opportunity.<sup>2</sup>

Depending on your team’s demographic, personal motivation may stem more from a desire to advance one’s career than the pride that comes from contributing to human health (see Figure 7).

Main Motivation for Career Progression Opportunities



Main Motivation to Improve Human Health



**Figure 7.** What motivates your staff? Age affects the main personal motivation to work in a (bio-)pharmaceutical laboratory, with millennials more interested in career advancement while older lab managers are primarily inspired by the contribution their work has on improving human health.<sup>15</sup>

Ensuring a safe and content lab environment

## You Can Still Offer Career Enrichment Opportunities

Despite the challenges of juggling home schooling, elder care, and burn-out from working from home, many scientists are rising to the challenge and finding ways to contribute and move projects forward without being physically in the lab.<sup>16</sup> In addition to processing raw data and writing reports, there are opportunities to use the current situation to do a critical review of processes, annual checks of SOPs, and the authoring or updating of existing experimental protocols.

There are several online training resources that can be both a career-building and flexible use of time while working from home: [Agilent University](#) (both free and for-fee content), the [Agilent User Community](#), [educational webinars](#), [podcasts](#), the [Agilent YouTube channel](#), and the Agilent Information Center (included with every LC purchase—see Figure 8 on the next page) are just a few of the resources available for Agilent LC-specific learning content that are suitable for use while telecommuting.



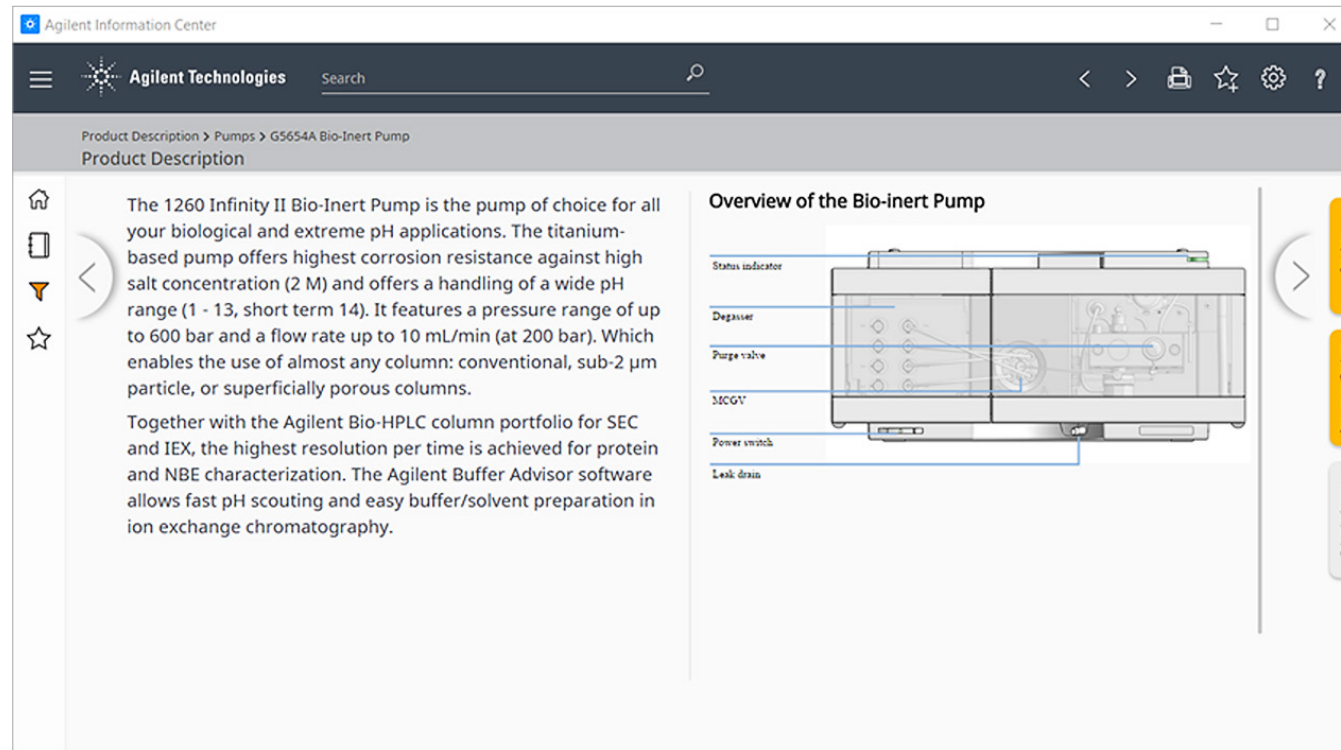
[Agilent University](#)

[Agilent User Community](#)

[Educational webinars](#)

[Agilent podcasts](#)

[Agilent YouTube channel](#)



The screenshot displays the Agilent Information Center interface. The top navigation bar includes the Agilent Technologies logo and a search bar. The breadcrumb trail indicates the location: Product Description > Pumps > G5654A Bio-Inert Pump. The main content area is titled "Product Description" and contains two columns. The left column provides a detailed text description of the 1260 Infinity II Bio-Inert Pump, highlighting its titanium-based construction, corrosion resistance, and performance specifications. The right column, titled "Overview of the Bio-inert Pump", features a technical diagram of the pump with labels for various components: Status indicator, Degasser, Purge valve, SICG, Power switch, and Leak drain. The interface also includes a sidebar with navigation icons and a right-hand sidebar with "See also" and "Related reference" links.

Agilent Information Center

Agilent Technologies Search

Product Description > Pumps > G5654A Bio-Inert Pump

Product Description

The 1260 Infinity II Bio-Inert Pump is the pump of choice for all your biological and extreme pH applications. The titanium-based pump offers highest corrosion resistance against high salt concentration (2 M) and offers a handling of a wide pH range (1 - 13, short term 14). It features a pressure range of up to 600 bar and a flow rate up to 10 mL/min (at 200 bar). Which enables the use of almost any column: conventional, sub-2  $\mu\text{m}$  particle, or superficially porous columns.

Together with the Agilent Bio-HPLC column portfolio for SEC and IEX, the highest resolution per time is achieved for protein and NBE characterization. The Agilent Buffer Advisor software allows fast pH scouting and easy buffer/solvent preparation in ion exchange chromatography.

### Overview of the Bio-inert Pump

- Status indicator
- Degasser
- Purge valve
- SICG
- Power switch
- Leak drain

See also

Instrument Products

Related reference

**Figure 8.** The Agilent Information Center has introductory overviews of LC modules such as this one, as well as videos demonstrating maintenance procedures for when chemists return to the lab.

## Chapter 2

# Maintaining Sample Throughput and Compliance During a Pandemic



Maintaining sample throughput and compliance during a pandemic

## Business Continuity

In pre-pandemic times, it may have been acceptable to have idle, backup, or “boutique” instruments—those that served a single purpose and are rarely used. As “re-shoring” (the opposite of off-shoring) becomes more prevalent, analysts may need to run newly incoming methodologies or experiments that were previously delegated to other sites or departments.

It is therefore imperative to leverage the full operating ranges of each LC instrument. In this way, staff can be confident that the instrument is not limiting their ability to run new samples when they arrive in the lab.

*“With our InfinityLab LCs, we go between HPLC and UHPLC experiments frequently. Though some optimization was initially required, we find this very straightforward.”*

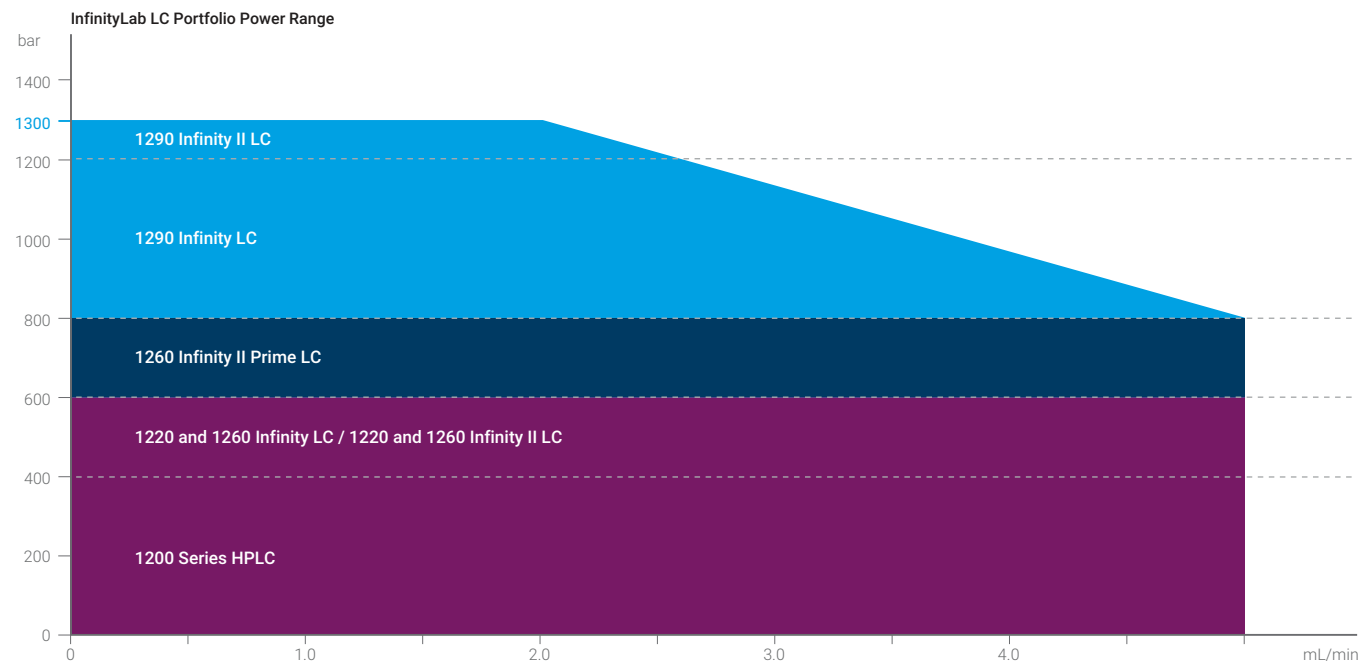
– **Keiko Yamane**  
Researcher,  
Taiho Pharmaceutical Co., Ltd.



### [Download white paper](#)

Read our white paper on how the 1260 Infinity II Prime LC can improve your return on investment in LC.

The ideal state is to be able to seamlessly transfer between more historical HPLC-style experiments and those that require a low-dispersion instrument while running sub-2-micrometer particle column chemistries, as can be achieved on the [Agilent 1290 Infinity II LC](#) and [Agilent 1260 Infinity II Prime LC](#) Systems.



**Figure 9.** The wide power range of the Agilent InfinityLab LC Series ensures that both HPLC and UHPLC methods from narrow-bore to standard-bore columns can be executed.



[Agilent 1290 Infinity II LC](#)

[Agilent 1260 Infinity II Prime LC](#)



#### Mind behind the science

*"The 1290 Infinity LC System was optimized for very low dwell volumes and high pump accuracy. Some customers wanted to run their legacy methods on the new system but got deviating results due to the differences in system characteristics... an issue that needed to be addressed right away. We decided to go for a software-based system emulation (ISET) as we needed to address a large number of different system configurations (including systems from other vendors), which would have been impossible to achieve with hardware-based approaches."*

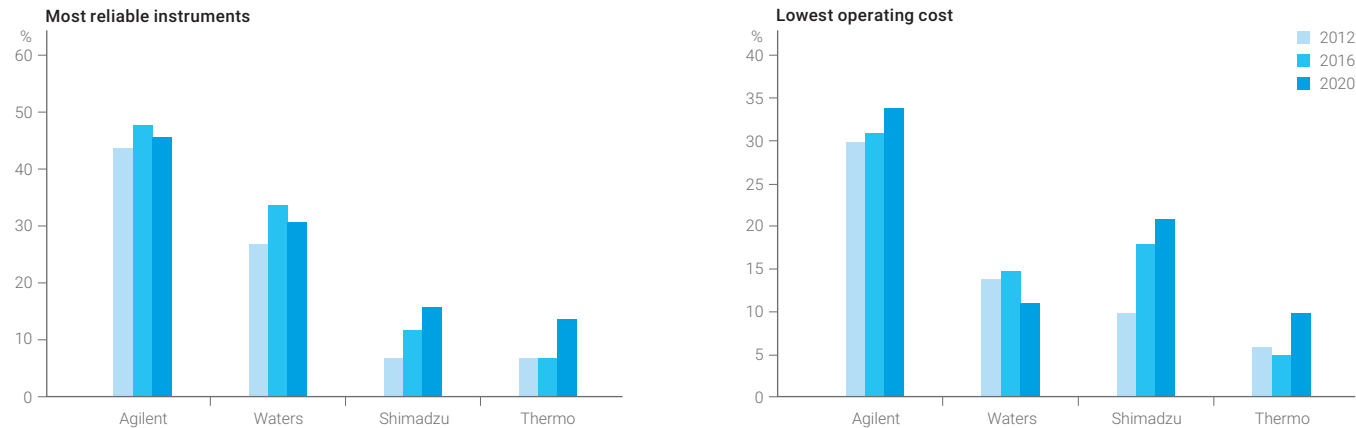
– **Monika Dittman, PhD,**  
Principal Scientist, Liquid Phase R&D,  
Agilent Technologies, Inc.

Maintaining sample throughput and compliance during a pandemic

## A Bad Time for Broken Instruments

As the relocation of manufacture of either new vaccines or existing drug products increases,<sup>17</sup> chances are high that your lab will be required to run more samples, not fewer, so tolerating instrument downtime is no longer feasible. Investing in replacement of aging instruments may become more of a priority; however, some suppliers require that you purchase an entire LC stack at once, which may deplete your budget.

A few vendors like Agilent allow for the replacement of a single module (sometimes referred to as “mix and match”), which enables flexible use of funds, and also offer custom compliance service solutions as needed. Of course, choosing a provider with a history of providing robust and reliable LCs can help ensure that downtime is further minimized in the long term.



**Figure 10.** A 2020 LCGC survey shows Agilent as the preferred vendor for reliable instruments and for the lowest operating costs since 2012. Surveys on "Liquid Phase Separation Instruments & Trends" commissioned by Agilent, conducted by LCGC in 2012, 2016 and 2020.



### Mind behind the science

*"When it came to testing, the challenge was with the reliability testing; you can find yourself in a delicate position if the robustness tests come back and show we need to make a change after the design is frozen. The trick is not be at the very edge; you need room to have the freedom to make important improvements as you learn more."*

– **Matthias Wetzel,**  
Senior Engineering Director,  
Agilent Technologies, Inc.

*"On top of easy-to-use software, the Agilent hardware is really solid. We have been running our InfinityLab LC Purification Instrumentation for 2½ years and there hasn't been a need for a major repair."*

– **Laszlo Varady, PhD,**  
President and CEO,  
Rilas Technologies

Maintaining sample throughput and compliance during a pandemic

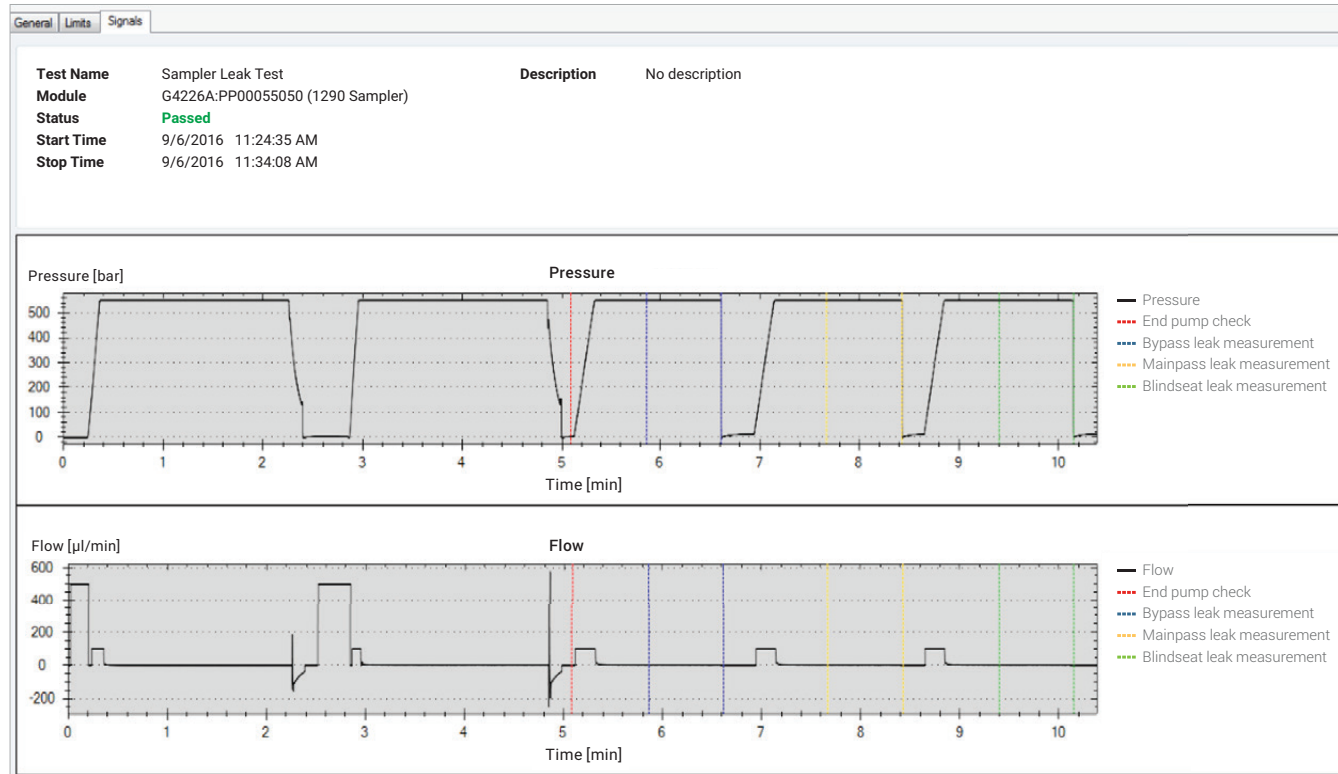
## Proactively Preventing Breakdowns

While the use of artificial intelligence (AI) is quite trendy right now, predictive maintenance practices have been around for years.<sup>18</sup> **Agilent Lab Advisor Software**, first introduced in 2006, provides lab managers with the ability to run instrument diagnostic tests on LCs that illuminate when parts need to be replaced before a serious breakdown occurs. For example, an evaluation of pump leaks or the monitoring of several UV signals can detect hidden problems and analyze LC system health.

Data from multiple systems can be aggregated to show an overall assessment of the laboratory's LCs, including early maintenance feedback (EMF) counters and limits, independent of what CDS is used for data collection. An example is shown in Figure 11 on the next page.



Agilent Lab Advisor Software



**Figure 11.** The Sampler Leak Test in Agilent Lab Advisor tests the specific leak rates of the rotor seal, metering device, needle seat, and system. The test requires that a blank nut gets installed at port 6 (outlet) of the injection valve. First, a pump head leak test is carried out on the selected channel, then a pressure test is carried out in the bypass position, then a pressure test is carried out in the mainpass position, and finally a pressure test is carried out in the mainpass position with the needle at the blocked seat position. At the end of the test, the results are evaluated automatically.

Maintaining sample throughput and compliance during a pandemic

## Decreasing Reliance on CROs

The global demands of a vaccine are also putting pressure on the suppliers of related products. For example, the supply for glass vials appropriate for parenteral products needs to be increased by 5–10%<sup>19</sup> and there is expanding interest in alternate vial materials like cyclic olefin copolymers.<sup>20</sup> Each new material will require extensive extractable and leachable experiments.<sup>21</sup>

Adding a “stackable” mass spectrometer, either a single quadrupole like the [Agilent InfinityLab LC/MSD iQ](#) or the [Agilent Ultivo triple quadrupole LC/MS](#), can also bring work currently outsourced in-house, leading to greater confidence and faster decision making without the need for additional lab space.



[Agilent InfinityLab  
LC/MSD iQ](#)

[Agilent Ultivo triple  
quadrupole LC/MS](#)

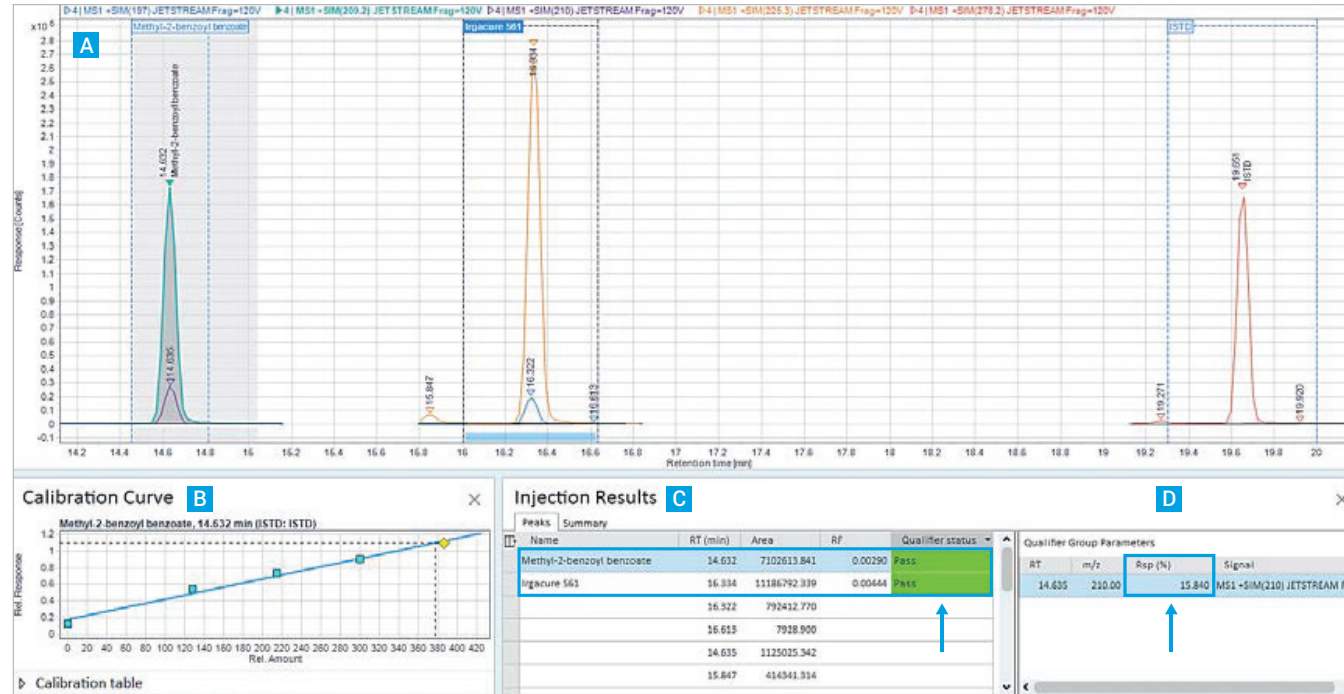


Figure 12. A) Drug formulation analysis showing SIM quantifiers of methyl-2-benzoyl benzoate. B) Calibration curve of the standard. C) Results of the analysis along with status of Pass for qualifier status. D) The qualifier response percentage achieved.

Maintaining sample throughput and compliance during a pandemic

## Rethinking the Lab Setup for Mobility and Versatility

Small-molecule drug products are more susceptible to the supply chain challenges we have seen in recent months compared to biopharmaceuticals, but getting closer to point-of-care and a focus on mobile factories are certain to be components of drug delivery in the near future.<sup>33</sup> In the meantime, the idea of mobile instruments and sharing assets between departments is possible.

The **Agilent InfinityLab Flex Bench** is specifically designed to allow for the safe transportation and sharing of LC instrumentation within a facility, for example moving an LC from one type of mass spectrometer to another. The superior usability includes built-in storage that ensures that the correct tools and accessories travel alongside.



**Agilent InfinityLab  
Flex Bench**



**Watch a video**

Learn more about how to gain flexibility with the InfinityLab Flex Bench family.

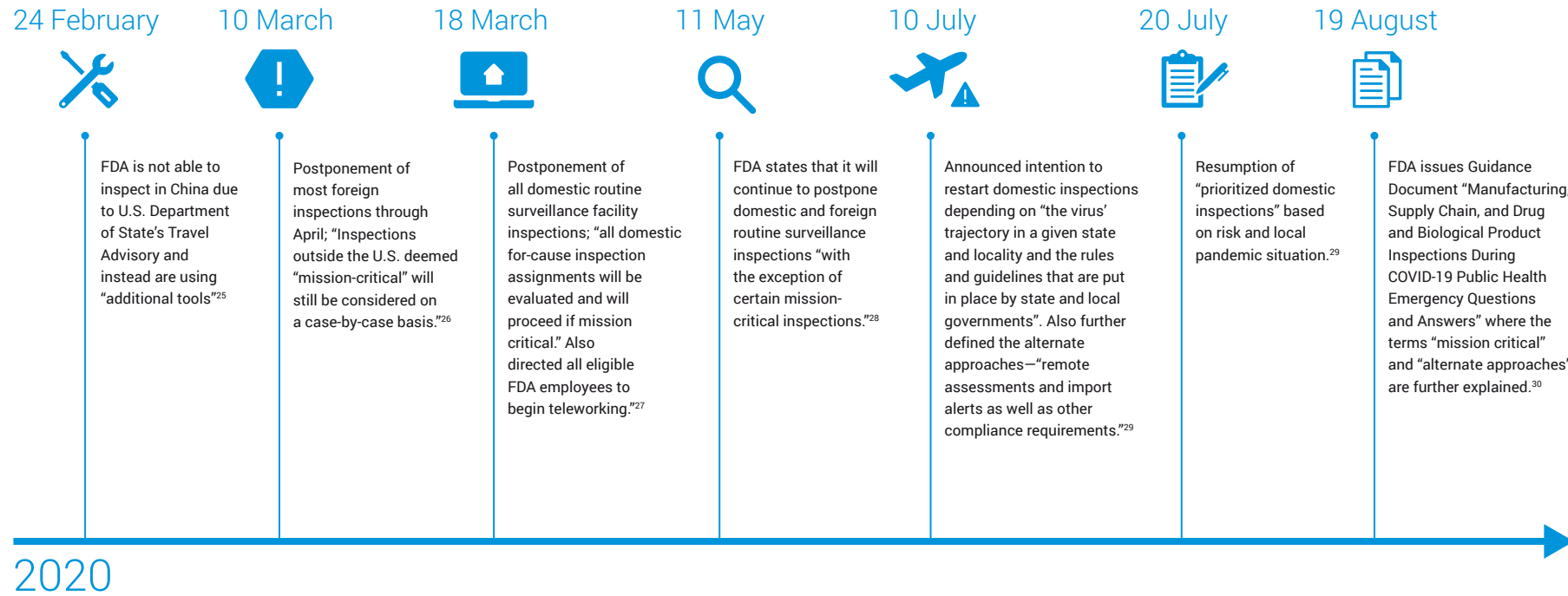


Maintaining sample throughput and compliance during a pandemic

## To Inspect or Not Inspect Remotely

While the U.S. FDA has had the option to request documents for remote viewing as a prequel or follow-up to an inspection as a core component of Section 702(a)4 in the Food and Cosmetic Act (further clarified under section 706 of Food and Drug Administration Safety and Innovation Act (FDASIA)), few information requests have been formally made of drug and device firms, perhaps due to lack of data security (for example, in an emailed quality log), and some report that this authority has only been used for preparing for an inspection or as a follow-up after a warning letter or observation has been issued.<sup>22</sup>

Also of import is to plan for the availability of Quality personnel who may be working from home and/or have day care challenges,<sup>23,24</sup> as it is currently unclear how much advance warning regulatory bodies (for example, the U.S. FDA) plan to provide for onsite inspections.<sup>22</sup>



**Figure 13.** Timeline of U.S. FDA communications of plans related to domestic and foreign inspections. An uptick in remote review of documents and quality metrics is expected as the pandemic limits inspectors' ability to travel, enter non-U.S. countries, and perform physical onsite inspections.

Maintaining sample throughput and compliance during a pandemic

## Preparing to Virtually Engage with Regulators

As the pandemic continues, firms will be more and more expected to provide information in a digital format, and (bio-)pharmaceutical companies both inside and outside the U.S. should consider instituting plans and policies—including SOPs—to prepare for regulatory requests for information via electronic and even video formats.<sup>25</sup> Unlike onsite inspections, remote assessments mean that regulators can coordinate behind-the-scenes and bring in many more experienced subject matter experts (SMEs) to ask more detailed and informed questions about the documents they receive.



### Security

Which tools and procedures need to be in place to confidently provide documents and logs electronically in a secure way



### Access

Who retrieves the requested documents and their work-from-home situation



### Expertise

Which SMEs need to be on call to answer more technical questions and how to provide them with the selected tools and the necessary training



### WiFi coverage

Assess if WiFi coverage needs to be improved in spaces like the manufacturing floor or clean rooms if video conferences are in the plan

Figure 14. What to plan for if a remote assessment/document request is received from a regulatory body.

## Chapter 3

# Preparing for the Post-Pandemic New Normal



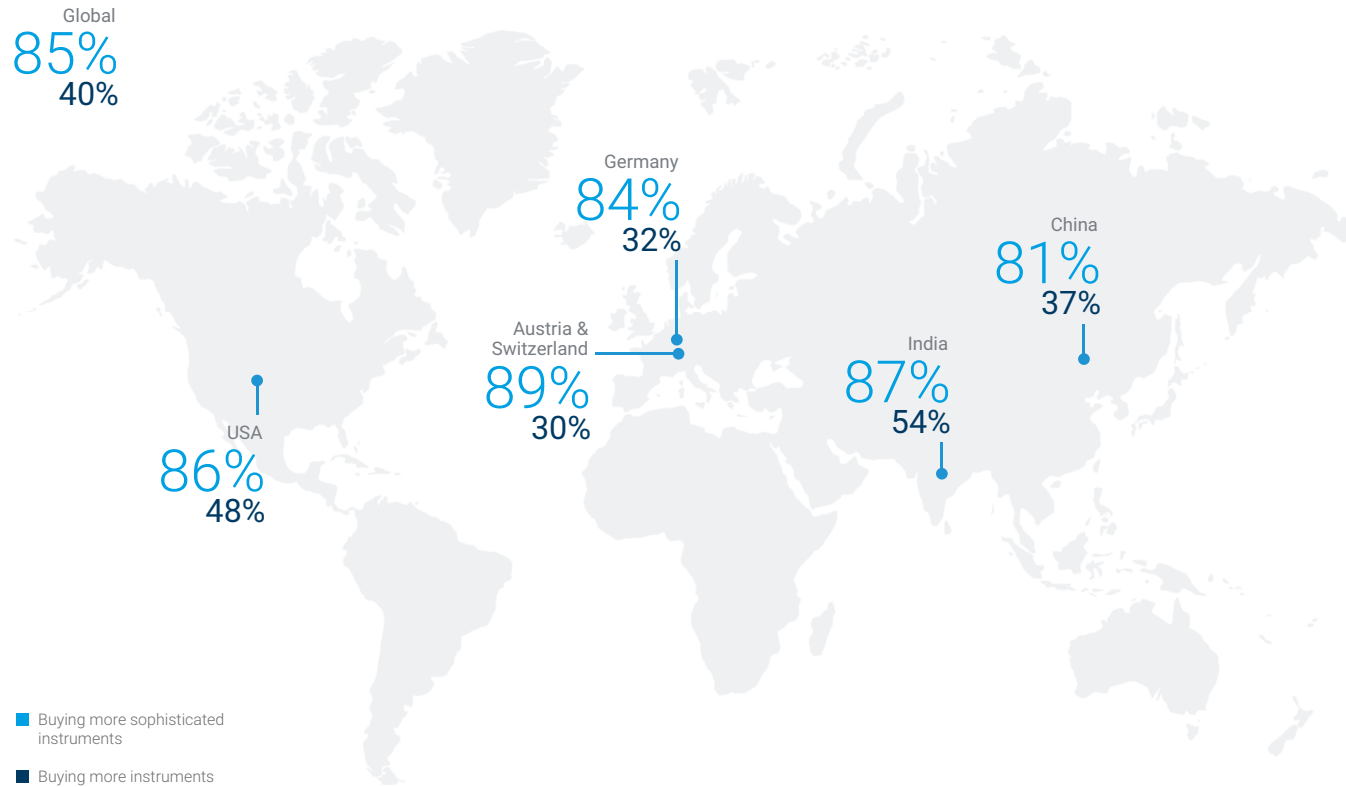
Preparing for the post-pandemic new normal

## Increasing Throughput by Buying More Instruments—a Losing Proposition

Historically, a quick fix to decrease sample turnover time was to buy more and more instruments. However, a 2019 Frost and Sullivan survey shows that the majority (85%) of lab manager respondents in the large pharmaceutical, biotechnology, and contract research organizations (CROs) agreed that buying more sophisticated instruments with a greater degree of specificity helps them to optimize their laboratory to progress drugs through the pipeline and market faster.<sup>15</sup>

Stocking the lab with more instruments of the same kind is not actually the key to speeding up the process, the key instead is to invest in technology with more advanced capabilities. See Figure 15 on the next page.

### Optimizing the lab to bring drugs to market faster



**Figure 15.** Results from the 2019 survey conducted by Frost and Sullivan showing the % of companies listing the top three strategies to optimize time to market. Investing in more sophisticated instrumentation was a clear winner over just investing in more of the same instruments in all geographies.<sup>15</sup>

Preparing for the post-pandemic new normal

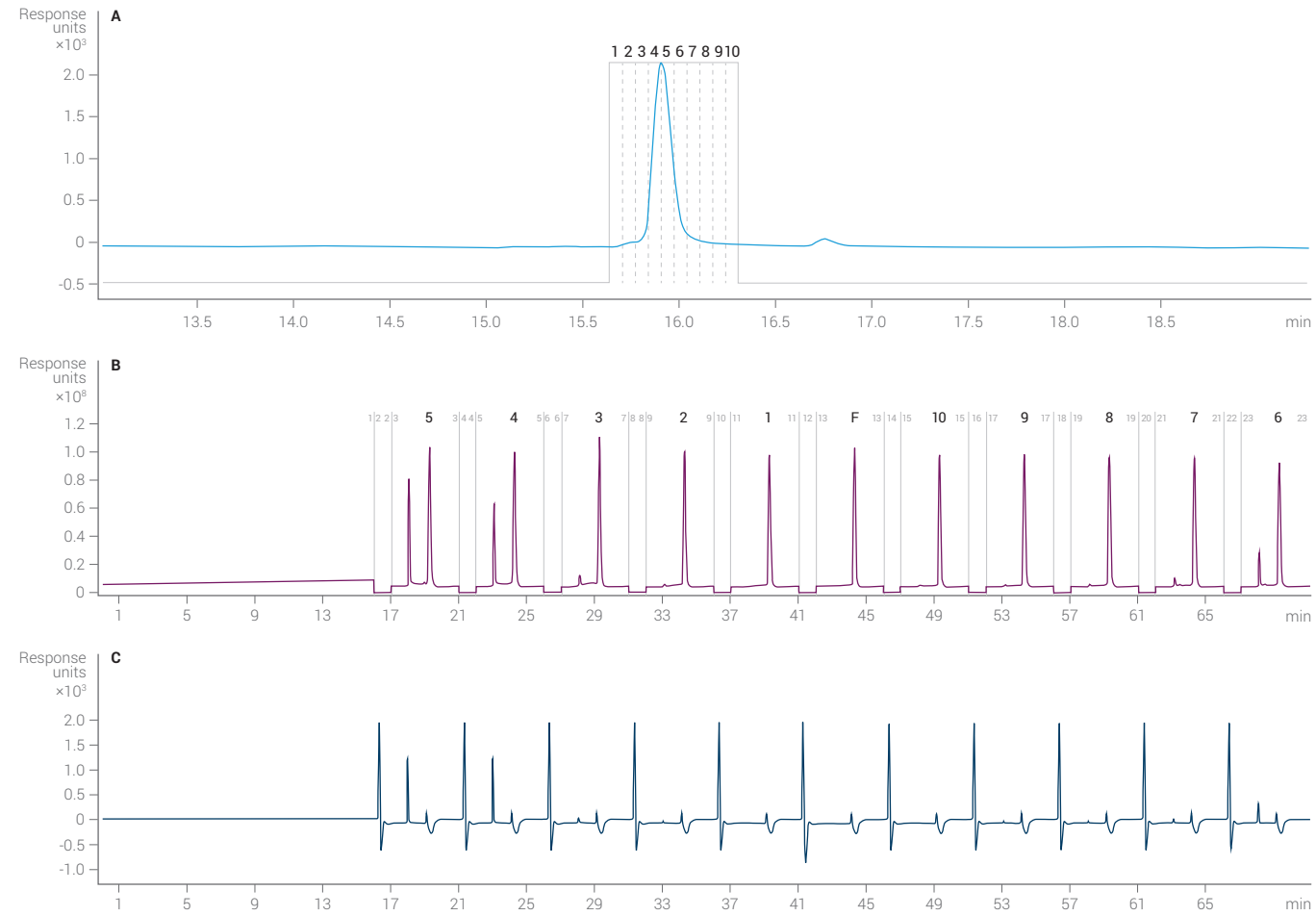
## More Specific Instruments

The use of the most specific LC technique, **2D-LC**, is becoming more and more mainstream due to its unique ability to provide insight into samples that no other methodology can provide.

Pairing the power of a 2D-LC separation (often on the order to 3,000 peak capacity)<sup>32</sup> with high resolution mass spectrometry, as shown below in Figure 16, offers insight into how the impurity profile and coelution characteristics change over the width of the deamidated insulin peak.



Agilent 1290 Infinity II  
2D-LC System



**Figure 16.** Signals displayed in Agilent MassHunter for the analysis of deamidated insulin. A) 1D-UV signal with cuts taken in high-resolution sampling. B) Full 2D-LC/MS signal. C) Full 2D-LC UV signal.

*“Our lab supports the CMC and manufacture of many generic drug formulations and we run a lot of sophisticated LC/MS analyses, including LC/QQQ and LC/Q-TOF, often with extreme time pressures to answer important analytical questions. We get urgent, sometimes unexpected, formulation samples every day for structure elucidation of unknown impurity peaks. The Agilent InfinityLab 2D-LC Solution allows us to easily remove the phosphate buffers common in pharmacopeial methods and we can quickly and accurately determine the peak identity using the Agilent 6550 iFunnel Q-TOF LC/MS while maintaining the original chromatography that is run in QC. This gives us absolute confidence in the peak assignment and ensures the quality of the medicines we produce.”*

– **Koji Umimoto, PhD**,  
Deputy Chief,  
Pharmaceutical Research & Technology Division,  
and **Nobuko Hirai**,  
Deputy General Manager,  
Physical Chemistry Research Department,  
Pharmaceutical Research & Technology Division,  
Towa Pharmaceutical Co., Ltd.



#### Mind behind the science

*“It is great to see the improvement of data quality while still reducing the analysis time. I once worked with a collaborator on a bio-pharmaceutical sample to be analyzed with 2D-LC coupled to mass spectrometry. Together, we took a 400-minute analysis down to 60 minutes, with the data quality similar to an offline fractionation, which actually took about 2 days. To have that kind of impact on the analysis of a life-saving medicine that so many of us take, makes me very proud.”*

– **Stephan Buckenmaier, PhD**,  
R&D Principal Scientist,  
Agilent Technologies, Inc.

Preparing for the post-pandemic new normal

## Get More from One Injection

Another way to get more from one injection is to deploy the elegant [Agilent 1290 Infinity II High Dynamic Range-Diode Array Detection \(HDR-DAD\) Solution](#), which is a core component of the [Agilent 1290 Infinity II HDR-DAD Impurity Analyzer Solution](#) and combines the signals from two DADs with different path length DAD flow cells to nearly triple the linear dynamic UV range (>5.6 AU).

The facilitating technology for these systems is the Agilent InfinityLab Max-Light Cartridge Cell, a coating-free flow cell made from fused silica.



[Agilent 1290 Infinity II High Dynamic Range-Diode Array Detection \(HDR-DAD\) Solution](#)

[Agilent 1290 Infinity II HDR-DAD Impurity Analyzer Solution](#)

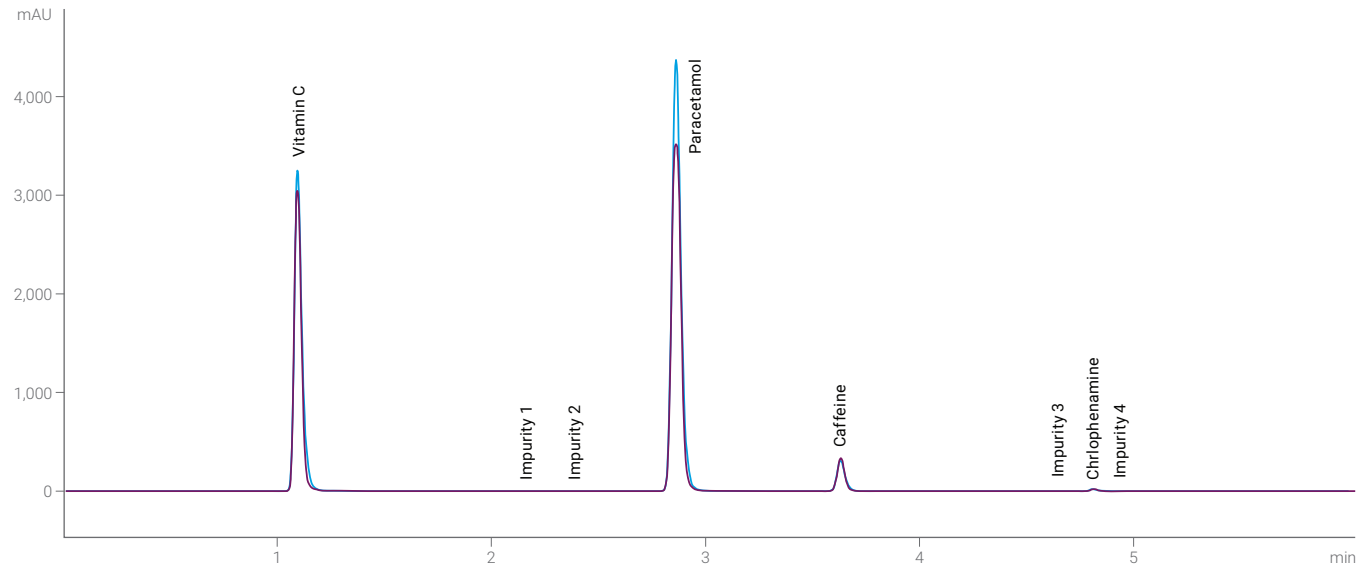


### Mind behind the science

*"At the time, UHPLC refraction variation in UV cells was very high and showed very bad apparent absorption effects. I did a huge number of so-called ray-tracing simulations and after a certain time I came to the conclusion that I cannot achieve the goals with classical approaches, so I knew we needed a technology leap... The light-guiding technology was the technology leap we needed. It took me a long time to get this working... In the end, we tried fused silica, and with this, we made it, and we were the first supplier to offer this in a robust and stable configuration."*

– **Beno Müller, PhD**,  
R&D Manager,  
Agilent Technologies, Inc.

## Assay and related substance results from a single injection



**Figure 17.** Overlay of 5- $\mu$ L injection of the Agilent 1290 Infinity II DAD signal (purple) signal and the Agilent 1290 Infinity II HDR DAD signal (blue). By using HDR technology, the impurities are detected with greater sensitivity and more reliable integration but the response of the main peaks (Vitamin C and Paracetamol) are still within the linear range of the UV detector.



### [Download application note](#)

Learn how to perform impurity testing of fixed-dose combination drugs in a single run.

Preparing for the post-pandemic new normal

## Be Ready for Any Method

The pandemic has exposed the fragility of the supply chain.<sup>33</sup> Also, as competing companies come together to collaborate as never before,<sup>34</sup> your lab may be required to run LC methods developed in other geographies or on other instrument platforms. The inherent differences in instrument design may lead to substantial shifts in analyte retention time, making tech transfer, product release, and stability trending near impossible. The Agilent Intelligent System Emulation Technology (ISET) is the answer to this fundamental problem.<sup>35</sup>

*"By using ISET, the retention time and separation pattern obtained under the analysis conditions developed by other companies' LC will be assured. It can be reproduced, enabling technology transfer without changing complex impurity profiles. It is a very important function for us."*

– **Kazuaki Kanai, PhD,**  
President and CEO of  
JITSUBO

Using ISET, the **Agilent 1290 Infinity II LC System** can be both an HPLC and UHPLC in a single flow path and can also provide similar results, emulating seven instruments from three different vendors using a single selection in the instrument control software. ISET is also available in the **Agilent 1290 Infinity II Bio LC System** for analyses that require a biocompatible flow path with a backpressure rating of 1300 bar.

*“We use ISET to transfer methods from method development to in-process where they have HPLCs from other vendors. The agreement of results from the emulated chromatogram and what we see on the other instrument are excellent; they are nearly identical.”*

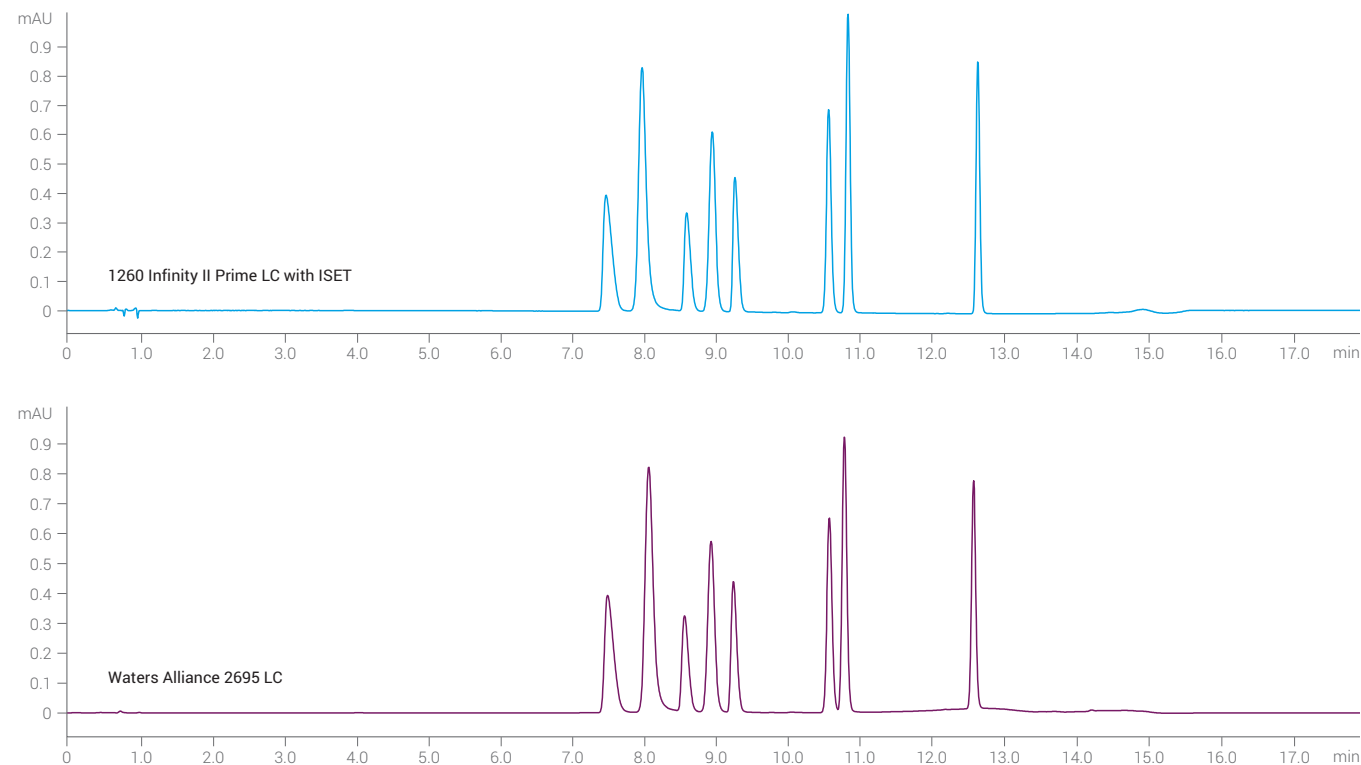
– **Keiko Yamane**,  
Researcher,  
Taiho Pharmaceutical Co., Ltd.



**Agilent 1290 Infinity II  
LC System**

**Agilent 1290 Infinity II  
Bio LC System**

## Seamless method transfer with ISET



**Figure 18.** Overlay of an Agilent 1260 Infinity II Prime LC System emulating a Waters Alliance 2695 HPLC using ISET, delivering similar retention times and chromatographic resolution as the original method.



### Mind behind the science

*"ISET is flexible—you don't need to do plumbing and get parts and pieces out of a drawer to modify your instrument. If you have an overnight run—possibly with different problems, different methods, even different columns—there is a lot of additional work that you have to consider. It isn't simply a matter of automating the process, because automation doesn't account for someone swapping components, verifying that the pumping is correct, checking for leaks, and so on. You could do automated valve switching but still, you are limited to what is installed in the instrument. If you use ISET, and use what is in the software implementation, then you don't worry about what is installed in the equipment. You can adapt to whatever has been the historic method development platform and then you can execute the method on the more modern instrument. You need to have lower volumes on the smart instrument than you have been using on the historical equipment... That is the only limitation."*

– Klaus Witt, PhD,  
Senior Technology Lead, Liquid Phase R&D,  
Agilent Technologies, Inc.

Preparing for the post-pandemic new normal

## Sustainability is Still Important

As the impact of COVID-19 extends globally, it can be difficult to continue to focus our efforts on considering the future of the planet. Unfortunately, the pandemic is only exacerbating existing environmental catastrophes; for example, trash in the oceans: it is estimated that 129 billion face masks and 65 billion plastic gloves are consumed every month, many ending up in the worlds' oceans after disposal.<sup>36</sup>



### Sustainability report

Read about our sustainability strategies in our most recent corporate social responsibility report.



Agilent InfinityLab LC Solutions have **recently been graded by an independent organization** scoring the environmental impact of the instrument manufacture, use, and disposal.



My Green Lab

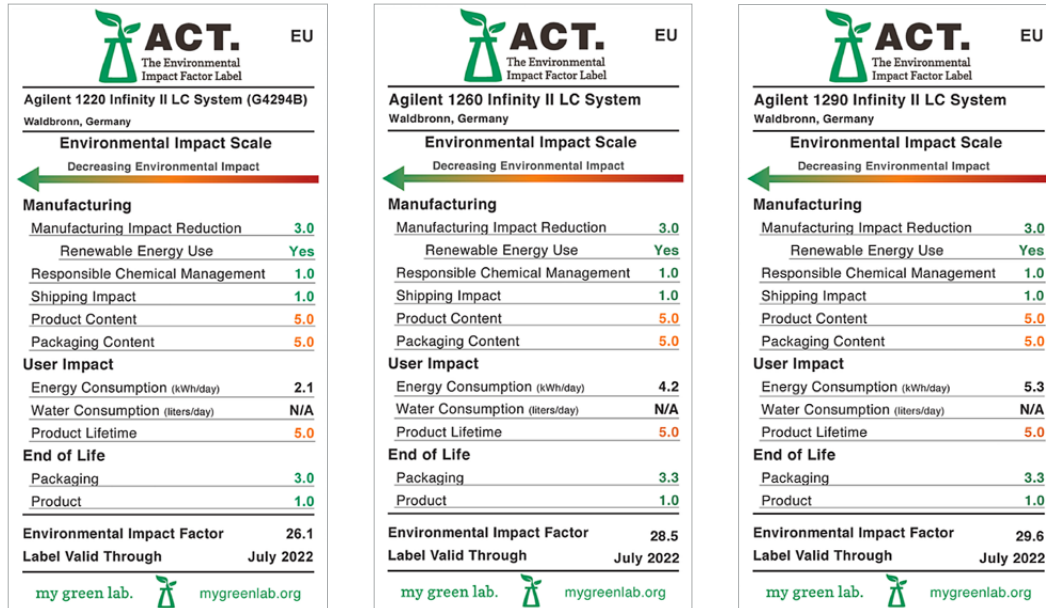


Figure 19. Accountability, Consistency and Traceability (ACT) label for European shipments of the Agilent 1220 Infinity II LC System, 1260 Infinity II LC System and the 1290 Infinity II LC System that accounts for the environmental impact of not just the use of these LCs but also the manufacture and end-of-life practices.

Preparing for the post-pandemic new normal

## Investing in Vendor Relationships for the Long Term

In addition to considering instrument providers for their record of sustainability, the commitment of vendors to provide service and training support during challenging times such as these can be an indicator of the type of partnership the relationship will evolve into over time. As part of a purchase decision, carefully analyze your suppliers' response to your needs during the crisis; for example, their call-back time or the quality of instrument repairs done in the midst of lockdowns. Also consider their reputation and global footprint, as you may require their expertise at sites around the globe.

*"We feel safe buying Agilent equipment; we know that any problems that arise will be solved and that Agilent will always do their best to resolve any issues quickly and satisfactorily."*

– **Li Lin, PhD**,  
Director of Analysis,  
Bellen Chemistry Co., Ltd.

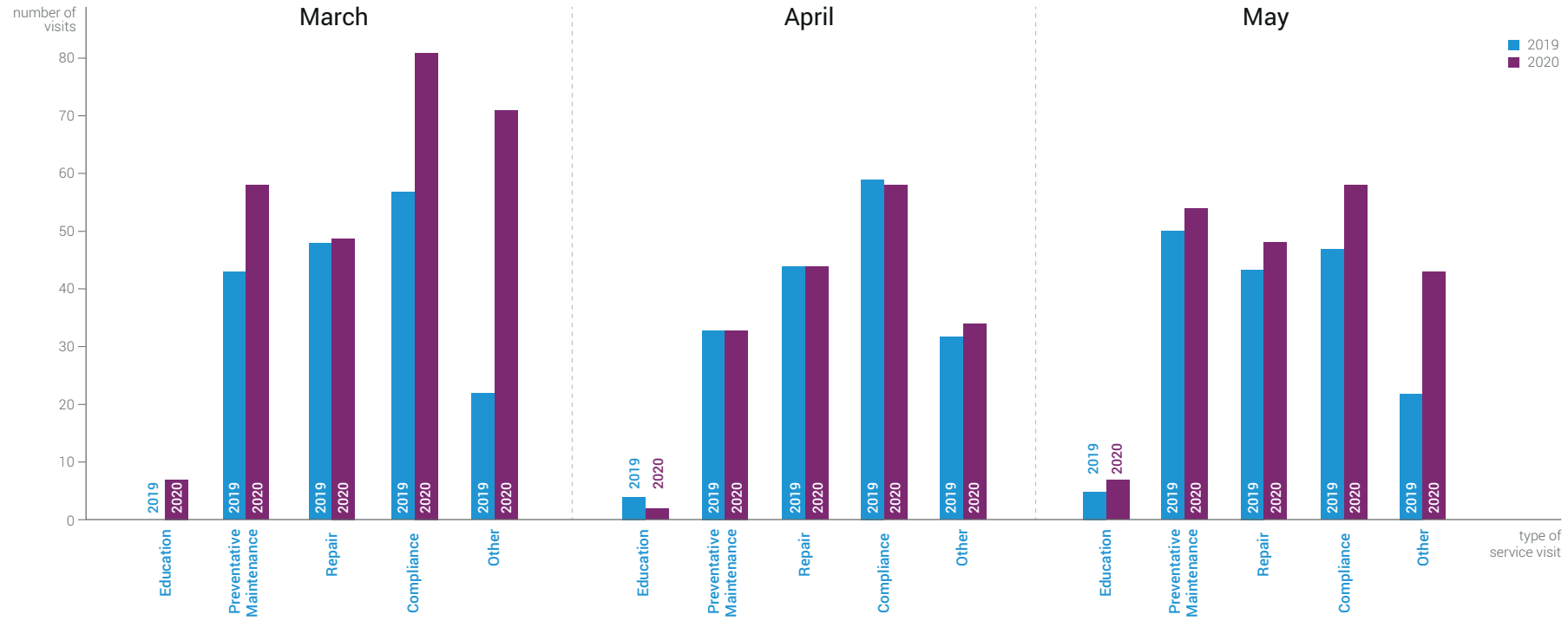


### Mind behind the science

*"You can't just be a technical expert—in customer support, you need to understand their core issue and then merge that with your technical expertise. You must first bring empathy and take the customer from the point where they are, understand that they are in a very unpleasant situation, and only then bring in the technical side of the discussion. You must work together to solve the issue, and I really enjoy this."*

– **Daniel Kühner**,  
Global Scheduling Service  
Systems Architect,  
Agilent Technologies, Inc.

Anecdotal information, such as their treatment of employees during the pandemic or major leadership changes, may also be telling in gauging their suitability as a reliable partner as the new normal emerges.



**Figure 20.** Comparison of pre- and post-pandemic service activities provided by Agilent at a large pharmaceutical company in Europe. The “other” category includes instrument relocation services, application consulting and specialized or custom instrument qualification tests.

Preparing for the post-pandemic new normal

## Crises Bring Innovation Opportunities

New approaches to manufacturing and Pharma 4.0 will be accelerated by the fallout from the COVID-19 pandemic.<sup>37</sup> Research shows that companies that invest in innovation during a crisis are more successful in the recovery period and 90% of executives expect that the pandemic will fundamentally change the way business is conducted in a variety of industries.

Interestingly, the pharmaceutical sector is being a trend setter in investing in innovation today<sup>38</sup>—for example, an independent study in the U.K. showed that 17% of over 6,000 laboratory-driven organizations expect there to be a potentially positive impact due to COVID-19.<sup>39</sup> Now is the time to challenge the old way of doing things, shift away from archaic technologies, and fully embrace risk-based thinking.



### Help Agilent innovate!

If you are based in the Americas or Europe, please consider joining our exclusive panel of experts to influence our future Biopharma offerings in the **Agilent Influencers Community!**

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From routine analysis through cutting-edge research, the Agilent InfinityLab LC Family provides the broadest portfolio of liquid chromatography solutions. You can rely on InfinityLab LC instruments, columns, and supplies to deliver rugged quality and robust analytical results. Every component is uniquely designed to work together, and to help you continuously improve your workflow.

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Disclaimer: Agilent products are NOT approved for COVID-19 testing, diagnosis, treatment, or mitigation. Agilent has not validated a product to detect the novel coronavirus.

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