Endress+Hauser
People for Process Automation

Analytics in exceptional circumstances

Many companies are finding themselves in an exceptional situation due to the coronavirus crisis. The employees of the laboratory and analytic technology manufacturer Analytik Jena have been doubly affected: Their normal work routine has been significantly restricted due to remote working and contact reduction, while at the same time production requirements have drastically increased. Product Managers Christine Marion Gräfe and Melanie Kelm describe how the company is playing its part during the crisis.

Analytik Jena supplies laboratories around the globe; what has changed for you in light of the coronavirus crisis?

Gräfe: The main point is that the demand for our products at Analytik Jena has changed. The number of requests and orders for certain devices has grown tremendously due to the increase in tests being carried out in laboratories.

Where exactly does the challenge lie for you? Have you had to modify your instruments due to the new virus?

Gräfe: No, we have been working with nucleic acid extraction for several years and have several clients who work in-depth with our instruments in terms of both genomic DNA and viral or bacterial DNA or RNA. From an analytical point of view the coronavirus is ultimately an RNA virus like any other. Analytik Jena offers devices that support and automate the virus detection workflow. And the mode of operation hasn't changed much for laboratories that carried out flu tests, for instance.

Kelm: In relation to the new virus I think the challenges are more on the assay manufacturer side. They have to guarantee that their chemistry – in other words the standardized reaction process – works on devices such as ours. Our colleagues in China quickly determined external suppliers' corresponding detection assays in a proof-of-principle process at the start of the crisis, for instance. Joint experiments were carried out as quickly as possible to determine settings that ensured the chemicals and instruments were compatible. The challenge is now down to the sheer number of tests. The number has increased so drastically, as has the demand for reagents and our products, that it has caused bottlenecks along front areas of the supply chain.

Can you give an example?

Gräfe: Examples include the alcohol required for extraction. Alcohol is also used to manufacture disinfectant and is currently in short supply. Supplies of the salts required to produce buffers for these reagents are also scarce, so that makes it difficult not only for us as manufacturers but also for suppliers worldwide to meet demand.

How have you coped with this?

Gräfe: There are major advantages to being part of a large network in the current situation. We identified the global supply bottlenecks for substances used to manufacture kits relatively early on.
With the help of the Endress+Hauser network we were able to gain new suppliers to be able to continue production.

And what is the situation like with producing laboratory instruments and extraction kits?

Gräfe: The number of orders we are receiving has increased tenfold. For some this number is not quite as high, but for others it's even higher. It became evident as early as January that the demand for instruments was set to vastly increase with the demand from China. But it didn't really take off until the end of February. You should know that all of our devices are made in Germany and are produced in Jena and Göttingen, so all of the orders coming from the Sales Center in China took the usual route during the crisis. Our ordering, production and delivery methods follow a stringent process that is clearly documented in compliance with the standard procedure, and none of that has changed throughout the coronavirus crisis.

Kelm: Allow me to add that we have heard about these unpleasant aspects where suppliers have taken advantage of the demand situation to increase prices. Analytik Jena has not done this. Our prices and performance have remained as they were before the crisis. And we are not compromising on quality parameters.

Where exactly does the bottleneck occur during the production of your instruments?

Kelm: That's hard to say. Many components are manufactured in assembly groups. We usually have lead times of one to two weeks within Europe for our Thermocycler qTOWER^3, for instance, and we are currently at seven to eight weeks. The buffer that we have in place under normal circumstances has been depleted, even though we have drastically increased production and almost tripled our output. The greatest risk would be someone in production contracting Covid-19. We are combating this through group work and distributing production so that only part of the team would need to be quarantined if there were a case, preventing the entire production from having to shut down.

Gräfe: What's more, our documentation has been set up to allow employees to switch from one place to another. We are currently applying this to our production capacity, which we have freed up for those devices that are in heavy demand.

But employees aren't transferring within the Endress+Hauser Group?
Kelm: We looked into that and decided against it, as it would go directly against the objective of reducing contact. Unfortunately, there are no Endress+Hauser production plants nearby, which means the employees would have to travel from afar and stay in hotels or other accommodation. This isn't possible under the current circumstances as we also want to contribute to preventing the spread of the virus. That's why we are working from home as much as possible, following strict hygiene regulations, etc.

Are there certain requirements that need to be met so your products can be used for diagnostic purposes?

Kelm: Yes, this is where IVD certification should be mentioned. Any medical products such as reagents and instruments designed to examine samples from the human body for diagnosis purposes must be certified. Directive 98/79/EC applies to the European Economic Area and formulates in vitro diagnostic requirements. We only offer this certification for certain extraction kits, and only in Germany. Registration and certification take a lot of time and effort and there are national differences that must be taken into consideration. On a global scale almost every country has established its own highly elaborate IVD certification procedures. But due to the coronavirus our current clients are almost exclusively from the medical field.

Are these devices of any use at all during the crisis?

Kelm: Yes, of course. On the one hand research needs to continue, and on the other hand we have many international clients who can use our devices in accordance with their national regulations due to the current exceptional global situation. Due to the urgency of the situation, it may be the case that a missing certificate is accepted during a crisis. Furthermore, we have an especially high number of medical laboratories in Germany in particular that are able to offer their in-house development to detect Covid-19 as a service in their own laboratories. The laboratories are, of course, still obliged to adhere to certain certified procedures, which is why more and more laboratories are carrying out their own validation and documentation processes to prove that non-certified assays are suitable and fit for purpose.

Has the crisis caused any changes to startup operations and training of staff who use the devices?

Kelm: A lot of laboratories already have that knowledge and know how to operate machinery and handle results. These existing customers are currently expanding their capacity and are ordering the corresponding devices through us. But there is also a growing number of smaller laboratories which may not be as experienced. This is where we keep an eye on the training aspect: These users can contact our team of application specialists in Jena. Colleagues who are able to give additional training are providing support across the globe at our own subsidiaries as well as with our distribution partners. But it must also be said that the products have been set up and prepared so that they are not too elaborate to use, particularly when only one test is predominantly carried out.

Gräfe: Yes, that's right. When it comes to extraction devices in particular the devices have been set up so that laboratory technicians can follow the kit's user guide, equip their device, push a button and wait for the nucleic acid to come out at the end. It's not so much about programming and more about setting the required parameters, and we are always happy to provide support. The assay user guides for the real-time PCR are also described simply and can often be automated with the help of our devices.

Will your devices have a new configuration in future due to this crisis, such as a higher sample throughput?

Kelm: Automation plays a very big role in our product roadmap, which was created before the coronavirus crisis. It's a shame, of course, that the new products that were planned have not

yet been launched, but the contents of the roadmap meet our customers' increased demands.

What are the next steps? What are the subsequent milestones you want to achieve?

Kelm: Our main objective at the moment is to close the gaps in production as soon as possible in order to be able to attend to incoming orders. We reconcile our production capacity and the outcome and delivery of the products on a daily basis in order to achieve this. The thing that has changed is the reconciliation of customer supply to keep laboratories running. Beyond that, the goal is to overcome the entire production processes, requests and challenges that have arisen during the crisis due to increased demand and to settle into a new kind of normal.

Background information: in vitro diagnostics (IVD)
In vitro diagnostics (IVD) is a term that refers to medical products that are used to examine samples derived from the human body for the purpose of diagnosing diseases or monitoring a person's health condition or therapeutic measures. The following is a comprehensive definition: In vitro diagnostics (IVD) is defined as any medical device that is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue samples, derived from the human body, solely or principally for the purpose of providing information

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

IVD is subject to multiple regulatory requirements. Analytik Jena's laboratory instruments are not IVD devices and are intended to be used for research purposes. Some of the kits of Analytik Jena's subsidiaries are IVD certified and/or registered.

Author:
Frank Jablonski, mylk+honey
Agentur für verbindende Kommunikation

Interview partners Analytik Jena:
Dr. Christine Marion Gräfe, Product Manager Analytik Jena

Melanie Kelm, Head of Product Management Analytik Jena
Melanie Kelm has worked for Analytik Jena since graduating. She has been able to get to know all areas of the company since 2003 and is now Head of Product Management. But her roots lie in life sciences, or rather molecular biology, meaning she has plenty of experience with detecting bacteria and viruses.

Contact for journalists: Maik Dirumdam, Specialist Corporate Communications, Analytik Jena