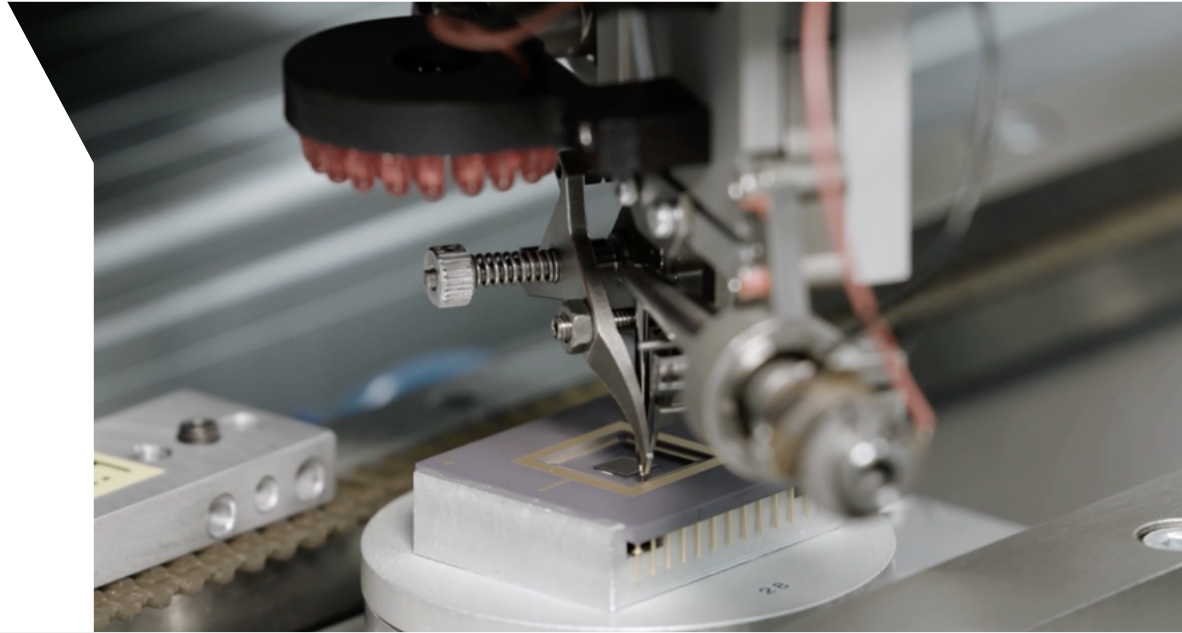


ams

OSRAM



COMPANY

ams OSRAM

INDUSTRY

Optical Solutions

COUNTRY

Premstätten, Austria

EMPLOYEES

26,000

WEBSITE

ams-osram.com

CHALLENGES

- **Urgent and Reliable:** The COVID-19 pandemic caused massive demand for easy-to-use, highly accurate and cost-effective point-of-care testing
- **New Technologies:** ams OSRAM, a global leader in optical solutions, had developed spectral sensor technologies to digitize highly reliable, easy-to-use lateral flow tests, however needed a partner well versed in healthcare with scalable manufacturing capabilities
- **Need for Speed:** ams OSRAM wanted to deliver a 15-minute rapid test at lab quality powered by ams OSRAM spectral sensing technology, as a cost-competitive, over-the-counter product solution in less than 12 months

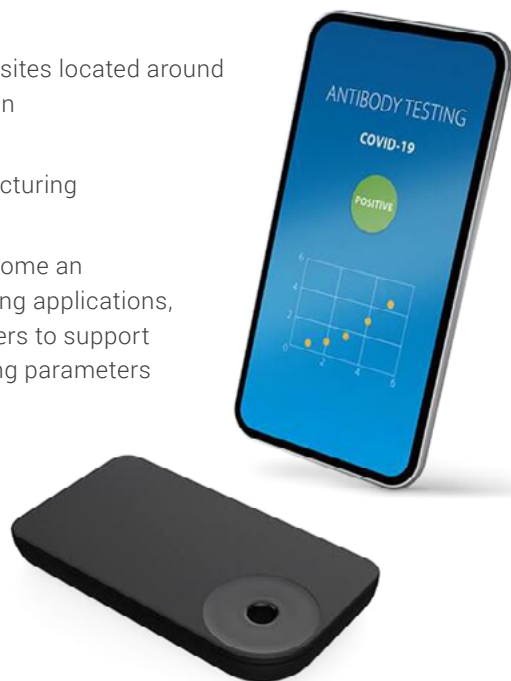
SOLUTIONS

- **Global Footprint:** Jabil's expertise in medical device manufacturing and global footprint allowed ams OSRAM to scale manufacturing up or down as needed
- **State-of-the-Art Manufacturing:** Driven by industry-leading design for manufacturing capabilities, Jabil's automation processes and injection position molding fulfilled extremely challenging run rates with uncompromised quality and reliability
- **Production Speed:** The final product was completed just nine months after the project began and met all stringent medical certification requirements

BENEFITS

- **Global Support:** With over 30 ISO 13485-certified medical device manufacturing sites located around the world, Jabil supports production around the clock, across all time zones and in nearly every market
- **Massive, Variable Scale:** Jabil's proven processes and highly automated manufacturing lines led to a 1.2 million unit run rate per month for the sub-assembly
- **Proven Production:** ams OSRAM's digital health solution has the potential to become an expanded testing platform with various point-of-care applications and home testing applications, like screening for infectious diseases, measuring cardiac and inflammatory markers to support rapid clinical diagnostics for life-threatening events, and even monitoring wellbeing parameters like vitamins or lactates.

ams OSRAM's Spectral Sensing Technology Provides Answers in the Fight Against COVID-19



Jabil Helps ams OSRAM Launch Highly Accurate Digital Point-of-Care COVID-19 Tests in Record Time

Digital point-of-need and point-of-care testing, along with advances in reagent technology and test processes, have increased the availability of remote, mobile laboratory-quality testing in easy-to-use formats.

Unlike testing done at the central lab – involving sample collections, transport steps and sometimes long wait times – point-of-need and point-of-care diagnostics provide more convenient means for securing test results that drive medical treatment decisions. The COVID-19 pandemic certainly brought the topic of testing to the forefront and spotlighted the need for fast-turnaround, lab quality testing that can be conducted remotely if needed. While the pandemic focused our view on testing, the need for high quality, remote diagnostics also has benefits across the medical ecosystem beyond the COVID-19 era.

A global leader in optical sensors, ams OSRAM develops high-precision, high-quality solutions with rapid design cycles. In early 2020, the company was in the initial stages of incorporating its innovative spectral sensing technology

into a lateral flow testing solution for numerous applications. When the pandemic began, they decided to pivot the solution to match the need and market demand. Quickly, the ams OSRAM team made a commitment to integrate its highly sensitive sensor technology into small, easy-to-use, cost-effective rapid COVID-19 antigen and antibody tests.

“When COVID hit, it was quite clear for us that we wanted to contribute to fighting this pandemic,” said Alexander Volk, a senior marketing manager for digital health solutions with ams OSRAM.

The company had a vision and set a challenging goal: Get tests to market in less than a year.

Considering the average digital healthcare product takes between 12 and 18 months to develop, this accelerated timeline would be pushing innovation to its limits. When ams OSRAM needed a partner to make their ambitious ideas a reality and support their need for quality and speed, they contacted Jabil.

For additional information, visit jabil.com/case-studies/ams-osram-case-study.html



Innovative Sensor Technology Enables a New Kind of COVID-19 Test

“ We had technology and we had a system solution, but we needed to bring it to a product in record time. If you look at developments of these kind of medical-grade products, it normally takes way longer. ”

WIM RENIRIE

ams OSRAM
Vice President &
General Manager
BL Accessory and
Wearable Solutions

Before the COVID-19 pandemic, most people’s interactions with lateral flow tests were likely limited to at-home pregnancy tests. COVID-19 antigen and antibody tests presented some challenges for the layperson not used to swabbing their own nose or determining whether the test readout showed one line or two. The teams at ams OSRAM and Jabil saw an opportunity to bring these lateral flow tests into the digital age, adding optics and connectivity to provide users with clear results in 15 minutes.

“It’s disrupting the way testing is done,” said Christa Schnider, Jabil Healthcare’s business development director. “All of a sudden, we now have the opportunity to go from visual interpretation to a quantitative digital way to interpret the results and share the results with stakeholders.”

Together, ams OSRAM and Jabil designed the test’s essential component — a complete printed circuit board assembly (PCBA), manufactured by Jabil, that leverages

ams OSRAM’s spectral sensing technology. An LED illuminates the lateral flow test, and a highly sensitive spectral sensor reads the color of the line, providing an objective “positive” or “negative” result. The connection module sends that result via Bluetooth® technology to a cloud-based smartphone app that clearly states the patient’s COVID-19 status.

“With the digital platform, the optical readout really makes it very easy for the user to determine the result and avoid mistakes during the measurement itself,” said Volk. “What is currently limiting point-of-care diagnostics is that you don’t want to jeopardize the performance of the test with a poor reading,” said Filip Frederix, director of ams OSRAM’s digital health segment. “That’s also why we wanted to add the electronics and optical components to an existing, established lateral flow test with the ambition to deliver lab-based quality. You need to be able to mass produce it in a cost-effective way.”

“ Jabil is a company that is known for manufacturing components in the medical field and in the diagnostic field. We wanted to have a partner that is flexible, that can scale and that had the same vision and passion. ”

FILIP FREDERIX

Director of the Digital Health Segment, ams OSRAM

“ We were starting with a whiteboard, with a brand-new circuit board design and new manufacturing processes for this lateral flow device. So, to achieve this in 12 months or less was probably one of the toughest timelines that we’ve ever had to achieve. ”

JEFFREY ROBERTS

Business Unit Director, Jabil Healthcare

He adds, “To do that, we needed to have the right partners. Jabil is a company that is known for manufacturing components in the medical field and in the diagnostic field. We wanted to have a partner that is flexible, that can scale and that had the same vision and passion.”

ams OSRAM brought the sensor and LED technology to the table, along with their expertise in high-volume miniaturization which had been sharpened by their extensive experience in consumer devices. They needed a partner who could not only manufacture a digital healthcare device – one that puts the power of a laboratory in the hands of individuals – but also ensure it was designed for manufacturing at scale. The pandemic’s ebbs and flows meant demand was unpredictable, so an ability to scale up and down as needed across a global manufacturing footprint was a critical asset.

Bringing a New Digital Health Product to Market in Record Time

With the COVID-19 pandemic in the foreground of every interaction, ams OSRAM and Jabil had a shared vision for success and a sense of social responsibility to get it right – quickly.

The race against the clock to get the device approved and on the market galvanized the teams to reach the finish line. The ams OSRAM team was confident that Jabil, with extensive certifications in healthcare manufacturing, particularly in diagnostics and microfluidics, meant there was an inherent understanding of the manufacturing techniques needed to assure regulatory approval. Also, with over 30 ISO 13485-certified medical device manufacturing sites located around the world, Jabil had the ability to support production across all time zones and in nearly every market.

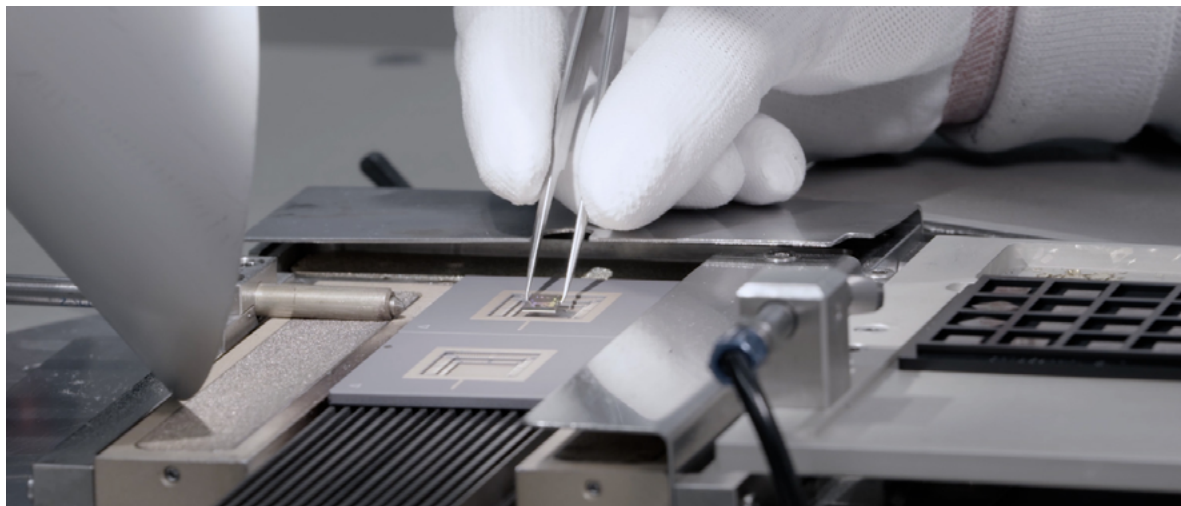
“We had one saying throughout the project’s development, which was that we are basically walking the bridge while we are building it. And that was definitely true for both sides,” said Volk.

While the team had the technology in hand going into the project, the time constraint was their most persistent challenge.

“At ams OSRAM, we try to imagine the impossible. In the COVID crisis, imagining the impossible would mean bringing a test to the market tomorrow,” said Frederix. “Of course, that’s not possible, but we wanted to launch our test as soon as possible. With Jabil, we found a partner who had the same drive and passion to do that, and we pulled in the timelines without jeopardizing the quality or any regulatory aspects.”

“Given the fact that this normally that would take two years, and we wanted to do it in six to nine months, that was kind of imagining the impossible,” said Renirie.





“ Jabil’s expertise in the supply chain helped, especially at the beginning, in selecting suppliers that were capable of providing the huge volume of components needed in a very short time. It’s not so easy to provide 100 million units of a component in half a year. Jabil’s supply chain team was able to select the right partners and companies for these challenges. ”

WALTER FORSTHUBER

Senior Manager of Technical Business Development, Jabil Healthcare

Navigating Supply Chain Constraints and Issues Caused by the Pandemic

When Jabil joined the project in the spring of 2020, supply chains were already constrained due to border closures, plant shutdowns and staffing reductions in logistics and manufacturing. Supply chain orchestration rapidly became a top priority, with Jabil’s supply chain managers identifying the product’s vital components and leveraging their supplier relationships to procure the necessary parts at both the required volumes and the most competitive prices.

“Jabil’s expertise in the supply chain helped, especially at the beginning, in selecting suppliers that were capable of providing the huge volume of components needed in a very short time,” said Walter Forsthuber, Jabil Healthcare’s senior manager of technical business development. “It’s not so easy to provide 100 million units of a component in half a year. Jabil’s supply chain team was able to select the right partners and companies for these challenges.”

Most critically, Jabil’s design for

manufacturing (DfM) and precision injection molding capabilities ensured ams OSRAM’s design for the printed circuit board incorporating their optical sensor and LED technologies would translate well to the consistent replication of mass manufacturing.

“Jabil’s design expertise and understanding of manufacturing capabilities were really important because in this project, there was a clear target. There was no time for a second try,” said Forsthuber. “These DfM capabilities, which are more or less in the DNA of the designers, made sure that the design and the layout from the beginning was ready for production.”

As the Jabil and ams OSRAM teams evolved the product design, Jabil’s manufacturing lines were being set up in parallel so they could be tested and evolve as well. These DfM principles, coupled with manufacturing automation, made for a seamless transfer of the design to production lines and subsequent ramp up in production.

Due to pandemic safety concerns, the entire collaboration between ams OSRAM and Jabil was conducted remotely via Microsoft Teams and email. To help overcome the challenges of coordinating the workstreams of decentralized teams operating around the world, the team relied on Jabil's workcell model. In this style of project management, ams OSRAM had a single point of contact from Jabil's business unit team who was responsible for the strategic and day-to-day direction of the project. As needed, they brought in experts and leadership teams from Jabil's manufacturing sites to develop the ideal solution that met ams OSRAM's needs.

"[Having] the right relationships to run a project like this is crucial," added Renirie. "Understanding each other's way of working, the expectations, what can be done, what cannot be done, and how you jointly overcome the challenges is really crucial. I think this project has been a great example of [what can happen] if teams have a joint goal. ... In the discussions with the Jabil team and the ams OSRAM team, it felt like we were one company."

“ This is giving new life to lateral flow testing for the next 10 to 20 years because you open up a whole range of new use cases for old-fashioned lateral flow testing, combined with very innovative technology. ”

WIM RENIRIE
ams OSRAM
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Developing New Applications for Digital Point-of-Care Testing

"This is one of the most highly automated applications that I've seen possible in my lifetime at Jabil based on the sheer volume that was required," said Jeffrey Roberts. "Running at a rate of approximately 1.2 million units per month, a circuit board smaller than your pinky fingernail, was pretty amazing. To have this level of automation, cleanliness, and clean rooms producing with such predictability, quality and reliability was just truly amazing."



As new variants prolong the COVID-19 pandemic, the need for rapid, widely available point-of-care testing will remain high for the foreseeable future. The success of ams OSRAM and Jabil's joint endeavor was about more than just successful manufacturing. ams OSRAM and Jabil are just beginning to explore the potential applications for this device beyond COVID-19, from cardiac conditions, to wellbeing parameters like vitamins or lactates, and even veterinary testing.

"This is giving new life to lateral flow testing for the next 10 to 20 years because you open up a whole range of new use cases for old-fashioned lateral flow testing, combined with very innovative technology," said Renirie.

Armed with their expertise in optical sensing technology, Volk sees future collaboration with Jabil to bring cutting-edge digital health products to the market. "We are looking

to various different applications in this segment, so it's not only limited to lateral flow testing," he said. "I think we are quite complementary here, and we are definitely seeking to address customers' [needs] together and provide them with the most innovative solutions."

This project drove home that clarity of mission, willingness to take calculated risk, and commitment to excellence in innovation and manufacturing can make just about any goal a reality.

"When we started this project together with ams OSRAM...it was very clear for every single one of us where we wanted to go," said Schneider. "The end vision was very focused, and we accepted this challenge. We went on this journey together, and at the end really fulfilled the claim of Jabil Healthcare: **"Made possible, made better."**

For additional Information, visit [jabil.com/case-studies](https://www.jabil.com/case-studies)

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