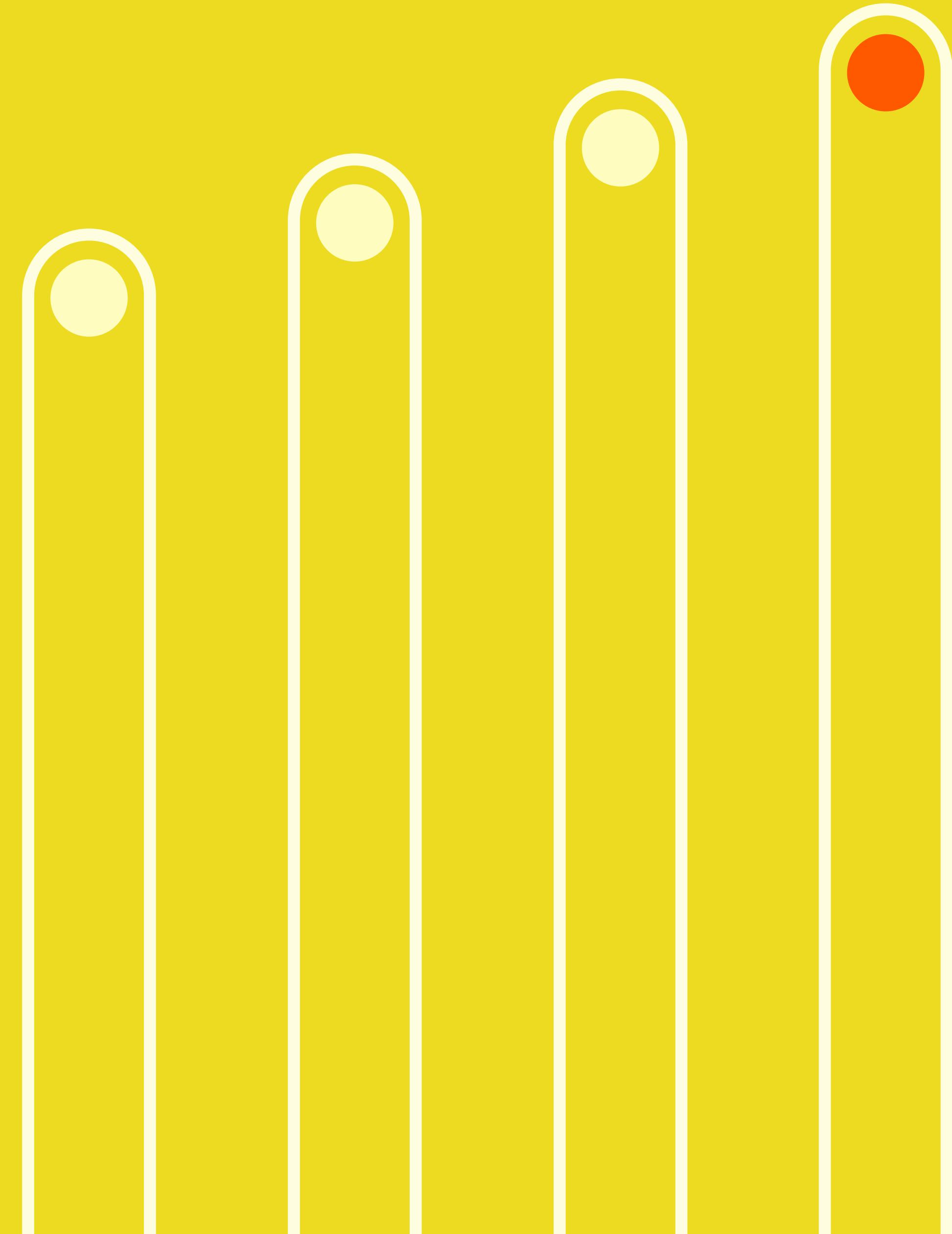


Powering diagnostics at scale

Small- to mid-size custom projects



Introduction

Each of your molecular or immunoassay development projects is unique. So, you need solutions tailored to your specific needs. Cytiva has a proven track record of delivering innovative diagnostic design and development services. This case study eBook highlights small- to mid-size real-world examples of successful custom service collaborations with diverse clients.

From assay design and optimization to high-throughput production and validation, our comprehensive capabilities and technologies can help you overcome challenges and deliver impactful outcomes. Whether you are a scientist or business leader working on or looking to accelerate your diagnostic assay and kit development, you can depend on us.



[Download our large scale projects eBook](#)

Read our
customer
success
stories

Scope and scale of the project



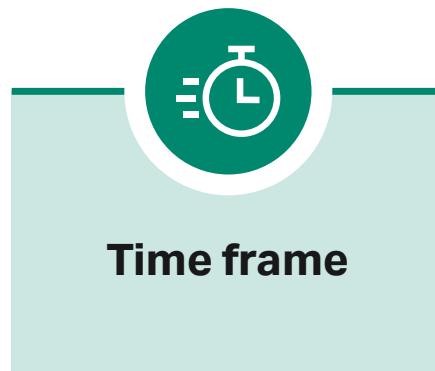
Company size

Indicative of the number of employees



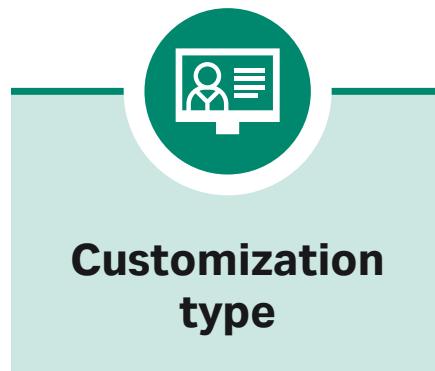
Project size

Indicative of the number of units produced



Time frame

Indicative of the time from project start to completion



Customization type

Indicative of the type of customization provided



Rapid scale up of a rapid COVID test



Company size
Small



Project size
Medium



Time frame
6–8 months



Customization type
Service

Project story

- The customer designed a COVID-19 test and needed to quickly scale up production because of the pandemic.
- The customer needed contract manufacturing services and was specifically looking to collaborate with a supplier based locally.
- The project was difficult because the customer found a functionality problem after launching the project with Cytiva.
- The research and development team at Cytiva was flexible and worked with the customer to determine the root cause of the problem.
- Even after the project wrapped up, we continued to give them support.
- The ongoing support and flexibility from Cytiva impressed the customer so much that they asked us to work with them on four new assays.



During the pandemic, everyone was rushing to produce tests, vaccines, and treatments. We had previously met the customer at a conference, so they knew of our experience and capabilities. Happily, we had capacity to take on their project when they needed it.

Anish Senan, Diagnostics Account Manager

✉ Speak to Anish to learn more: anish.senan@cytiva.com



Learn more about our contract manufacturing and kitting services

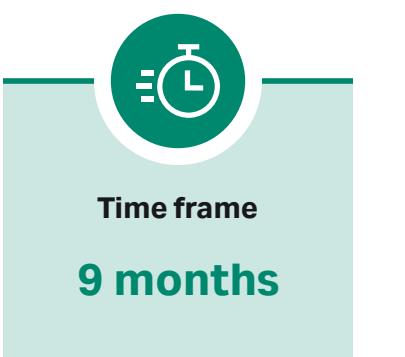
Taking the pressure off your glass fibers



Company size
Small



Project size
Medium



Time frame
9 months



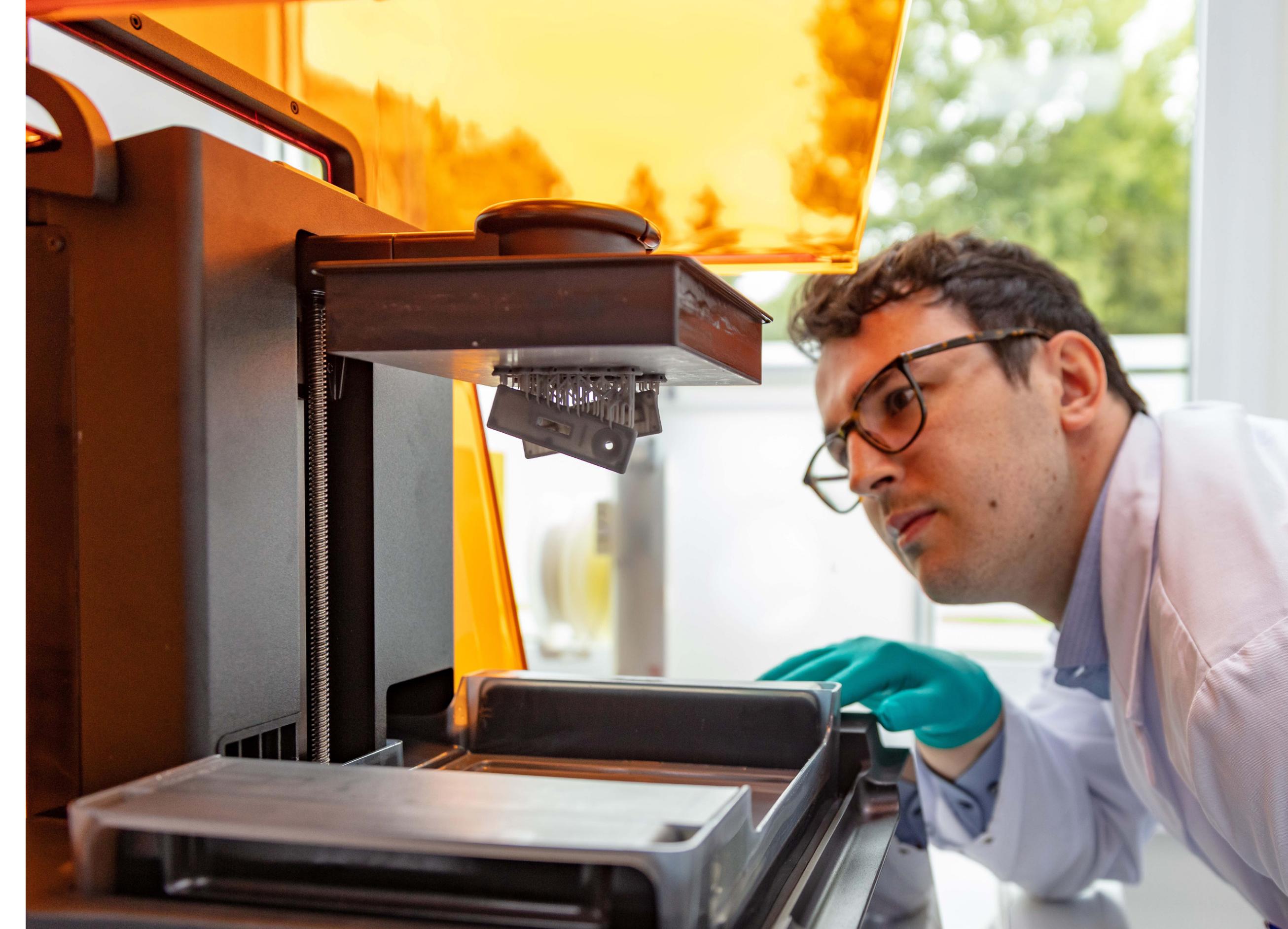
Customization type
Product

Project story

- When developing tests for the food and beverage industry, the customer found that the Cytiva glass fibers they were using were tearing.
- The customer asked us if we could strengthen the fibers without altering their functionality.
- The scientists at Cytiva found a way to mechanically reinforce the glass fibers by laminating the fibers with a substance that absorbed the force on the fibers.
- The customer received multiple prototypes, had direct access to the Cytiva scientists, and received continual updates.
- We had to work with supply chain issues due to the COVID-19 pandemic, and the customer was pleased with the final product and continues to source their fibers from us.



Get in touch to discuss your immunoassay rapid test component needs



“

The customer was already using Cytiva glass fibers, but our product didn't measure up to the criteria they had for a particular test. They appreciated the fact that we were able to do this small-scale custom product, particularly because the fibers worked in every other way already.

Dominik de Cassan, Site Leader Research and Development

✉ Speak to Dominik to learn more: dominik.decassan@cytiva.com

Saving customer time with contract kitting

 Company size	 Project size	 Time frame	 Customization type
Small	Small	4 months, ongoing	Service

Project story

- The customer developed an immunodiagnostic kit for a specific disease that predicts a patient's disease course and can be used to recommended treatment plans.
- The customer came to Cytiva for help packaging the product.
- All parts of the kit were supplied by the customer, and Cytiva assembled the final kit in a compliant way. The completed kits were shipped back to the customer ready to be distributed.
- Though the packaging process was not difficult, made business sense for the customer to outsource this to a company with scale and capability in this area.
- The team at Cytiva found a way to optimize the assembly process and deliver the kits to the customer faster.
- The customer plans to continue to work with Cytiva as they scale up production.



[Learn more about our diagnostic services](#)

Assembling and packaging materials is not the most exciting part of the immunodiagnostic kit development process, but it needs to be done. At Cytiva, we are more than happy to take on this tedious task so that our customers can spend their time on strategic tasks.

Anish Senan, Modality Sales Diagnostics Account Manager

✉ Speak to Anish to learn more: anish.senan@cytiva.com





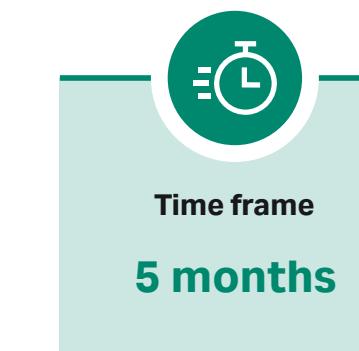
Dealing out lateral flow test cards



Company size
Small



Project size
Small



Time frame
5 months



Customization type
Product

Project story

- The customer needed a company to produce preassembled lateral flow cards that they could put into their diagnostic kits.
- Cytiva worked closely with the customer. We sent regular updates and prototypes and met all the customer-set timelines.
- However, it became clear that the product was not performing as expected.
- Our scientists communicated directly with the customer and helped them troubleshoot the issues with the product.
- The customer appreciated the fact that Cytiva had the experience and knowledge to discover why the product wasn't working and that we were willing to share this knowledge with them.
- We were able to complete validation of the product.

The customer chose to work with Cytiva because we are happy to provide custom products and services to small-volume companies. This willingness is rare among other large custom service companies.

Dominik de Cassan, Site Leader Research and Development

✉ Speak to Dominik to learn more: dominik.decassan@cytiva.com



[Learn more about our immunoassay development services](#)

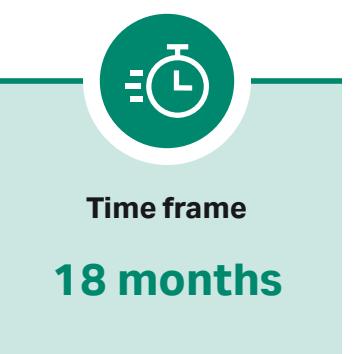
Packaged for you in the perfect plastic



Company size
Small



Project size
Medium



Time frame
18 months



Customization type
Product

Project story

- The customer had a new product for early cancer detection.
- Cytiva magnetic beads worked well with the customer's product, but the beads were not supplied with the optimal buffer or in the correct container.
- The customer asked Cytiva for a custom product that used the correct buffer and had the beads loaded in a 96-well plate.
- Cytiva and the customer had regular meetings and site visits, and Cytiva did audits for the customer.
- The customer was happy that they had direct contact with the scientists working on the project and that they had access to technical experts when needed.
- Cytiva's flexibility in working with the customer was also praised.



[Learn more about our magnetic bead conjugation services](#)



The customer liked the performance of our magnetic beads, but we didn't provide the beads in the format that like wanted. For one thing, they wanted the beads in a 96-well plate. We'd never done that before with our mag beads. But we did it. We made exactly what the customer wanted.

Math Davies, Custom Service Leader

✉ Speak to Math to learn more: matthew.davies@cytiva.com

Made-for-you membrane with QC and COA

			
Company size Medium	Project size Medium	Time frame 3 months	Customization type Product and service

Project story

- The customer was using an existing Cytiva membrane while developing a diagnostic test.
- The membrane's specifications were not tight enough for the customer's needs, so they asked us to improve it.
- The customer did not know the root cause of the problem and left it for Cytiva scientists to discover and eliminate.
- Cytiva scientists made changes to the membrane and provided validation products for the customer to test.
- The customer then wanted additional quality control (QC) done on the membrane.
- After the QC, Cytiva provided a custom certificate of analysis (COA) and all specification and work instruction documentation.



Request a sample of our point of care flow based immunoassay components

Like so many other companies, the customer was trying to develop a COVID-19 antigen test. Of course, time to market was extremely important. We kept in constant contact with the customer. We even checked up on their internal testing to make sure everything was going smoothly on their side.

Sarah Zachmann, Senior Diagnostic Scientist

 Speak to Sarah to learn more: sarah.zachmann@cytiva.com



More information



Checklist: 10 essentials for choosing a collaborator for diagnostic assay



Checklist

10 essentials for choosing a collaborator for diagnostic assay development

Find the right collaborator for you

1. How healthy are a collaborator's documentation, supply chain, and infrastructure?
Late delivery can severely impact your development timeline and cost your customers at the commercialization stage. Before committing to a project, ensure effective documentation, supply chain strategies are in place and that the potential collaborator has a cross-functional, data-driven culture to manage supplier management.

2. What level of ongoing service, support, and expertise can you expect?
Early access to knowledge and expertise will help you with the development and launch process and guide your workflow in research. The ability to troubleshoot and address challenges when things don't go to plan and to have a strong network of cross-functional technical teams is an advantage that some potential collaborators have.

3. Can they scale with you?
Ask whether a collaborator has the capacity and scalability to see you through to market. Look for a collaborator that is capable of accommodating manufacture of everything from prototypes through multi-million-unit lots for both low- and high-throughput needs? Can fluctuations in demand be accommodated and managed effectively and with minimal disruption to supply?

4. Will a single-supplier approach work for you?
Using one supplier for all diagnostic needs reduces the complexity of the supply chain and allows for a more efficient workflow. You may need to validate only one supplier. You may even be able to negotiate a long-term, firm commitment to supply. Make sure any company that you want to use as a single supplier has the right infrastructure, access to services and can support your entire workflow, from initial development and commercialization to manufacturing and commercialization.

5. Can a collaborator help you reduce environmental impact with sustainable solutions?
Sustainability is becoming a priority across the industry. Look for a collaborator to partnering can give you a business advantage. See whether a collaborator offers sustainable processes, for example, lyophilization (also called freeze drying) which removes moisture from a substance at a low temperature. A product or sample that has undergone lyophilization can be stored at room temperature, which is easier and more sustainable. The process also maximizes the product's stability and shelf life.

6. What's their track record?
Work with a collaborator who has evidence of success and experience in similar projects. This may help reduce development time. Ask a potential collaborator for examples of similar projects and their successes and failures to determine if they can handle your project.

7. Do they have the right facilities?
Be sure that you can tour a facility in person or virtually. That way you can see if the equipment, layout, and capacity of a collaborator's facilities are right for your needs. This can also provide reassurance that your assay will be in safe hands and that production can meet the expected demand.

8. What training workshops are available?
Some companies conduct workshops to co-develop an assay, maximize the collaboration, and help you take the development forward. These workshops can also provide insights for future projects.

9. Can they offer a full-workflow solution?
A collaborator should be able to support you from start to completion. They should have a diverse portfolio of resources and services. If they do not develop all the components or expertise in-house, they should have the ability to work with others via a strong network to make the process as smooth as possible. You should ask if you can access different reagents in the development process.

10. Do they provide support when you need it?
Operating in a global environment means you might not be located physically close to a manufacturing site. Multiple manufacturing sites may be needed to optimize timelines and costs. In these cases, your partners must be located close to the sites. Make sure a potential collaborator can provide timely, timely updates, and round-the-clock technical support that coincide with your operating hours. You should also make sure they have a strong supply network for shipping efficiency, which will positively impact your project's success more than the site location.

Use this checklist to find the right collaborator for you.

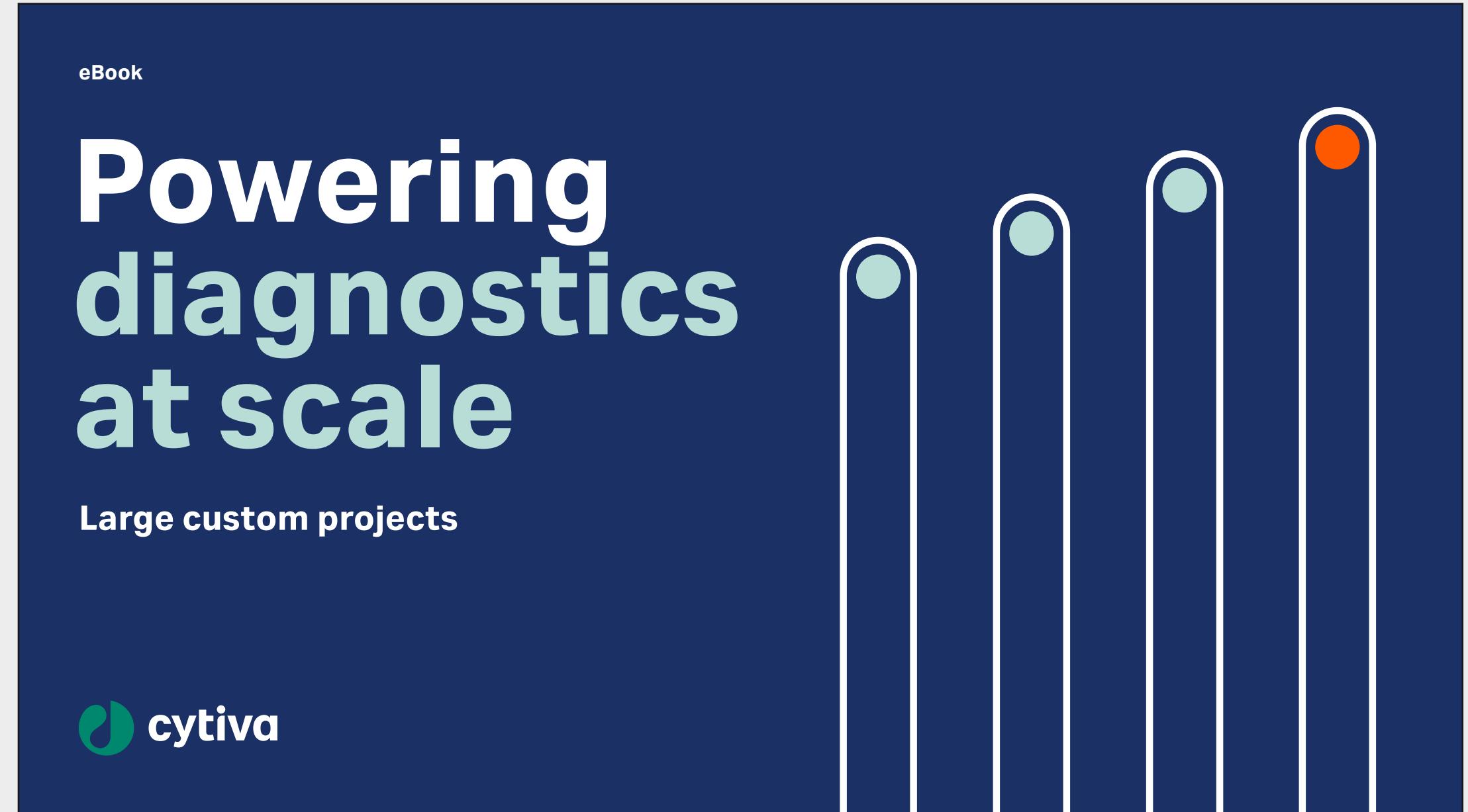
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