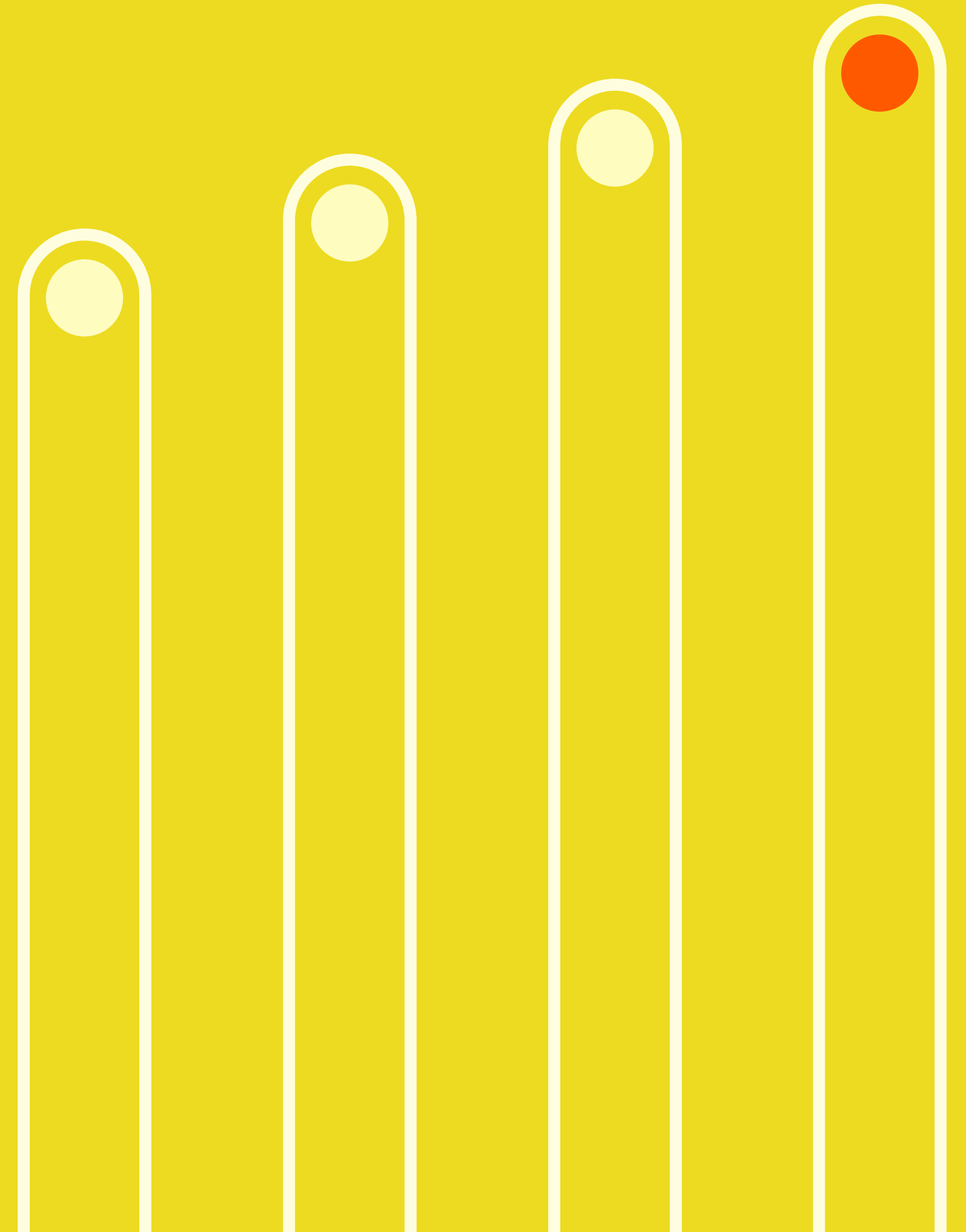


eBook

Powering diagnostics at scale

Small- to mid-size custom projects



Introduction

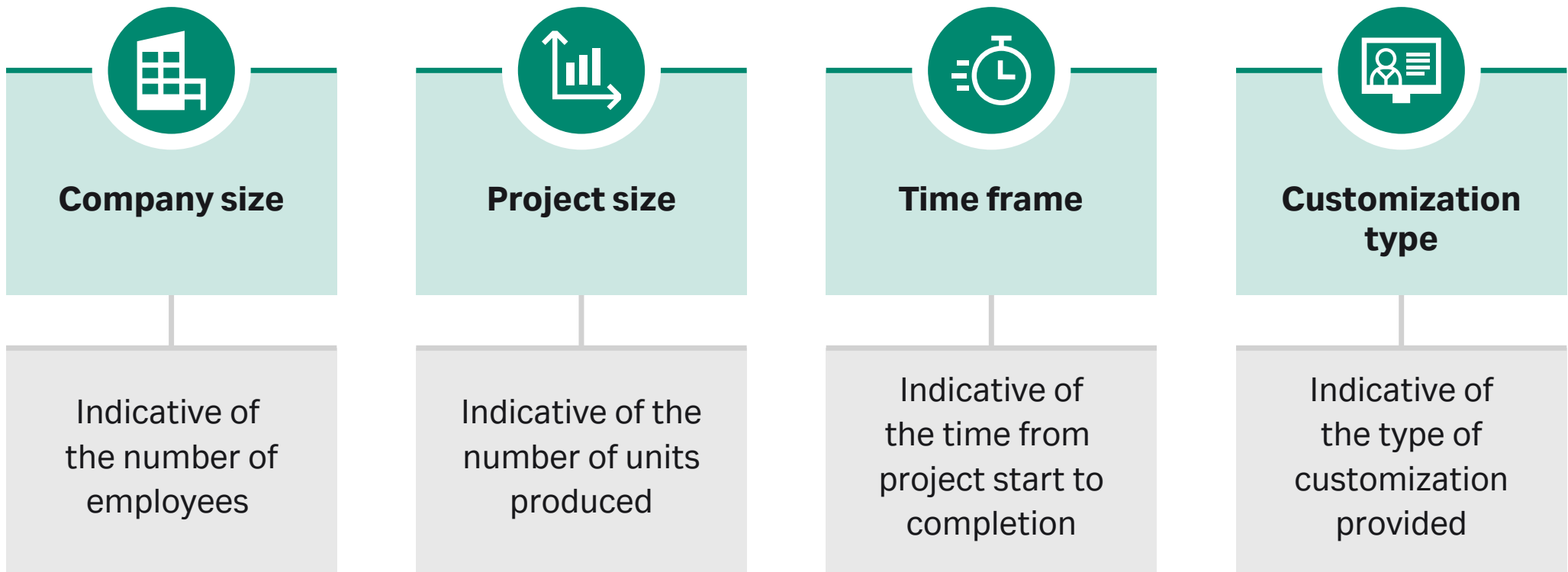
Each of your molecular or immunoassay development projects is unique. So, you need solutions tailored to your specific needs. Cytiva has a proven track record of delivering innovative diagnostic design and development services. This case study eBook highlights small- to mid-size real-world examples of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



Scope and scale of the project





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.



Learn more about our contract manufacturing and kitting services



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*

Taking the pressure off your glass fibers



Company size

Small



Project size

Medium



Time frame

9 months



Customization type

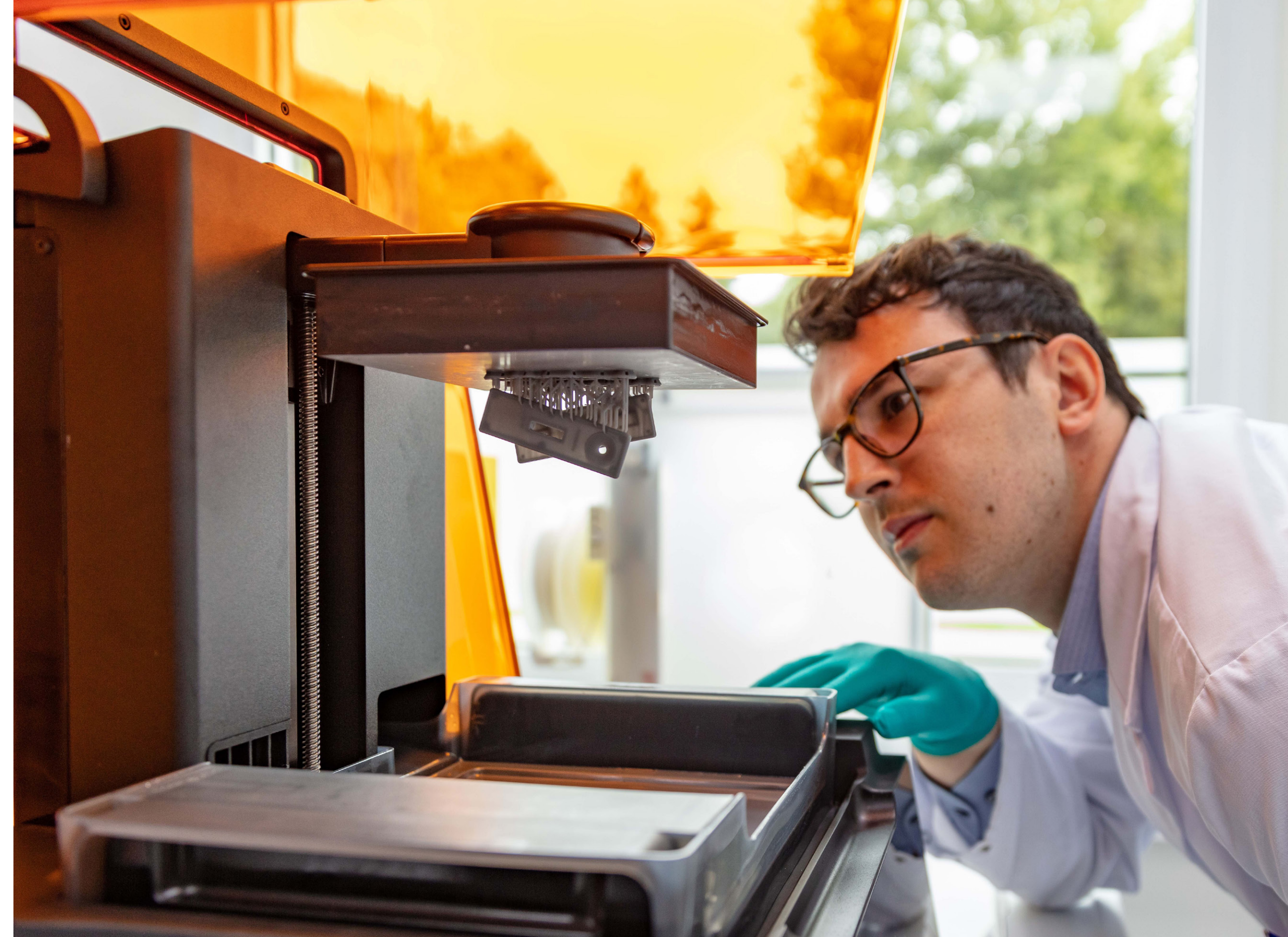
Product

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

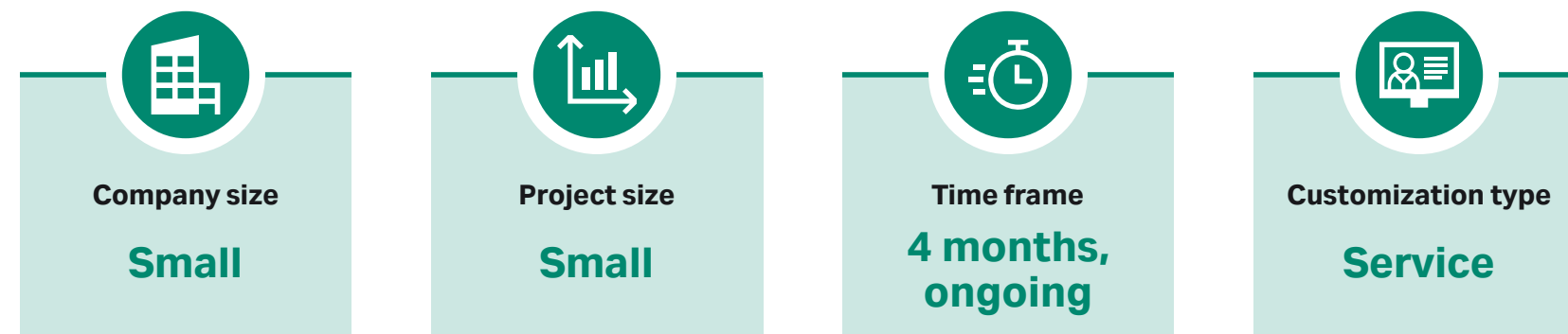


The customer was already using Cytiva glass fibers, but our product didn't measure up to the criteria they had for a particular test. They appreciated the fact that we were able to do this small-scale custom product, particularly because the fibers worked in every other way already.

Dominik de Cassan, Site Leader Research and Development

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

Saving customer time with contract kitting



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.



Learn more about our immunoassay development services

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

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

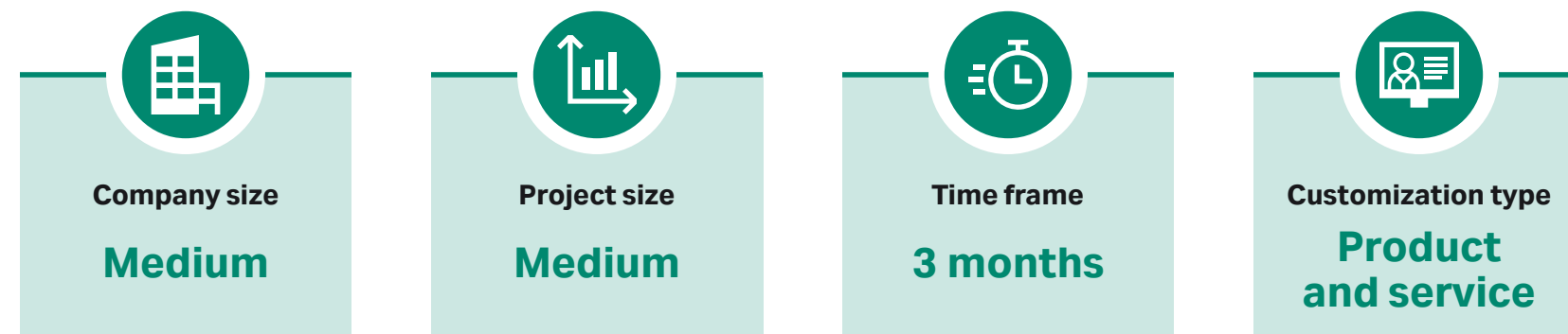


The customer liked the performance of our magnetic beads, but we didn't provide the beads in the format that like wanted. For one thing, they wanted the beads in a 96-well plate. We'd never done that before with our mag beads. But we did it. We made exactly what the customer wanted.

Math Davies, Custom Service Leader

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

Made-for-you membrane with QC and COA



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

Download our large scale projects eBook

Checklist

Find the right collaborator for you

1

How healthy are a collaborator's procurement, supply timelines, and infrastructure?

Let's deliverables can severely impact your development timeline and can disrupt customers at the commercialization stage. Before committing to a project, ensure effective risk assessment and mitigation strategies are in place and that the potential collaborator has a cross-functional, data driven commitment to supplier risk management.

3

Can they scale with you?

Ask whether a collaborator has the capacity and scalability to see you through to manufacturing stages. Are the facilities capable of accommodating manufacture of everything from single buffers through multi-component kits for both low- and high-throughput needs? Can fluctuations in demand for the different products be managed effectively and with minimal disruption to supply?

5

Can a collaborator help you reduce environmental impact with sustainable solutions?

Sustainability is becoming a priority across the industry and a commitment to supporting it can gain you a business advantage. See whether a collaborator offers sustainable solutions. For example, lyophilization (also called freeze drying and cryodesiccation) removes water from a substance at a low temperature. A product or sample that has undergone lyophilization can be shipped and stored at room temperature, which is safer and more sustainable. The process also maximizes the product's stability and shelf-life.

What level of ongoing service, support, and expertise can you expect?

Timely access to knowledge and expertise to help you with the development and launch processes and to guide your workflow is essential. The ability to troubleshoot challenges when things don't go to plan and to find solutions directly with scientists and technical teams is an advantage that some potential collaborators have.

Will a single-supplier approach work for you?

Using one supplier for all diagnostic needs reduces the complexity of the supply chain and saves time and resources because you need to validate only one supplier. You may even be able to negotiate better terms through economies of scale. Make sure any company that you want to use as a single supplier offers everything from components to services and can support your entire workflow from initial development and clinical trials to manufacturing and commercialization.

What's their track record?

Working with a collaborator who has evidence of success and experience in similar projects may help reduce development timelines. Ask a potential collaborator for examples of similar projects undertaken and their successes and learnings to determine if they can handle your project.

10 essentials for choosing a collaborator for diagnostic assay development

Imagine you have an idea for a lateral flow device and need help with development. Or maybe you need support scaling up the commercialization of a molecular assay. Or perhaps you're simply searching for a collaborator you can depend on now and in the future.

The race to commercialize diagnostic tests is faster than ever. Molecular and immunodiagnostic tests using nucleic acid and protein assays in a lab-based or point-of-care format are now an essential component in the evaluation and early detection of many diseases. Working with an organization who you trust allows you to share insights, access equipment and specialized infrastructure, and benefit from broader expertise and skills without capital investment or development time.

Use this checklist to find the right collaborator for you.

2

Can you test the facilities?

Be sure that you can have a facility in person or virtually. That way you can check the infrastructure, equipment, and capacity of a collaborator. Seeing the operation and talking with the people who work there can provide reassurance that your assay will be in safe hands and that production can meet the expected demand.

Can they offer a full-workflow solution?

A collaborator should be able to support you from project start to completion. They should have a diverse portfolio of reagents, membranes, magnetic beads, and services. If they do not develop all the components or excipients in-house, they should have access to reliable contractors via a strong network to make the process as smooth as possible. You should ask if you can use your current reagents in the development process.

What training workshops are available?

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

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. In fact, multiple manufacturing sites may be needed to optimize timelines and assay quality. In these cases, you probably can't be located close to all the sites. Make sure a potential collaborator offers virtual tools, timely updates, and round-the-clock technical support that coincide with your operating business hours. Also check that they have a strong supply network for shipping efficiency, which will positively impact your project's success more than the site location.

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Click here for more information on Cytiva's diagnostic services

eBook

Powering diagnostics at scale

Large custom projects

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