

Understanding
your vaccine and
immunotherapy
efficacy.



revvity

Certimmune Global Immunology Service



A trusted partner for adaptive immunity testing for clinical trials

- **Certimmune overview**
- **Assay types and techniques**
- **Flow cytometry services**
- **Partners and regulatory approvals**
- **Contact us**

Certimmune's global immunology services are brought to you by Revvity. Certimmune is built on the foundations of Revvity nearly 20 years' experience developing more reliable, high throughput, standardized tests for measuring the adaptive immune system.

Our team of experts can support your T and B cell immunoassay needs from start to finish of your clinical trials, including:

- Assay design, development and validation
- High-volume testing implementation and operations
- Data interpretation and reporting
- Regulatory responses and quality management
- Global partner lab onboarding and monitoring
- Sample cryopreservation and long-term storage



Specialty testing services

Our assay development team are immunology experts. We take a consultative approach to assay development with our clients to ensure we maximize the relevance of quality data produced. Additionally, we have standardized in-house protocols to draw from, for quick turnaround of new assays from concept to validation.

Immunology testing expert

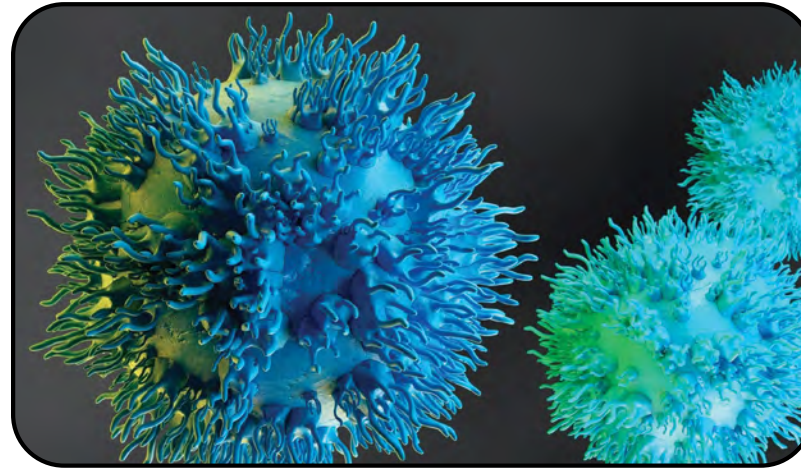
| Consultative approach to new assay development

| Standardized in-house protocols



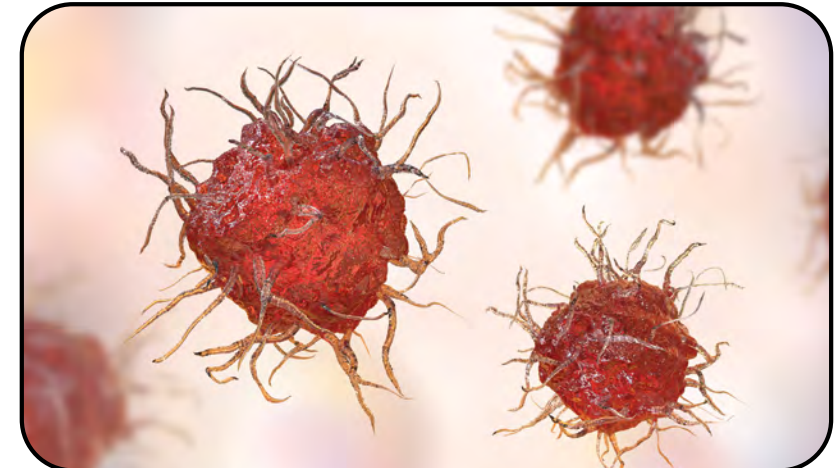
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Today, we are equipped to evaluate:



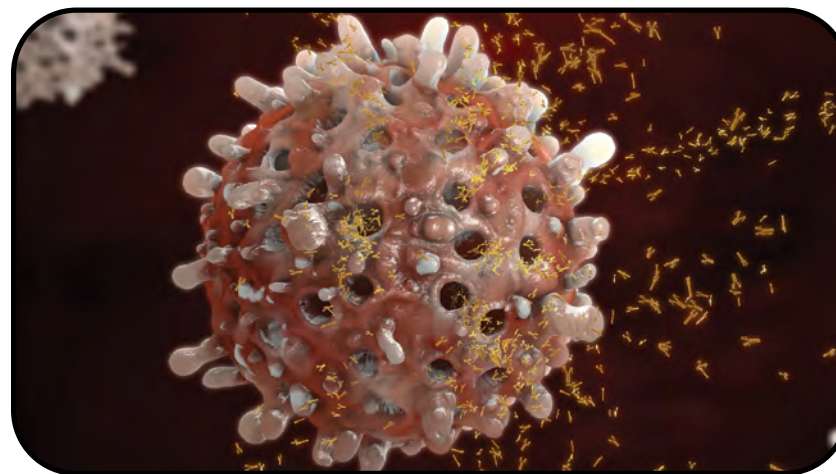
T cells

Memory/differentiation status | T_{reg} differentiation cytokine profile | effector function | cytotoxicity | activation exhaustion | transcription factor profile | survival | signaling



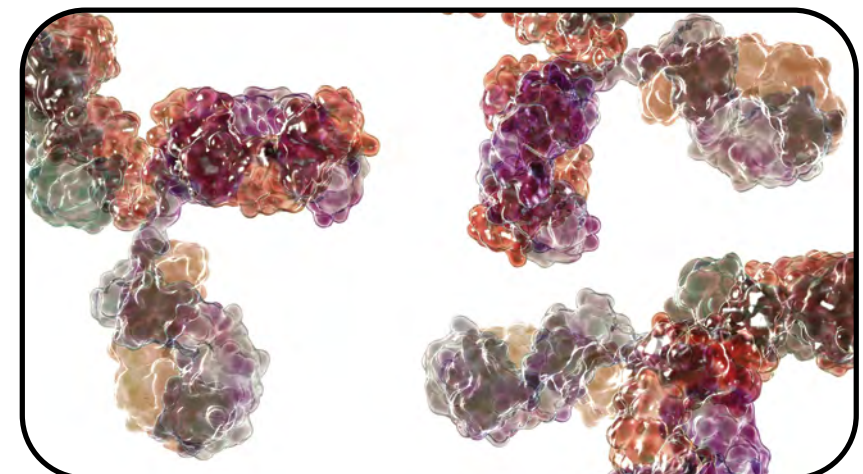
Dendritic cells

Subset analysis | T cell activation



B cells

Memory/differentiation status | plasma cell development isotype class switching | cytokine production | activation transcription factor profile | survival | signaling



Antibodies

Target protein binding | Isotype classification



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Assay types we currently offer

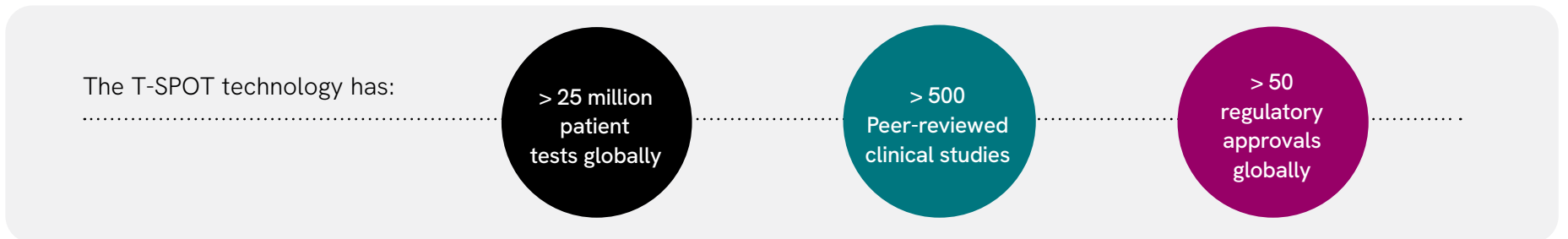
- Enzyme-linked immunospot assays (ELISPOT)
- Multi-parametric flow cytometry (up to 16 parameters)
- 2- color ELISPOT
- Enzyme-linked immunosorbent assay (ELISA)
- Multiplex analysis (up to 50 analytes simultaneously)
- T cell expansion protocols using *in vitro* culture

Our development team is always evaluating new testing methodologies to add to our current library of protocols. Contact us if you have interest in:

- Multi-parameter cell sorting for downstream applications
- Drop-Seq molecular platforms for DNA-Seq/RNA-Seq microarray analysis
- 4-color Fluorospot

Experts in ELISPOT technique

Revvity has taken the classic ELISPOT methodology and developed it into the T-SPOT® technology platform, which is used by Certimmune.



Unlike other techniques, the T-SPOT technology can:

Measure antigen-specific response at the single cell level	Increased ability to discern a measurable response
Remove 'noise' of irrelevant background signals	Allow for easier and more accurate result interpretation
Enumerate the number of immune cells tested	Limit reduction in data quality for immunocompromised populations
Process blood up to 32 hours after collection	<p>Longer blood stability means improved trial logistics:</p> <ul style="list-style-type: none"> ▪ Longer windows for patient enrollment daily ▪ Ability to centralize samples ▪ Capacity to expand testing to remote enrollment sites <p>However, if using frozen cells is necessary, Certimmune's standardized protocols will ensure a high-quality response from the cells you are evaluating</p>



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High-volume, multi-parametric flow cytometry

Certimmune has the capability and the facility to perform multi-parametric flow cytometry at high volumes.

1 Clinical expertise: experts who can work with your clinical teams to create the right flow cytometry panels and readouts for your clinical trial

2 High-volume capabilities: standardized validation and protocol implementation process by a team with experience running high volume testing ensures that data quality is not compromised as the trial ramps up

3 Well-equipped laboratory: we use flow cytometry equipment that allows for up to 16 parameters to be run with each sample. This allows you to maximize data readouts so you can learn as much as possible about how the adaptive immune system is responding to your vaccine or immunotherapy

Working with you through large-scale Phase 2 and Phase 3 trials

Managing testing at high volumes without compromising data quality can be a big challenge. However, our operations teams have many years of experience running cellular immunoassays in high volumes, making us an ideal solution for large clinical cohorts. For example, we completed ELISPOT and flow cytometry work on over 26,000 clinical trial samples in 2021.

Global scalability for clinical trial growth

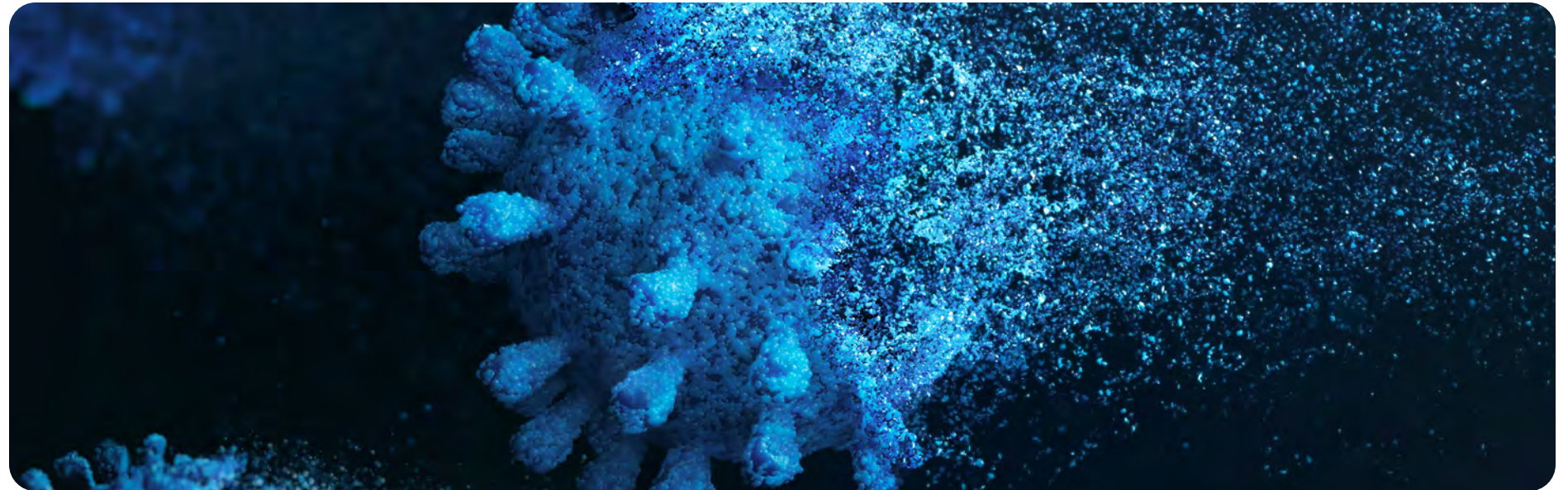
Certimmune can grow with your clinical trials across multiple geographies. We have an established global network of trusted laboratories who have worked with us to implement our IVD test kits into their own labs. We are now working with many of these same labs to provide testing services for our Certimmune customers.

Our technical services team is situated across the globe and have been training labs to provide our testing services for many years. If a new lab partner is identified, by our team or yours, our technical service team can quickly onboard the partner lab.





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Current partnerships pharmaceutical: companies, researchers, governmental bodies

Prior to the launch of Certimmune, Revvity was selected as sole provider of T cell testing for SARS-CoV-2 vaccine research with the UK Vaccine Task Force (VTF). Since then, we have provided immunology testing services for over 20 vaccine developers and research institutions.

Visit www.certimmune.com for peer-reviewed papers that include data generated by our team

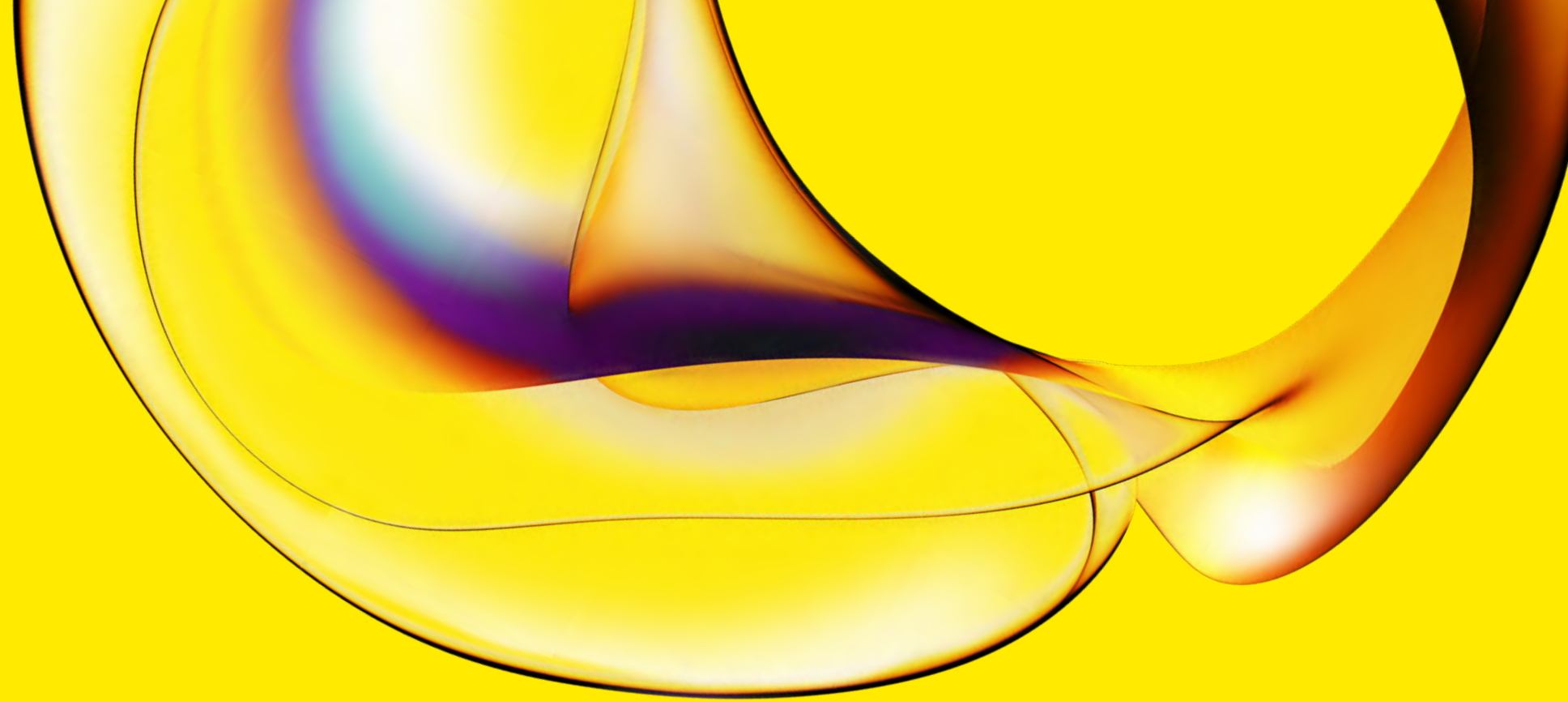


History with regulatory approvals

All our products and services adhere to rigorous laboratory standards and practices, guided by Quality Assurance and Clinical Affairs teams, which is important for regulatory submissions.

We have developed IVD test kits that have received regulatory approval in 50 countries, including US FDA and CE mark authorization, as well as approvals in Japan and China.

Additionally, we built an accredited clinical laboratory, called Oxford Diagnostic Laboratories (ODL®), which has been in service for over 18 years providing both routine clinical testing services and custom services in support of clinical studies.



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