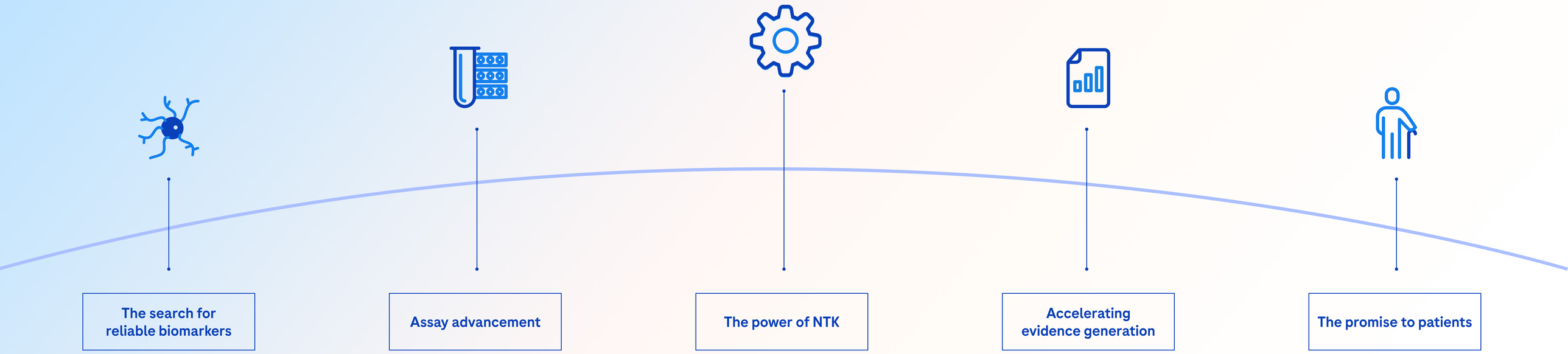
NeuroToolKit (NTK)

The bridge between the biomarker and the patient



The search for reliable biomarkers

Today, there is a rising sense of urgency to advance science for the fastest growing societal burden—neurodegenerative disorders.

As new therapies for neurodegenerative disorders are introduced, it is increasingly important to have diagnostic solutions along the patient care continuum.

Once the need for a diagnostic solution is identified, the proper immunoassay needs to be developed. The first step in immunoassay development is the identification and thorough assessment of antibodies, which can be either generated in-house at Roche or supplied by external partners. Antibodies are then characterised and tested for suitability on the Elecsys® platform with a special focus on kinetic properties and specificity for the biomarker of interest.

Once suitable antibodies are identified, the biomarker can proceed to the robust prototype assay (RPA) development phase.

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Assay advancement

During Robust Prototype Assay (RPA) development phase, it is ensured that assays are designed with a special focus on performance, quality, and robustness. This includes a rigorous assay validation, for example, including precision, interference, stability and different sample type testing. As a result, only assays that meet the high quality standards are implemented in the NTK.

Not only biotech and pharmaceutical research development teams, but also academic partners rely on RPAs when conducting early clinical or research studies to explore the potential value of specific biomarkers.

RPAs are implemented to analyse samples from early clinical and research studies collected by industry and academic partners.

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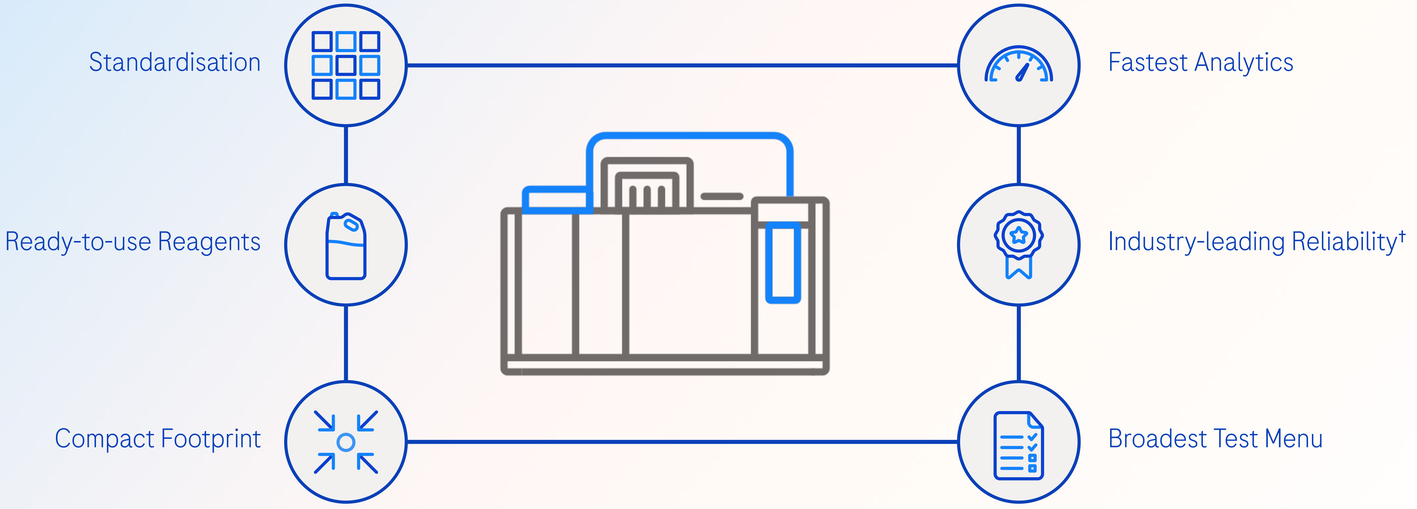
Assay evolution beyond RPAs

Exploratory studies	Clinical and registrational studies	Commercialisation and clinical practice
Robust Prototype Assay (RPA)	Clinical Trial Assay (CTA) **Learn more**	In Vitro Diagnostic (IVD) Assay **Learn more**

All assays types (RPA, CTA, and IVD) can be **Research Use Only (RUO)** and run on the Elecsys (cobas e) platform* **Learn more on RUOs**

Reliable results powered by the Elecsys® (cobas® e) platform

The simplicity of a fully-automated IVD analyser, built on the same core values, delivers standardisation for quality and reliability, and also streamlines workflow.



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†Competitive mean time between failure rate published by CAP Today: Chemistry and Immunoassay Analyzers for Mid- and High-Volume Laboratories, July 2022. Internal Roche MTBF data on file.

The power of NTK

The NeuroToolKit (NTK) represents a transformative change, providing an innovative bridge between biomarker research today and the clinical utility of tomorrow.

The NTK offers a step forward in biomarker statistical analysis using analytical apps for a collaborative approach through results-sharing that creates an ideal ecosystem for scientific discussion—resulting in groundbreaking connections for a greater understanding of the biomarker potential clinical utility. NTK is a cutting-edge proof statement that working together gets us further.

The NeuroToolKit facilitates and accelerates the journey from biomarker research to the biomarker clinical application, with the vision of bringing High Medical Value assays to the clinical community when and where they are needed most.

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The power of partnership

Through a combined effort between academia, industry, and philanthropy, NTK sets the foundation upon which new diagnostic solutions will be built. As part of NTK, we are proud of this groundbreaking path to the future, and even more proud of the partnerships that have made it possible.

Learn more

The power of results-sharing

NTK Portfolio

The NTK assays are run on the fully-automated Elecsys® platform, assuring the highest performance and quality in four validated labs.

Regularly the portfolio is updated with the most promising biomarkers as agreed upon by the key opinion leaders. These biomarkers are thought to be clinically useful in neurological disorders.

Learn more

Workbench

Digital research environment (DRE) is a collaborative, cloud-based platform with data analytics functionalities (apps). It provides access to data, tools and resources under one ecosystem.

Learn more

The Apps

From the Workbench, access to 3 interlinked Apps allows users to curate, analyse and compare results from different cohorts around the world.

Learn more

Accelerating evidence generation

The published NTK data is a step closer to understanding the role of neurodegenerative biomarkers and their clinical utility. This helps ensure that the right product is mapped to the right indication and is brought to market, further enabling novel physician decision-making along the continuum of a patient's journey.

The promise to patients

The final purpose of the biomarker journey is to bring solutions to patients. Through the NeuroToolKit collaboration, the field joins forces to understand the utility of biomarkers in neurological disorders. This is a big step towards accelerating future IVD solutions and bringing reliable products to clinical practice. This is a promise to further support the patient journey.

Contact us

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Partnering

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Diagnostic

Roche Diagnostics provides access to the NTK portfolio for measurement of reliable and high-quality biomarker data.

Philanthropic

Supports patients and science through ongoing commitment and advancement of digital innovation. An innovative and secured IT infrastructure enables data- and results-sharing, while preserving data ownership.

Academic

Academia collects patient cohorts and conducts research with the NTK biomarker portfolio to better understand the utility of the assays in the various patient populations. Using the NTK app, statistical analysis modules are developed and used to assess the clinical utilities around each biomarker.

Pharmaceutical

Pharma partners investigate biomarker utility in clinical trials.

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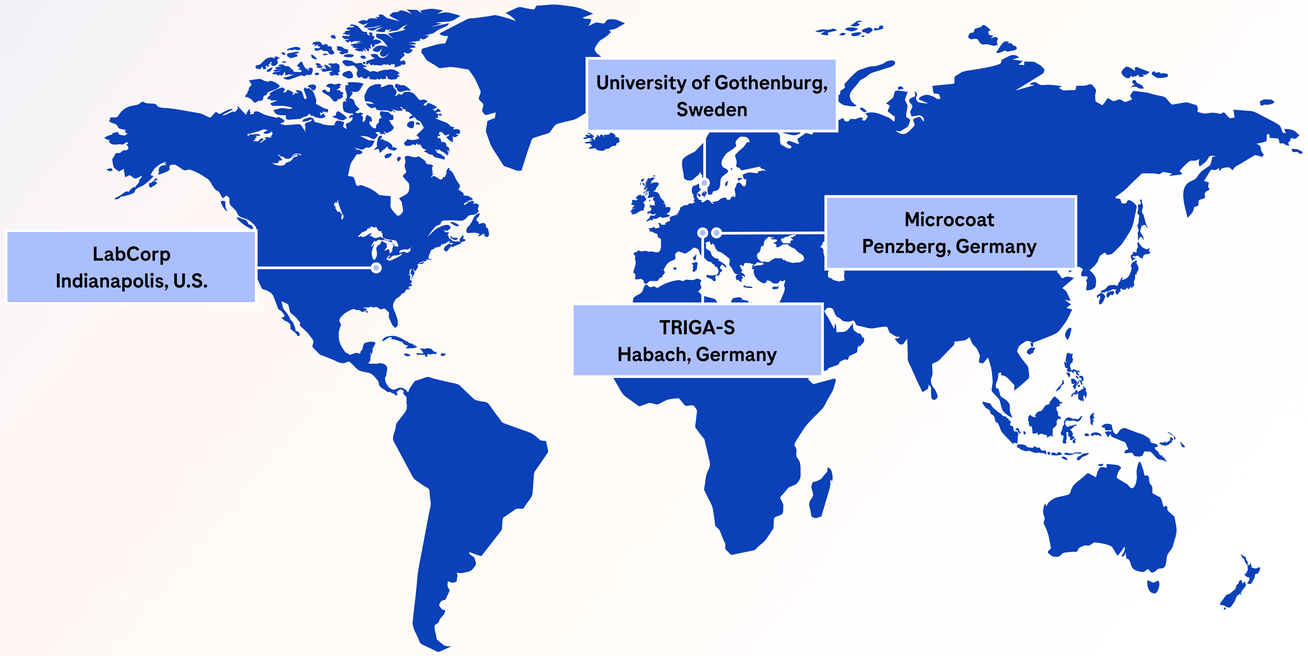
NTK Portfolio

NTK currently offers an intended-use agnostic portfolio of 14 CSF and 16 serum/plasma assays, with more in development.

Assay Maturity	CSF Assays	Plasma/Serum Assays
RPA	AB40	AB42
	NfL	AB40
	STREM2	tTau
	YKL40	STREM2
	GFAP	YKL-40
	Alphasynuclein	GFAP
	Neurogranin	IGFBP7
	IL-6	NSE
	S100b	pTau181
	SNAP25	APOE4
	NPTX2	SNAP25
		NPTX2
CTA		NfL
IVD	AB42	IL-6
	tTau	S100b
	pTau181	GDF-15

The NTK Portfolio is measured in four measurement sites.



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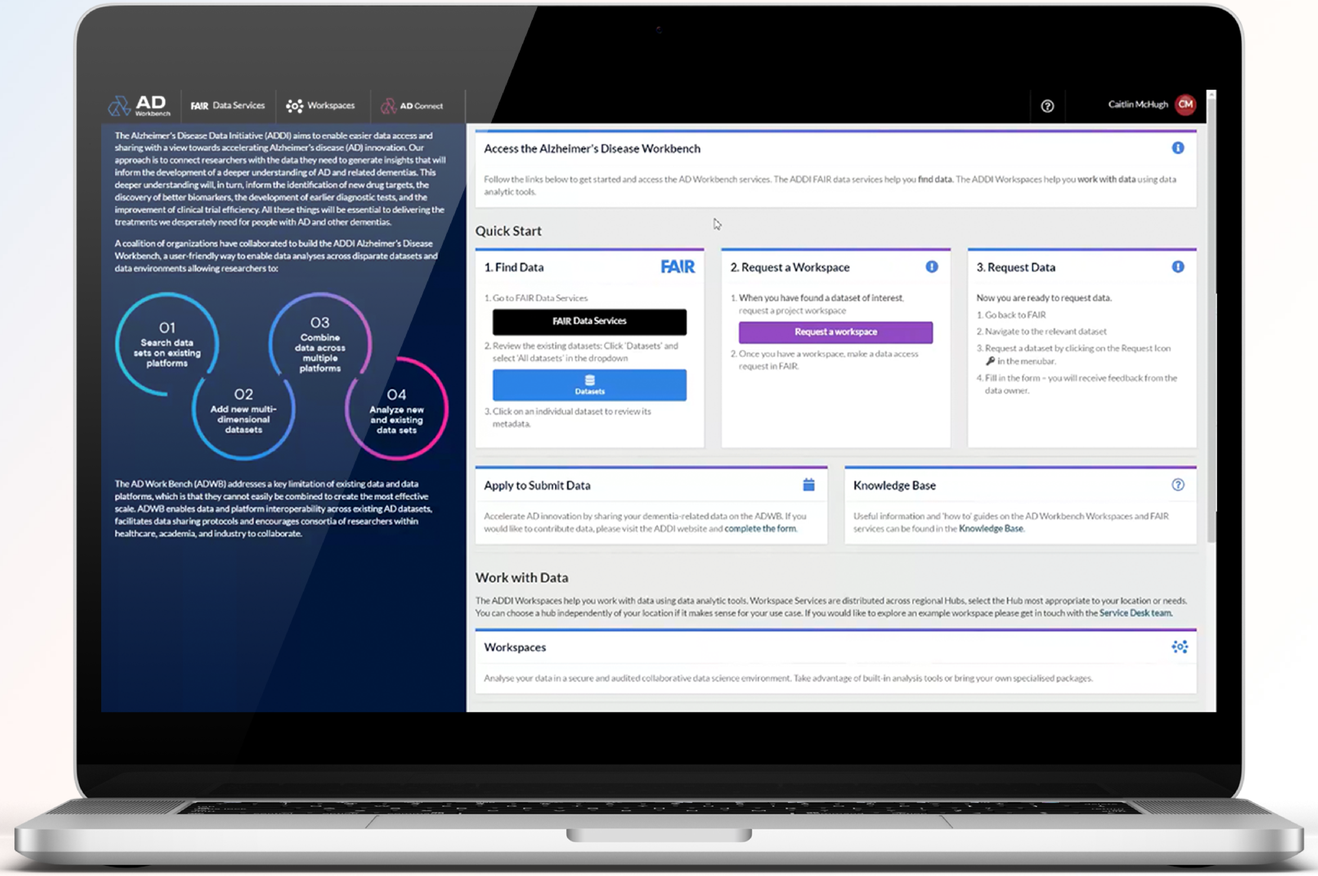
Workbench

The AD Workbench is a collaborative, cloud-based platform that offers access to data analytics and a suite of apps that fosters cross-domain research collaboration with:

- Secure workspaces
- Statistical analysis tools
- Trusted data governance
- FAIR data services



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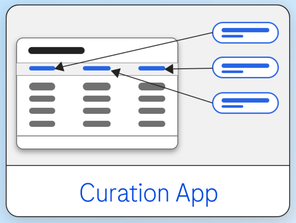
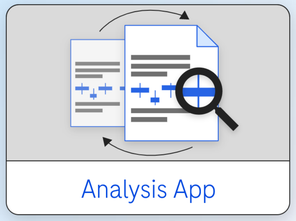
Apps

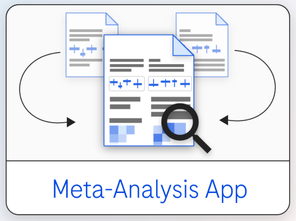
From the Workbench, access to the user-friendly Apps allows curation, analysis and comparison of data across cohorts, clarifying the clinical utility of biomarkers for a better understanding of which biomarkers deserve further IVD development.



Curation
Translate variables within a cohort to a common data dictionary so that datasets are harmonised and comparable.



Analysis
Select from a suite of statistic analysis to gain insight into data.



Meta-Analysis
Enables results comparison across cohorts.

Assay advancement

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What is a CTA?

While RPAs cannot be used for patient decisions, they can be further developed and validated as clinical trial assays (CTAs) and potentially also as in vitro diagnostics (IVDs) to support patient selection, treatment decisions and Phase 3 studies.

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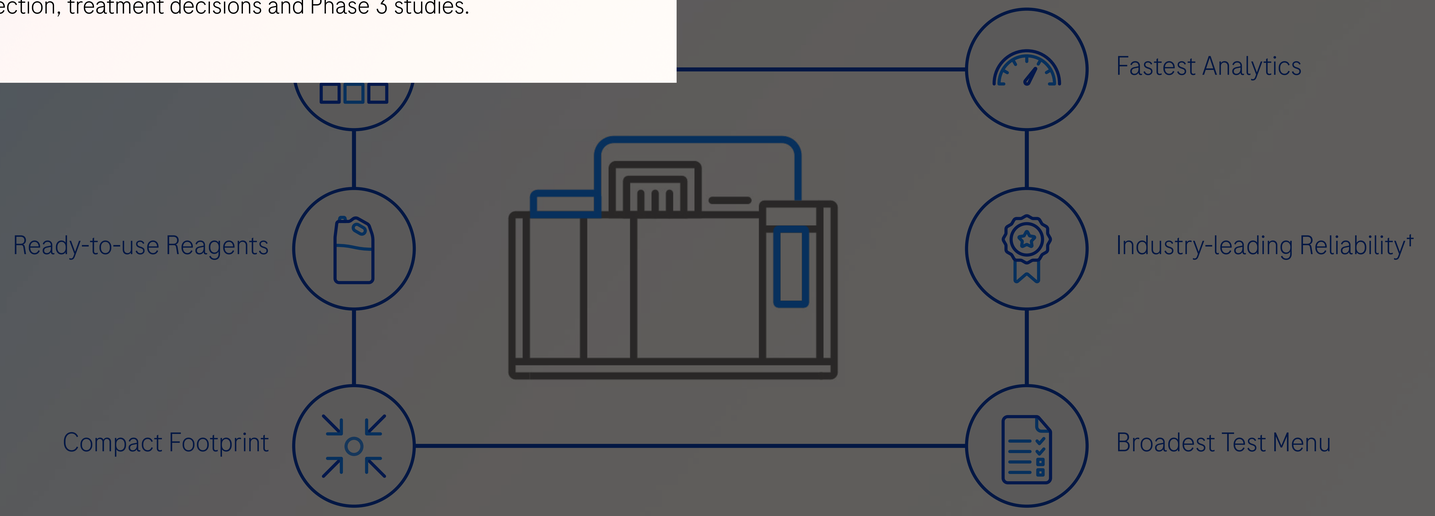

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What is an IVD?

In vitro diagnostic (IVD) assays are commercially available and are intended to be used in clinical practice with a specific intended use. IVDs have undergone extensive regulatory review to obtain approval by regulatory bodies.

IVDs provide robust and reliable test results during clinical and registrational studies and allow for global commercial implementation.

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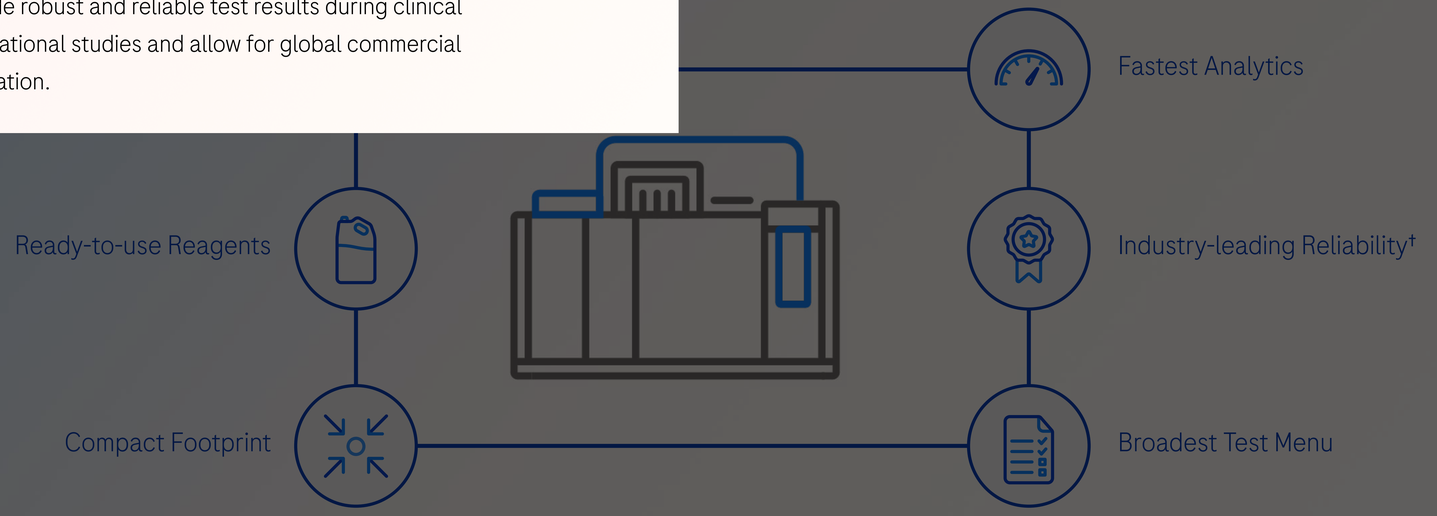

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What is an RUO?

Research use only (RUO) assays are in the laboratory research phase of development and cannot be used for clinical decision-making or diagnosis.

RPAs, CTAs and IVDs can be labeled as RUO assays and commercialised to external partners and customers for their purposes.

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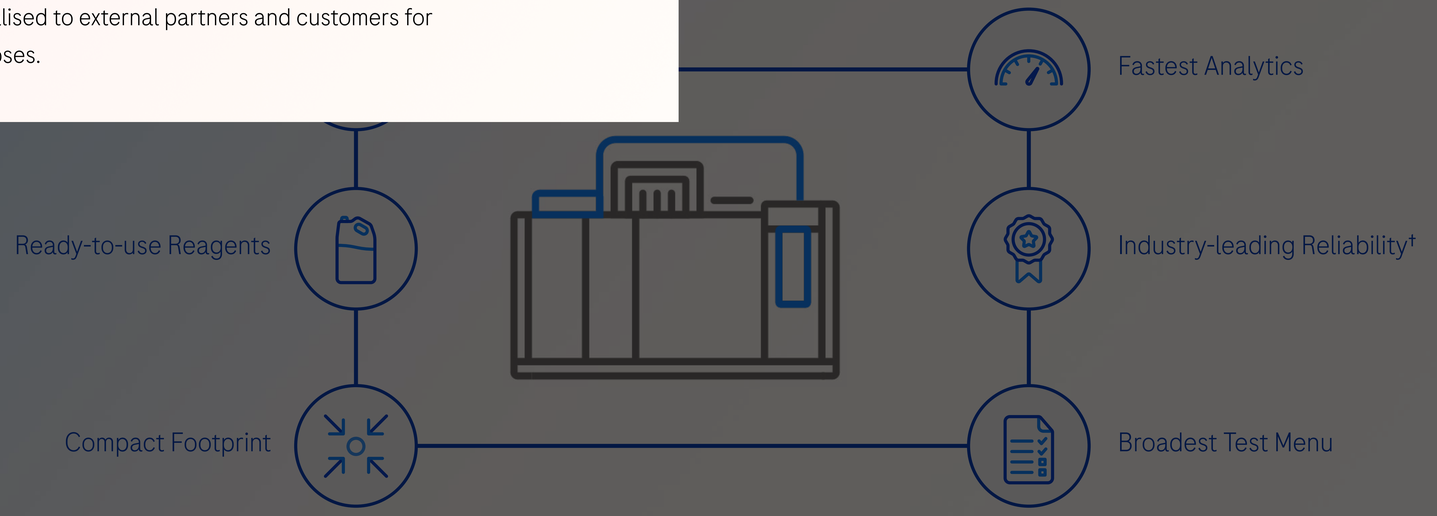

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Partneri

Diagnostic

Roche Diagnostics pro
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Academic

Academia collects pat
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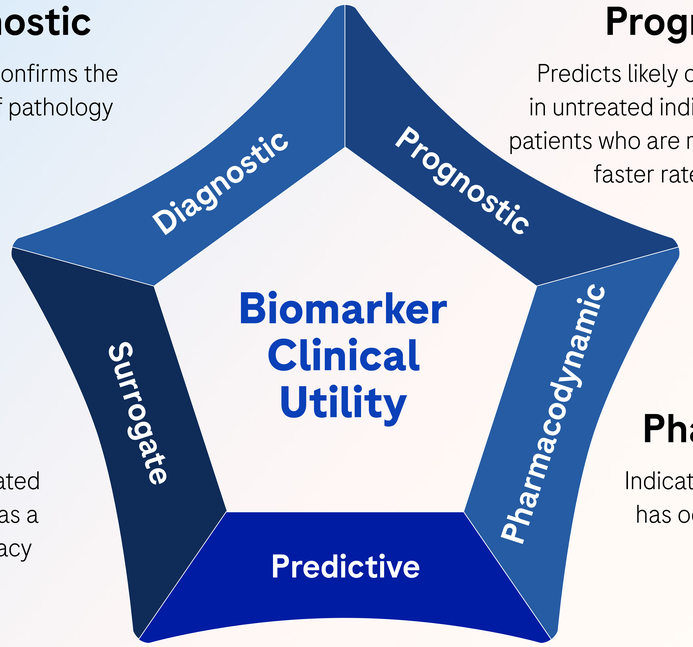
Diagnostic

Detects or confirms the presence of pathology

Prognostic

Predicts likely course of disease in untreated individuals; identifies patients who are more likely to have a faster rate of decline



Surrogate

Predicts specific disease-related clinical outcome and serves as a surrogate for a clinical efficacy endpoint

Pharmacodynamic

Indicates that a biological response has occurred and often precedes clinical outcome

Predictive

Discriminates between individuals who will respond or not to therapy