rarity BIOSCIENCE

CYTO 2026 – Innovation Showcase

# SuperRCA: Enabling ultra-sensitive molecular MRD on Flow cytometry

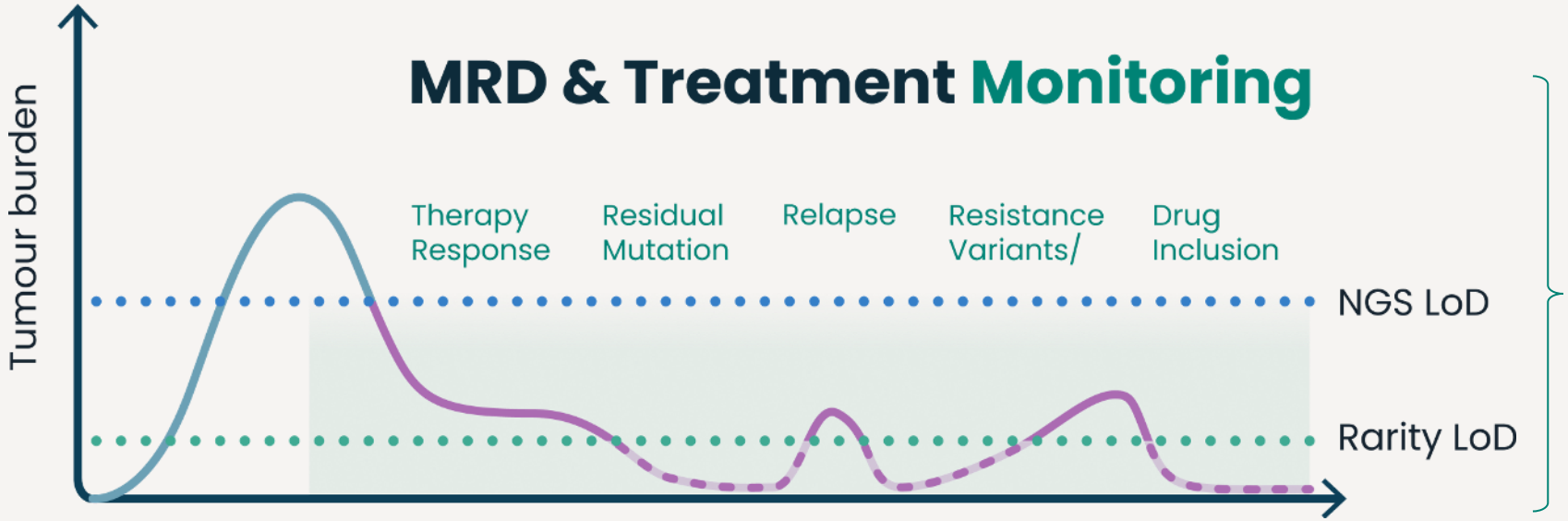
*Lei Chen, PhD*

*CTO/Co-founder*

# Unmet need

35M/y new cancer cases & 67M living with cancer by 2030[1]

→ **Increased need for precision diagnostics and monitoring**




**Enabling Precision Medicine**

Current methodologies for mutation detection cannot reach high sensitivities required to capture low mutation burden

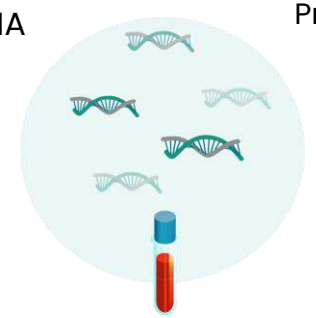
*For Research Use Only. Not for use in diagnostic procedures.*

# superRCA® Technology

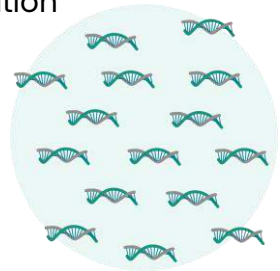
Patented chemistry that converts DNA in fluorescent particles. Combines 2 x Rolling Circle Amplification (RCA) and Padlock Probes.

OR

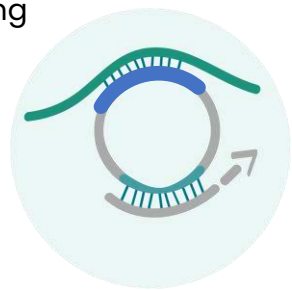
Starting material purified DNA (Blood, Bone Marrow, ctDNA/plasma)



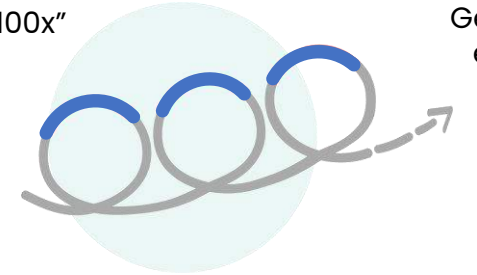
Pre-amplification 10 Cycles



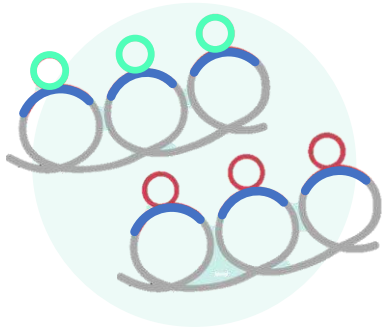
Circularization using padlock ligation template



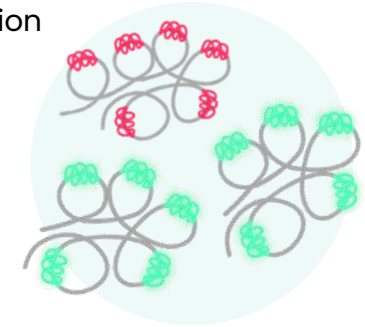
Circle replication using RCA "100x"



'Multi-factor' Genotyping enabling extreme precision



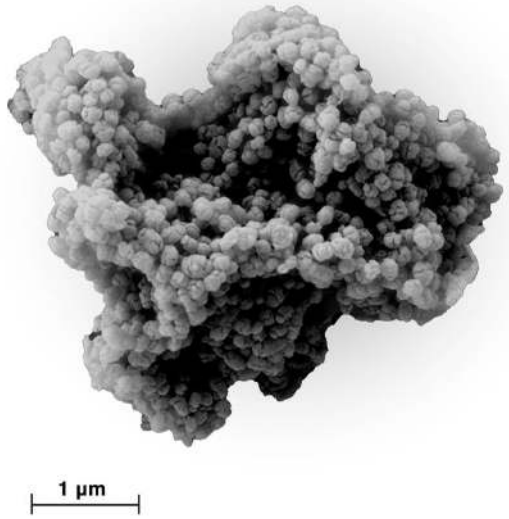
Signal amplification using 2nd RCA

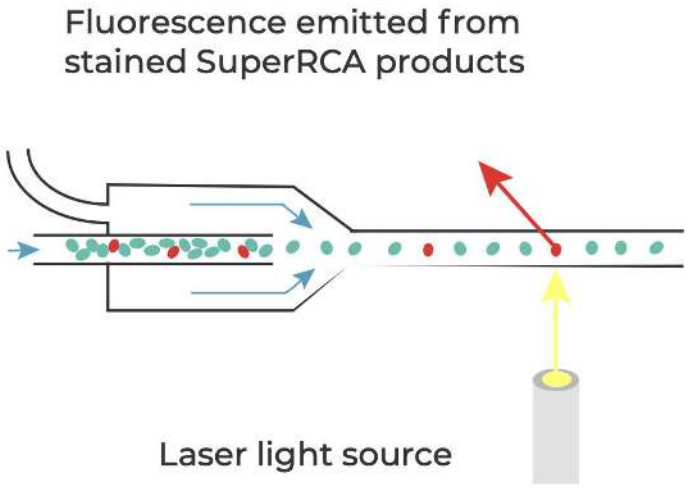


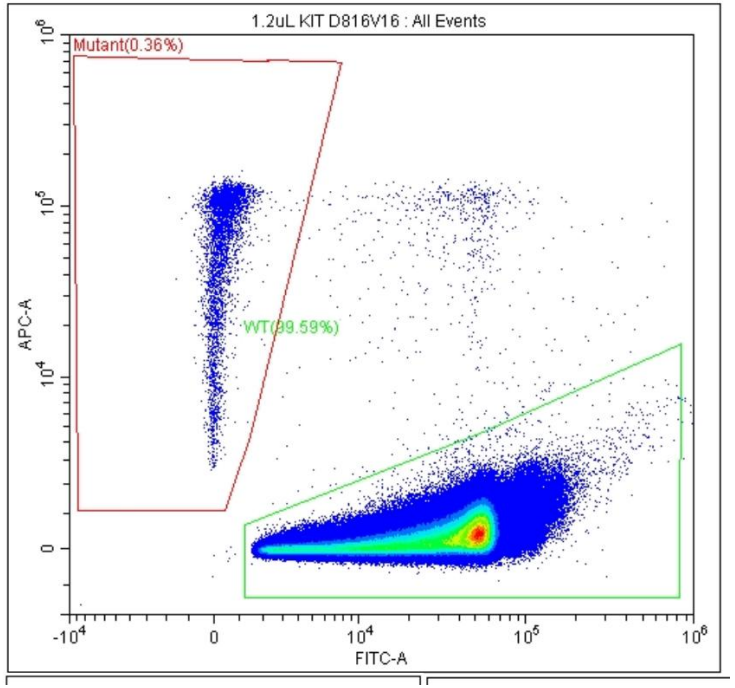
# superRCA® Technology

Single tube assay, TAT ~5,5h/sample; 96 < 8h

***~1,000,000 events***



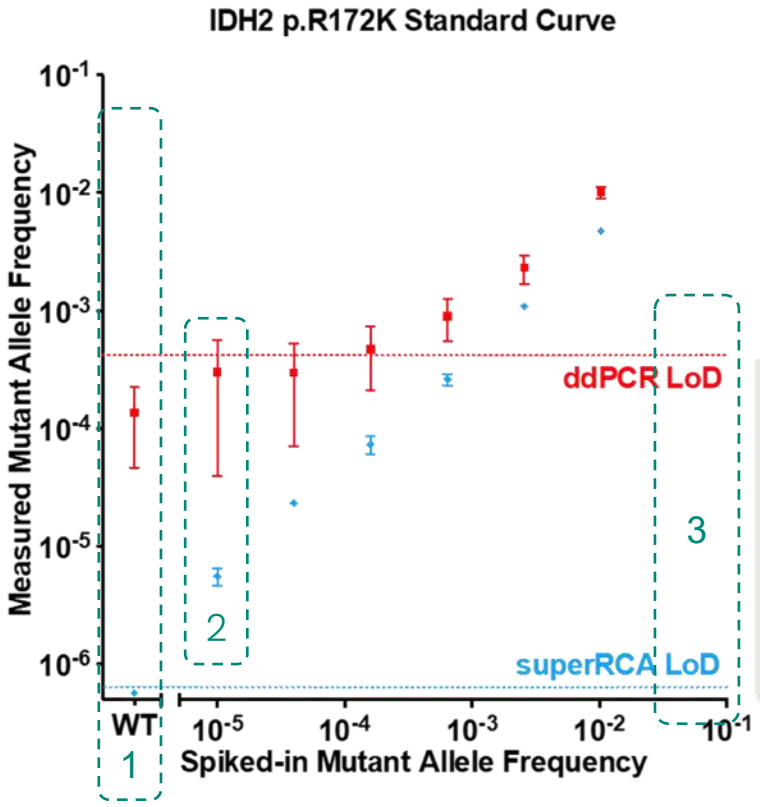




Direct digital readout, no bioinformatics or post processing

# Pushing boundaries in sensitivity

## superRCA vs ddPCR (BioRad qx200)




1 - Lower background - multi-factor genotyping

2 - High event numbers reduces variance

3 - High input allows low Limit of Detection

nature COMMUNICATIONS

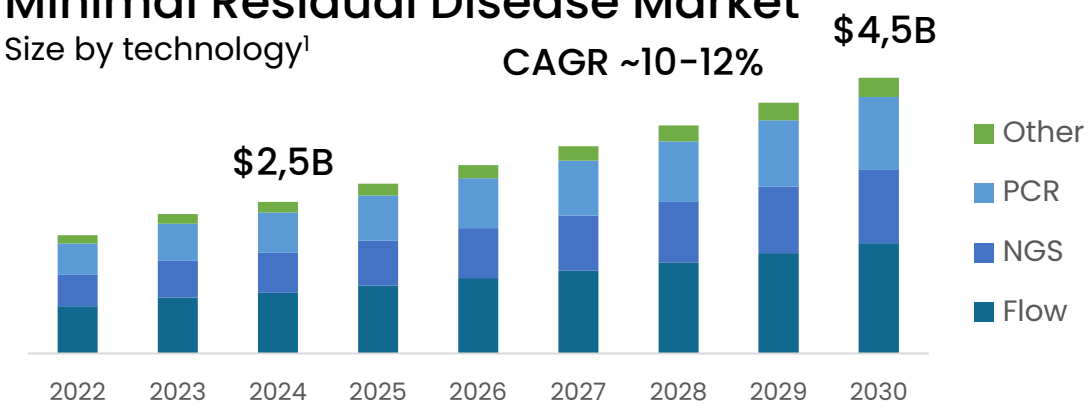
Ultra-sensitive monitoring of leukemia patients using superRCA mutation detection assays

*Nature Communications (2022) 13:4033. doi:10.1038/s41467-022-31397-y*

Low background & high specificity enables **mutation detection beyond current capabilities**

## Minimal Residual Disease Market

Size by technology[1]



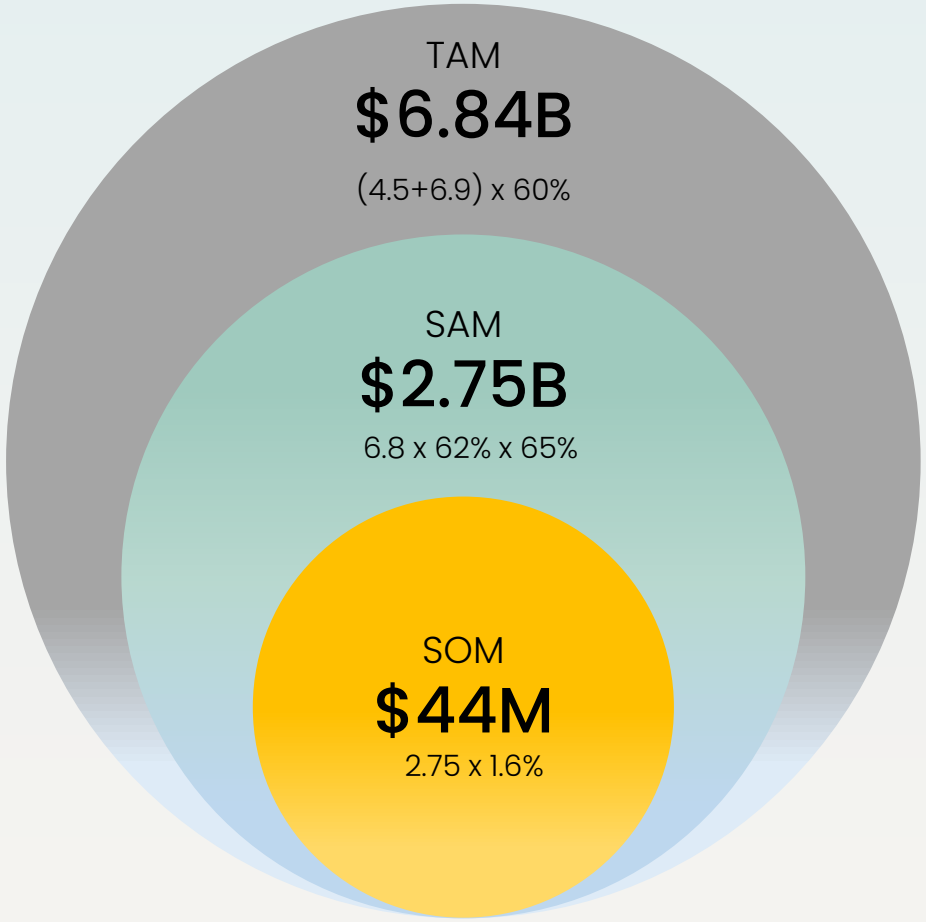

## Pharma/Biotech

**Molecular Biomarker testing/devevlopment**
$4 in 2024 to **~$6.9B by 2032**[2,3]

- Flow Cytometry ~40% of MRD today (phenotypic)
- Molecular (PCR + NGS) fastest growing segment ~60%
- Hematology represents ~65%
- Majority of testing in Hospital & Specialty labs ~62%

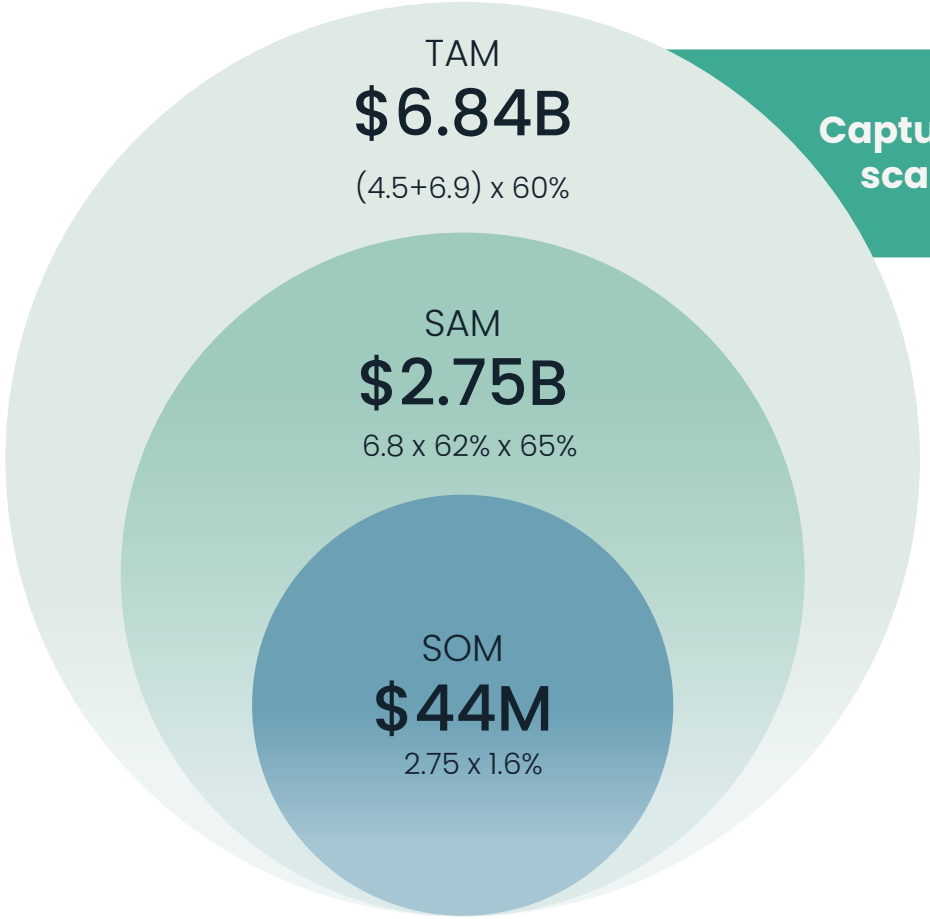
**Flow uniqly positioned for MRD expansion**

*Annual by 2031*



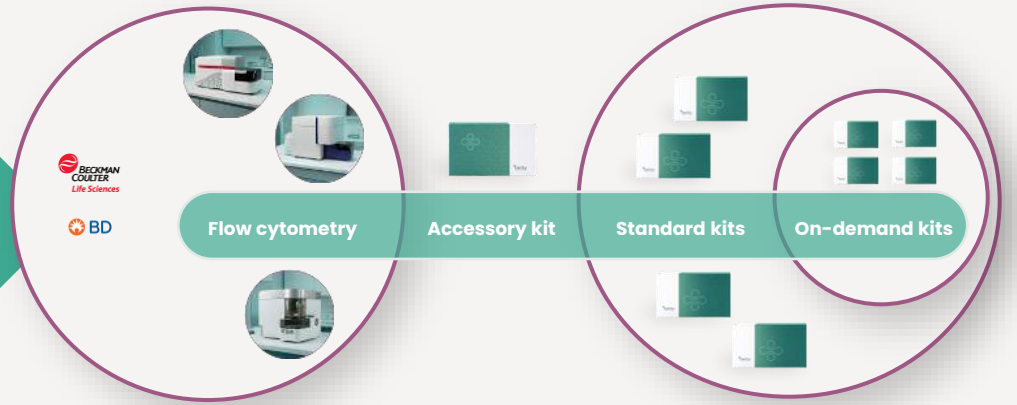
# Market opportunity and business model

*Market opportunity by 2031*




**Captured through our highly scalable assay platform**

## superRCA assay platform




### Focus on MRD and translation medicine

- Existing/emerging actionable mutations
- Use cases with clear sensitivity benefits
- Hematology → Solid tumors

\+ >200 library of on demand assay

\+ Custom design

**Driven by Padlock Studio**, proprietary probe design software

# Go To Market

## Entry through existing flow infrastructure

Co-exclusive distribution partnership (Jan 2025)

| Primary Segments | US | EU |
|---|---|---|
| Clinical Flow laboratories | ~2,500+ | ~4,000 |
| Hemato-oncology centers | ~400–500 | ~500+ |
| Academic leukemia / MRD centers | ~250–400 | |
| **Secondary Segments** | | |
| Large Ref. Labs | ~20–30 | ~30–50 |

- Initial focus - clinical researchers
- No instruments –> rapid in-lab validation
- LDT/IVD generates sticky recurring revenue
- Account value growth: volume + assay expansion

✓ **Rarity is ISO13485 certified**

- Primary business model RUO (for research and LDT)
- First CE-IVDR complied kit for NPM1 mutation under review

✓ **Proven sales using existing reimbursement codes and structures**

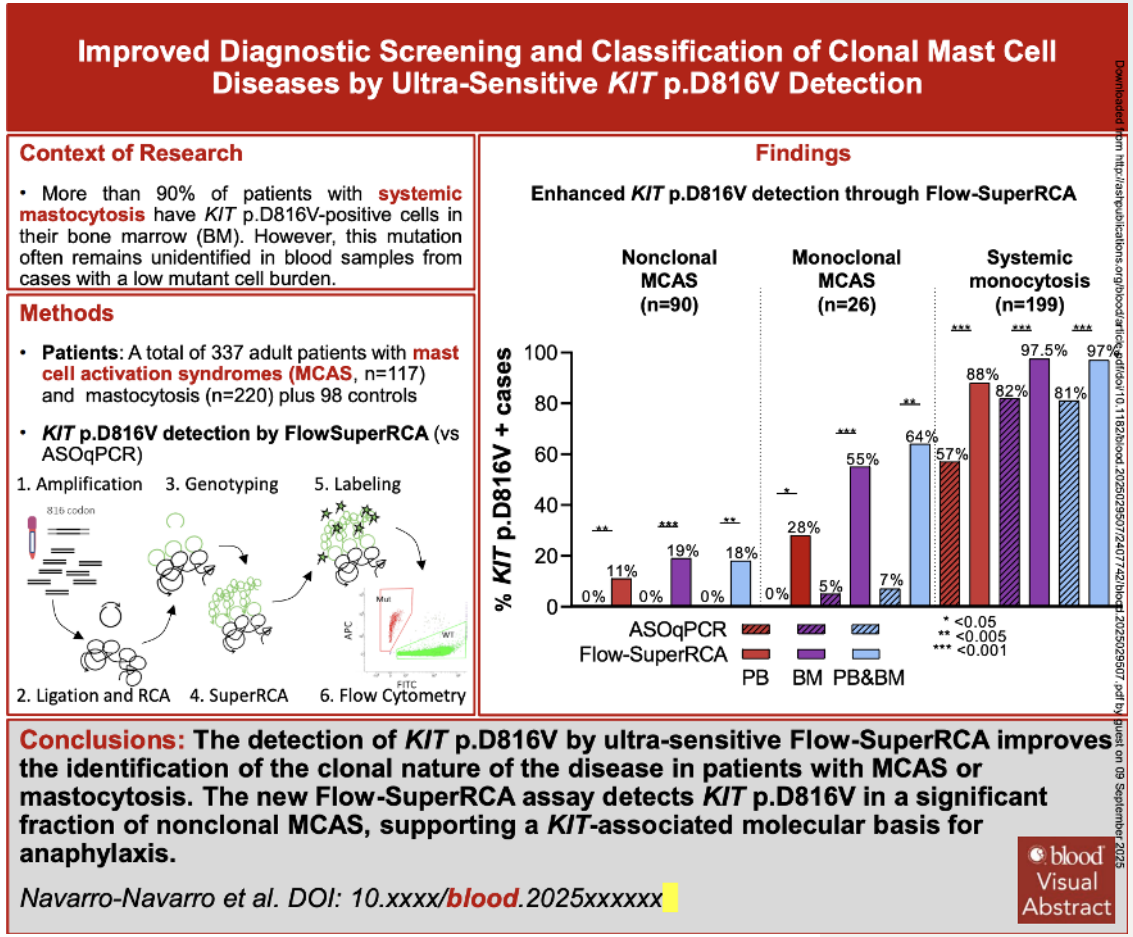
# Applications – key publications

"Improved diagnostic screening and classification of clonal mast cell disease by ultra-sensitive KIT p.D816V detection"

**>10x** higher sensitivty vs ASO-qPCR

**Same** detection rate in peripheral blood vs bone marrow

**18%** patients identified previously miss-diagnosed




Downloaded from http://ashpublications.org/blood/article-pdf/doi/10.1182/blood.2025029507/2407742/blood.2025029507.pdf by guest on 09 September 2025

VNiVERSiDAD D SALAMANCA

# Applications – key publications

cancers

Sensitive and Specific Analyses of Colorectal Cancer Recurrence through Multiplex superRCA Mutation Detection in Blood Plasma

"Sensitive and Specific Analysis of Colorectal Cancer Recurrence through multiplex superRCA Mutation Detection in Blood Plasma"

https://www.mdpi.com/2072-6694/16/3/549

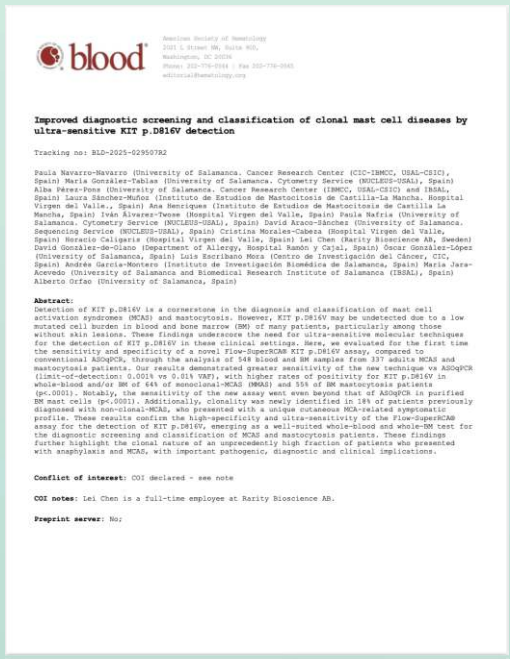
nature COMMUNICATIONS

ARTICLE

Ultra-sensitive monitoring of leukemia patients using superRCA mutation detection assays

"Ultra-sensitive monitoring of Leukemia patients using superRCA mutation detection assays"

https://www.nature.com/articles/s41467-022-31397-y


blood

Improved diagnostic screening and classification of clonal mast cell diseases by ultra-sensitive KIT p.D816V detection

"Improved diagnostic screening and classification of clonal mast cell disease by ultra-sensitive KIT p.D816V detection"

https://doi.org/10.1182/blood.2025029507

blood advances

Utility of IDH1/2 mutations as biomarkers for detection of measurable residual disease in acute myeloid leukemia

"Utility of IDH1/2 mutations as biomarkers for detection of measurable residual disease in acute myeloid leukemia"

https://doi.org/10.1182/bloodadvances.2025016726

**June 7th 10:30-11:30**. Flow cytometry-Enabaled **Multiplex** superRCA Mutation Assay in a Single Portion of Circulating Tumor DNA (**ctDNA**) Sample

# Key Applications / Publications

"Sensitive and Specific Analysis of Colorectal Cancer Recurrence through multiplex superRCA Mutation Detection in Blood Plasma"

https://www.mdpi.com/2072-6694/16/3/549

"Ultra-sensitive monitoring of Leukemia patients using superRCA mutation detection assays"

https://www.nature.com/articles/s41467-022-31397-y

"Improved diagnostic screening and classification of clonal mast cell disease by ultra-sensitive KIT p.D816V detection"

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"Utility of IDH1/2 mutations as biomarkers for detection of measurable residual disease in acute myeloid leukemia"

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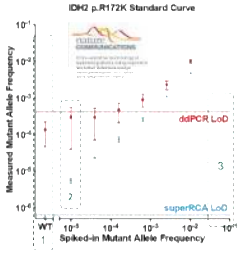
# Traction & Validation

Founded in 2021, Rarity has already proven innovative and commercial execution

## Performance

Logarithmic improved sensitivity over current gold standard



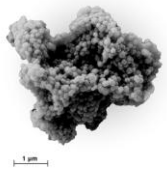

## Innovation & IP

Award-winning technology

6 patents filed

ADLM Association for Diagnostics & Laboratory Medicine Formerly AACC

Disruptive Tech Award Winner



## Publications

4+ high impact peer-reviewed, hematology & solid tumor applications

## Products

Launched products & growing pipeline
First CE IVD filed

## Collaborations

Collaboration with leaders across cancers

Karolinska Institutet

ARUP LABORATORIES

Quest Diagnostics

The University of Texas MD Anderson Cancer Center

Universidad de Salamanca

Uppsala Universitet

## Commercials

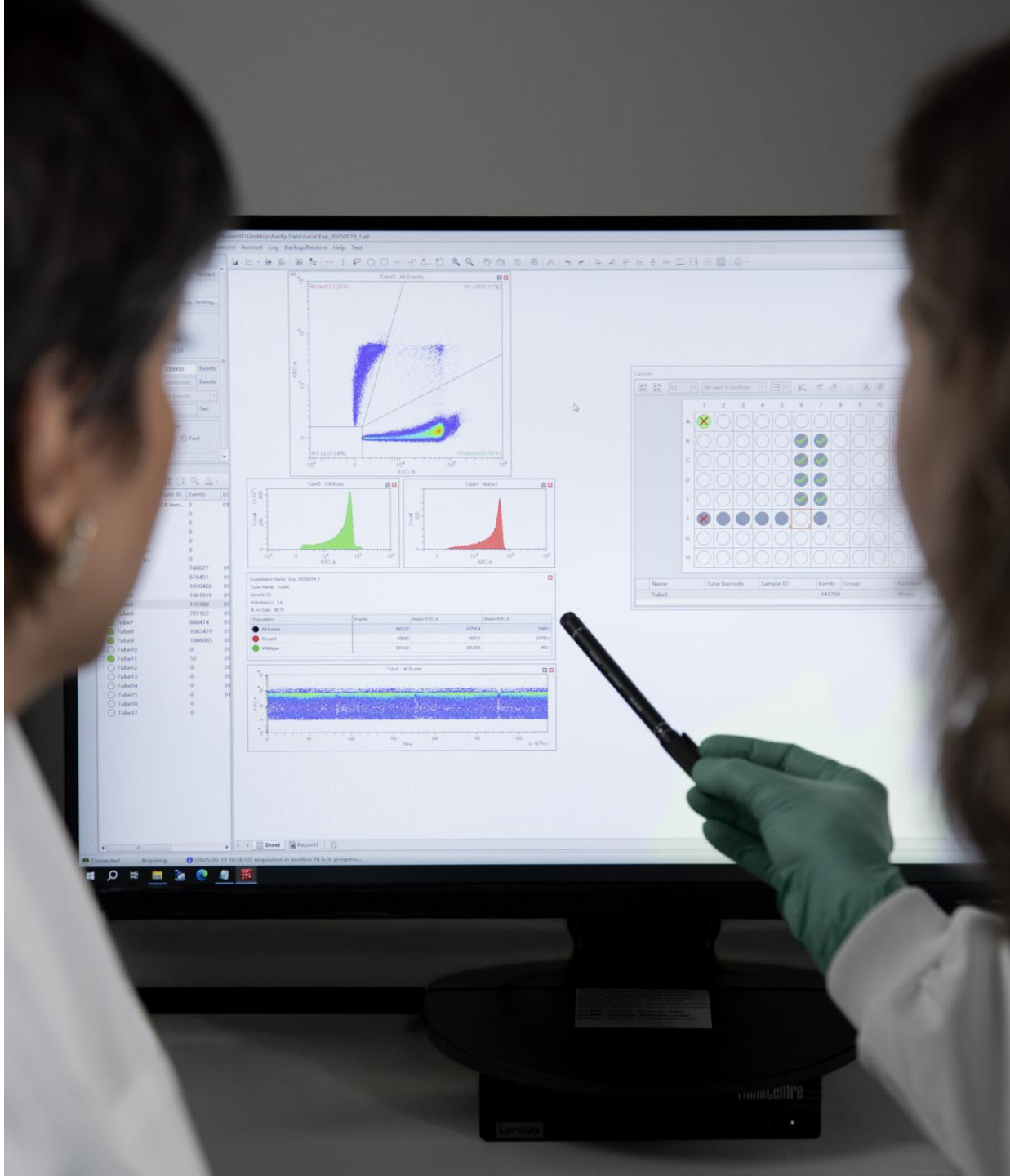
Traction, inc 'CDx' contract & dist. partnership

## Commercial adoption initiated – Platform & Market expanding

# Summary

- The need has always been there
- Sequencing has paved the way for precision medicine and diagnostics
- The MRD market is open for new competitive technologies
- superRCA fits in existing workflows, enabling near patient molecular MRD

Looking for customers and collaborators to scale this across cancer



# Team - Management

## Business // Industry // Science

**Magnus Aronsson**

Dir. Sales

MSc Science + Finance / KTH

20 years in MedTech, prior senior positions at Roche Diagnostics

**Hanna Kocken**

Dir. Operations, Q&R

MSc Engineering / KTH

20 years in MedTech, prior senior positions at Thermo Fisher

**Linus Bosaeus**

CEO

MSc Physics / UU

13 years in MedTech startups as CEO, commercial and Operations

**Lei Chen**

Co-Founder, CTO

PhD Molecular Tools / UU

Inventor of the superRCA technology under prof. Ulf Landegren

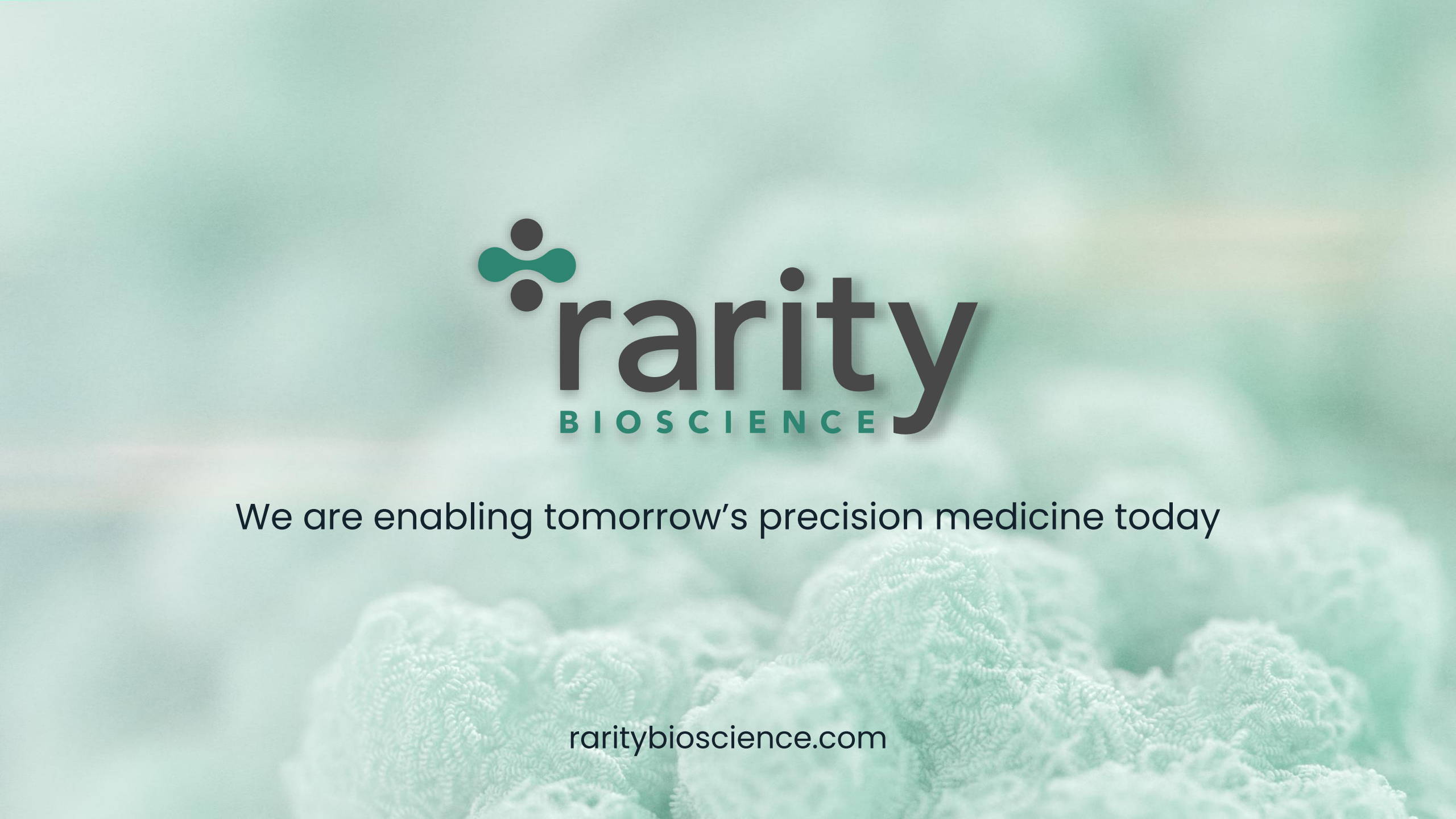
**Marie Engvall**

Dir. Scientific Operations

PhD in Medical Sciences / UU

Clinical Molecular Geneticist, 20 years in biomarker analysis, clinical and Olink Proteomics

Visit us at Booth #433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