RRPV Member Spotlight: FABimation, Inc.

Q: What does your company do? What specific capabilities or strengths does your company offer?

A: We are a biotech startup focused on delivering low-cost, high-sensitivity diagnostic solutions through our proprietary Precision Flow Assay (PFA) platform. Designed for flexibility, the PFA can be customized for a wide range of application-specific use cases, achieving trace analyte detection and supporting multiplex analysis from a single sample.

Our core technology uses antibody-based colorimetric signals that can be read visually or with a simple camera—such as a smartphone—making quantitative testing accessible and affordable. When needed, the platform can incorporate fluorescent or alternative labels to achieve even greater sensitivity.

While our early work centered outside immune response measurement, we now see strong potential to expand into this area through the right collaborations. We are committed to developing advanced, commercially viable diagnostic solutions that improve accessibility, performance, and impact across the healthcare ecosystem, and we welcome partnerships that help accelerate this mission.

Some key technologies and capabilities we offer include:

- PFA Platform — A flow cytometry-inspired system with an immunochromatographic concentration readout that delivers high sensitivity and quantitative results.
- Customizable Sample Prep Module — Adaptable for diverse applications, including cell-based immune response analysis and other specialized workflows.
- Multiplex Immune Response Profiling — Currently expanding the platform to enable quantitative measurement of multiple analytes from mucosal or cellular samples, supporting advanced immune response research and potentially single use case for evaluating the mucosal immune response state of individuals.

Q: Are there any specific partnership opportunities you're seeking with other members in the industry? What kinds of expertise or resources would be beneficial for your company to explore through partnerships?

A:

- Immunology and Biomarker Expertise — Seeking collaborators with deep expertise in immune response biology to help identify and validate biomarker targets for mucosal and cellular immune response analysis, and to guide optimized sample preparation workflows.
- Clinically Relevant Validation Support — Looking for partners who can assess and validate our customized PFA solutions in real-world, clinically meaningful testing environments.
- High Volume Diagnostic Manufacturing — Interested in teaming with large-scale lateral flow assay manufacturers capable of adapting existing production lines for PFA-based test kits with minimal modifications.
- Regulatory and Marketing Support — Seeking partners who can support a smooth transition to market introduction and help navigate a clear, efficient regulatory approval pathway for immune response and broader diagnostic applications.
- Antibody Development and Supply — Interested in collaborating with antibody manufacturers that have qualified, application-ready antibodies suitable for integration into our PFA platform across a range of targeted diagnostic uses.

Q: Provide some insight into your company's history, core business areas, focuses, or key ideas that you wish to describe.

A: Founded on the belief that breakthrough innovation emerges from disciplined engineering and deep scientific insight, our company has evolved into a leader in next-generation diagnostic technologies. From our earliest prototypes to our current modular platforms, we have remained committed to transforming how individuals and clinicians access, interpret, and act on critical health information.

Our core business focuses on the design and commercialization of high-performance diagnostic systems that integrate advanced assay chemistry, precision-engineered hardware, and intuitive software. At the center of our portfolio is our proprietary, modular, and scalable PFA platform—engineered for rapid adaptation to new

biomarkers, emerging public health threats, and diverse clinical settings ranging from centralized laboratories to decentralized and at-home testing.

Across all product lines, our work is guided by a commitment to accuracy, accessibility, and measurable real-world impact. We develop technologies that deliver laboratory-grade performance while reducing cost, complexity, and time to result, enabling broader adoption and more equitable access to high-quality diagnostics.

At the heart of our mission is a simple idea: empower people with reliable, actionable health insights whenever and wherever they need them. By building platforms that are modular, manufacturable, and future-ready, we aim to strengthen public health resilience, support personalized care, and accelerate the global shift toward decentralized diagnostics and treatment optimization—ultimately improving quality of life while reducing healthcare burden.

Q: What trends or innovations do you foresee shaping the future of the industry, and how is your company preparing for those changes?

A: We see a major shift toward decentralized, rapid, and personalized immune response assessment. Beyond large-scale clinical studies, there is a growing need for individuals to understand their real-time immune status—whether through mucosal, blood, urine, or other sample types—and to receive low-cost, overnight feedback without relying on remote, batch-based laboratory workflows. This trend is driven by the need to quickly evaluate a person's current health state, monitor their response to immunization, and track how that protection changes over time.

To prepare for this future, we are focusing both on high volume as well as on single-sample, high-sensitivity tests that can be performed at the point of collection and still deliver clinically meaningful insights. Our goal is to determine which test formats, biomarkers, and testing frequencies will be both commercially viable and medically relevant, enabling a new generation of personalized immune response diagnostics. By advancing our PFA platform in this direction, we aim to support more responsive, data-driven, and individualized healthcare.

Q: How can we contact you?

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Project Spotlight: High Sensitivity IVD Trace Analyte Detection Platform for Low Cost, Sample-Sparing Single and High-Volume Sample Processing

Q: Brief Description of the Project, Achievement, or Success Story.

A: We advanced our proprietary PFA platform to achieve trace analyte detection below 200 fg/mL, with active development toward sub 20 fg/mL sensitivity using manufacturing methods comparable in cost to traditional rapid test strips.

This milestone enables rapid, low-cost, sample-sparing testing across diverse analytes and sample types, including urine, saliva, blood, swabs, other liquids, and even exhaled breath. With no refrigeration needs and minimal power requirements, the platform is well-suited for point of collection use in outpatient clinics, industrial and clinical labs, at home, and in remote or resource-limited environments.

Q: Key Outcome or Impact.

A: Our work demonstrates that traditional lateral flow tests lack the sensitivity needed to achieve >95–98% diagnostic performance, often requiring ELISpot, ELISA, PCR, or flow cytometry confirmation that increases cost and delays results. In contrast, our application optimized PFAs achieve detection limits 250–100,000 times lower, enabling, for example, rapid, low-cost respiratory infectious disease testing from nasal swabs with the potential to reach PCR level sensitivity. This advancement positions PFAs as a viable alternative to ELISpot, ELISA, PCR, or flow cytometry in many use cases, dramatically improving accessibility, speed, and affordability. Beyond infectious disease, customized PFAs can reach detection limits as low as 40 fg/mL, enabling blood-based biomarker testing for conditions such as Alzheimer’s disease—an area with global impact affecting over 10% of the population.

The platform can also be tailored for individual mucosal immune response profiling, quantitatively measuring multiple biomarkers from mouth, throat, or nasal swabs, and supporting high-volume screening of mucosal or cellular immune samples. Together, these capabilities represent a significant step forward in decentralized, quantitative, and clinically actionable diagnostics that can both advance the overall immunization research and make it easier, lower cost, and more practical to measure an individual's response to immunization.