ADVANCED LATERAL FLOW CONFERENCE 2025

# ALFC 2025 POSTER PRESENTER GUIDE

- **Poster A0002**

## *Plasmonic Fluor-Enhanced Lateral Flow Assays: Advancing Sensitivity and Accessibility for Neisseria gonorrhoeae Point-of-Care Testing*

Yuxiong Liu, Graduate Student, Washington University in St. Louis

**Abstract:**
This study describes the development of a plasmonic fluor-enhanced Neisseria gonorrhoeae (NG) lateral flow assay (NG p-LFA) antigen test designed to meet the unmet need for a highly sensitive point-of-care (POC) diagnostic for NG, particularly among asymptomatic patients. Previously, a low-cost NG LFA antigen test demonstrated high sensitivity (>90%) and specificity (>95%) among symptomatic male and female patients, but its sensitivity was sub-optimal (65.8%) in asymptomatic pregnant females. The NG p-LFA antigen test employs plasmonic fluor conjugated with the same monoclonal antibody used in prior NG-LFA tests. Limit of detection (LOD) and inclusivity testing were performed using 14 World Health Organization NG reference strains. Clinical validation utilized remnant urine samples from suspected NG infected patients presenting at clinics and hospitals within the BJC Healthcare System in St. Louis, Missouri, with testing conducted within 24 hours of sample collection. The NG p-LFA achieved an LOD of 0.1 CFU/mL, approaching the analytical sensitivity of molecular assays. Between January 2023 and December 2024, 161 urine samples were collected from 64 symptomatic and 97 asymptomatic patients. Compared to molecular tests, NG p-LFA demonstrated 94.9% sensitivity and 98.1% specificity, with strong performance in both symptomatic (96.1% sensitivity; 100% specificity) and asymptomatic (87.5% sensitivity; 98.9% specificity) individuals. The assay costs less than US $2 per test, has a turnaround time under 30 minutes, and is compatible with a low-cost (US $250), portable battery-operated reader. Overall, the NG p-LFA assay fulfills the critical need for a rapid, cost-effective, and highly sensitive POC test for NG detection, particularly in settings where molecular tests are not accessible. Ongoing evaluation using vaginal swabs in women is underway, and future studies will assess its performance in field settings.

## • Poster A0003

### *Innovative tools and reagents for advancing diagnostic assays: synthetic replacements for proteins and next-generation enzyme substrates*

Adrian Hery Barranco, PhD, Biosynth

**Abstract:**
The evolution of diagnostic assays is tightly linked to the development of robust reagents and innovative technologies that address key challenges in assay sensitivity, specificity, and regulatory compliance.

One of the biggest categories in next generation reagents is the replacement of proteins and antibodies with synthetic peptides. These are more easily produced and characterised and with enhance stability profiles. Conformationally constrained peptides, stabilized via covalent bridges, mimic native protein epitopes and enable high-affinity targeting of protein-protein interaction interfaces, expanding the toolbox for developing highly specific capture and detection reagent. Here we present data on how a CLIPS™ (Chemical Linkage of Peptides onto Scaffolds) library screening approach further accelerates the discovery of novel binders.

Further, we showcase a portfolio of chromogenic, fluorogenic, and chemiluminescent enzyme substrates. These facilitate rapid pathogen detection, biomarker quantification, and high-throughput screening, with features such as polymer-penetrating dyes and ultra-sensitive chemiluminescence for improved assay readouts. Data here shows low limits of detection of active bacterial infection.

Finally, we also highlight recombinant enzyme replacements including advanced peroxidases and luciferases, which provide defined activity and enhanced stability. These enzymes facilitate sensitive and reproducible signal generation, supporting the performance and reliability of assay platforms.

## • Poster A0004

### *Advancements in Dual Lateral Flow Immunoassay Design for Sensitive, Rapid Detection of Rotavirus and Adenovirus in Stool Samples*

Ayan Isse, Triogene Biotechnology

**Abstract:**
Rotavirus and adenovirus are leading causes of acute gastroenteritis worldwide, posing a major health burden, particularly in low-resource settings where rapid diagnostic tools are urgently needed. Lateral flow immunoassays (LFIAs) provide speed and simplicity, making them well-suited for these environments. This study aims to develop and optimize a dual

LFIA capable of detecting both rotavirus and adenovirus antigens in human stool samples to enhance field applicability.

Monoclonal antibodies specific to each virus were conjugated to colloidal gold nanoparticles or latex beads and immobilized on nitrocellulose membranes, while custom extraction buffers were formulated to reduce sample viscosity and improve migration. The assay generated distinct, visible test lines within 10–15 minutes, and buffer modifications significantly improved flow dynamics. Sensitivity and specificity were evaluated with known positive and negative stool controls. Specificity testing demonstrated minimal cross-reactivity, while ongoing refinement of detection thresholds continues to enhance performance.

Additionally, recombinant enzyme replacements such as horseradish peroxidase (HRP) and luciferase variants were assessed, offering improved catalytic stability and reproducibility. These enzyme-based labels further strengthened signal generation, supporting assay sensitivity and reliability.

Preliminary data indicate that this dual LFIA represents a feasible, rapid diagnostic tool. Ongoing optimization and validation may extend its utility to additional enteric pathogens, highlighting the potential of this platform for deployment in both clinical and field settings.

- ## Poster A0005

### *A multiplex Point-Of-Care test for rapid identification of allergens triggering allergic asthma*

Ke Zhang, Founder and CSO, Allerdia Inc

**Abstract:**
This presentation describes a novel Reverse Lateral Flow ImmunoAssay (R-LFIA) based Point-Of-Care Test (POCT) capable of rapidly and accurately detecting allergic IgE to environmental allergens that trigger allergic asthma, aiming to facilitate diagnosis and guide management. IgE-mediated allergic asthma accounts for approximately 70% of all asthma cases, with specific types of allergen-specific IgEs causing these reactions. Currently available IgE tests are centralized laboratory assays with high false positivity rates (about 50%), leading to inaccurate recommendations for allergic asthma management. Therefore, a decentralized, convenient, low-cost POCT-enabled IgE test that can rapidly and accurately identify allergic IgE while overcoming false positivity is crucial for precision medicine in asthma diagnosis and management. The current absence of such a POCT underscores the need for this development. Instead of labeling anti-IgE antibodies as IgE detectors, this approach utilizes recombinant allergens fused with a mouse IgG1 constant region (mFc), conjugated to Gold NanoParticles (GNP), forming mFc-allergen-GNP conjugates that serve as Allergen-Specific IgE (AS-IgE) detectors in the R-LFIA. During sample migration, high-affinity, allergy-triggering AS-IgE binds to mFc-allergen-GNP within approximately 10 seconds to form a stable complex, which is then captured by anti-IgE antibodies at the test line for visible or measurable signal generation; the run-through conjugates are captured

by anti-mouse IgG antibodies at the control line to validate the assay. This 10-second window allows selective binding to high-affinity, allergy-triggering AS-IgE while minimizing binding to low-affinity, cross-reactive IgE, thereby maintaining high sensitivity and, importantly, high specificity that addresses the false positivity issue found in current laboratory-based tests. The R-LFIA multiplex assay simultaneously tests 10 types of allergic IgE using a single sample, targeting the most common environmental allergens associated with allergic asthma, with each allergen labeled with gold nanoparticles as IgE detectors and assembled into a disc panel. Testing with serum samples from 19 allergic asthma patients showed 100% detection of IgE in the 10-plex panel, with individuals presenting 1 to 9 types of allergic IgE, and most patients having multiple types. These preliminary results highlight the potential utility of this 10-plex disc device for clinical identification of asthma-triggering allergens in patient management.

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## • Poster A0007

## *Development and Validation of Lateral Flow Immunoassays for Confirmatory of Biopharmaceutical Products*

Robin Manouchehri, Forensic Scientist, Amgen
Robert Soto, Process Development Senior Principal Scientist, Amgen

**Abstract:**
Product identity confirmation testing is an integral part of the production and release process in the pharmaceutical industry. For biological drugs, this is often accomplished by time-consuming and laborious processes such as ELISA. In this work, we demonstrate the development of lateral flow immunoassays for the identity confirmation of seven different biological drugs. These visual assays demonstrate the utility of lateral flow immunoassays for quick and accurate confirmatory pharmaceutical testing, which can then lead to quicker product release.

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## • Poster A0008

### *Increasing Sensitivity in a Triplex Respiratory Lateral Flow Assay via Fluorescent Lanthanide-Doped Particles*

Kristin Cederquist, Principal Scientist, DCN Dx

**Abstract:**
In the years since the COVID-19 pandemic, lateral flow rapid tests have evolved from single-plex to multiplex formats, often with the capability to detect Influenza A and B in addition to COVID-19 on a single strip. These triplex tests incorporate individual test lines and conjugates to detect their respective targets. This approach necessitates minimal cross-reactivity between conjugates and lines, which typically complicates the development process.

Lateral flow assays can also suffer from low sensitivity due to short sample–biorecognition element incubation times and the absence of enzymatic signal amplification, such as that provided by PCR or ELISA. Europium(III) chelate–doped polystyrene microspheres have been shown to increase lateral flow assay sensitivity by as much as 100-fold compared to more common colorimetric labels such as colloidal gold.

In this work, a colorimetric, FDA EUA-approved COVID-19/Flu A/Flu B triplex assay (Status™ Rapid Antigen Test, Princeton Biomeditech) was transferred to a fluorescent system through the incorporation of Eu chelate–doped particles, and the sensitivity increase was determined for all three pathogens. Fluorescent signal readout was accomplished using the Hyperion Biosystems HALO® reader.

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## • Poster A0009

### *Metabolic Amino Acid Phenotyping (MAAP): a phenotypic antibiotic susceptibility test to guide antibiotic treatment of urinary tract infections by pairing lateral flow assay paired with bacterial metabolic labeling*

Emily Melzer, CEO, Latde Diagnostics

**Abstract:**
Objective. Rapid tests to guide antibiotic prescription have been limited to methods best suited for centralized clinical labs. There is an unmet need for antibiotic susceptibility tests (ASTs) that can provide actionable results rapidly, at the point of care and in resource-

restricted settings. To address this unmet need we paired two well-established methods, bacterial metabolic labeling and lateral flow assay (LFA), into one instrument-free, low-cost, easily-deployed, rapid diagnostic tool: Metabolic Amino Acid Phenotyping (MAAP).
Approach. The bacterial cell wall is a conserved structure encasing the vast majority of bacteria. D-amino acids (DAAs), distinctive components of the cell wall, are routinely conjugated to fluorophores for use as probes to metabolically label bacteria. Such labeling is indicative of bacterial viability, therefore we coupled this approach with LFA to create a novel AST. Antimicrobial resistant Escherichia coli and Klebsiella pneumoniae isolated from UTI cultures were incubated at clinically relevant bacterial concentration, in urine with DAAs conjugated to an antigen, +/-antibiotics. Bacterial growth detection as an indicator of antibiotic resistance, marked by DAA incorporation, was achieved via a custom-made LFA strip that detects the antigen conjugated to DAA. To further demonstrate the potential as a test that could be used in resource-restricted settings, the assay was also tested with or without a 37˚ C incubator and electrical agitation.
Evidence. We present data testing our LFA-based AST prototype against resistant and susceptible clinical strains isolated from urine cultures. Growth of all 17 clinical isolates tested was detected by custom-made LFA strip. Growth inhibition by ciprofloxacin, cefotaxime, sulfamethoxazole/trimethoprim, nitrofurantoin or meropenem was detected in susceptible strains while growth inhibition was not detected in respective resistant strains. Results also correlated with known susceptibilities when incubation was performed without agitation.
Impact. Our data support that this LFA-based AST is compatible with several organism-antibiotic combinations at clinically-relevant concentrations within clinically-relevant timeframes. Coupling cell wall metabolic labeling with LFA output obviates the need for specialized diagnostic instrumentation, enabling deployment in resource-limited settings, while equipping healthcare providers with actionable results to guide antibiotic prescription. This accessible, rapid AST has the potential to improve clinical outcomes and promote antimicrobial stewardship. While we are currently focusing on an AST to guide UTI treatment, this platform technology can be applied towards numerous clinical and non-clinical applications.

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- ## Poster A0010

### *Sample Preparation Method Development for a Phenotypic Antibiotic Susceptibility Test*

Stephanie Delzell, Lead Scientist, Latde Diagnostics

**Abstract:**
Urinary tract infections (UTIs) impact 400 million patients annually, with antibiotic treatment failing in 20% of these patients. This failure is largely due to the need for clinicians to empirically prescribe antibiotics in the absence of antibiotic susceptibility data, which takes

days to acquire by standard culture-based methods. Objective: There is an unmet need for a faster antibiotic susceptibility test (AST) to better inform treatment at the point of care. Our novel approach to develop an accessible, rapid, phenotypic AST relies on the incorporation of a modified cell wall component into actively growing bacteria. This probe then serves as an antigen in a lateral flow assay (LFA), resulting in a positive test band when bacteria are metabolically active and therefore successfully incorporate the probe into their cell wall. We have shown that this design can be used to indicate whether a clinical isolate is able to grow in the presence of a test antibiotic, indicating antibiotic resistance. These results have established the viability of using a metabolic label as an antigen for a phenotypic AST. Approach: Informed by input from potential end users, we have identified further optimization needed to maximize adoption. To meet user needs, we have defined method development goals: 1) reduce the lower limit of detection (LOD) of labeled bacterial cells;and 2) minimize the time and labor that goes into sample preparation. The Gram-negative pathogens that often cause UTIs have an outer membrane that inhibits access of antibodies to the probe embedded in the peptidoglycan cell wall. In order to detect the incorporated probe in an immunological assay, we introduced a step to disrupt this outer membrane, which is under development. We are screening surfactants to permeabilize the outer membrane, in addition to testing chemical and enzymatic lysis methods. Our current method relies on wash steps to remove excess probe, which would otherwise interfere with results on LFA. To streamline sample preparation, we are testing strategies to chemically sequester unincorporated probe such as utilizing zeolites to adsorb it from solution. Evidence: The culmination of this method development, which included combinations of different compounds, protocols, and approaches, has increased test band signal for E. coli clinical isolates and yielded a working prototype with an LOD of 1×107 CFU/mL and a turnaround time of 3 hours. Current hands-on processing includes washes to remove probe and cell lysis, increasing turnaround time and introducing human error. Impact: This work provides an example of a method development package involved in the innovative strategy to acquire phenotypic data utilizing metabolic labeling combined with LFA. Our assay development to date also sets the stage for future work on other critical additions to the assay including a pathogen identification readout and the development of an integrated sample collection and test apparatus.

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- **Poster A0011**

## *Quantitative Lateral Flow Assay System Using Smartphone Video and Artificial Intelligence: Design of a Fully On-Device Analytical Platform*

Edward Mamenta, President, Analyte Insight

**Abstract:**
A key challenge in developing reliably quantitative lateral flow assays (LFAs) lies in the unpredictable nature of capillary-driven particle flow. To address this, Analyte Insight has developed Flowrait, an AI-based platform that applies spatiotemporal pattern analysis to

digital video, including footage captured by smartphones. To improve scalability and accessibility, especially in resource-limited settings, a fully on-device implementation is desirable, wherein all video capture, preprocessing, and AI inference occur on the smartphone, without reliance on external servers. This presentation outlines strategies to enable such a platform, including low-cost accessories and novel data representation methods optimized for mobile deployment. The objective is to design an LFA platform in which all AI-based analysis—including video capture, preprocessing, feature extraction, and inference—is performed entirely on-device, requiring navigation of mobile hardware constraints such as limited memory, storage, and processing power. A typical 5-minute smartphone video at 30 fps yields over 25,000 frames and hundreds of megabytes of raw data, necessitating significant reduction without sacrificing key spatial or temporal information. Lighting variability must also be controlled to avoid inflating model complexity and compute demands. To address these challenges, a shallow transformer neural network architecture was selected for lightweight spatiotemporal modeling, and input data were structured as 3D tensors encoding time-resolved pixel intensities across a grid of regions of interest (ROIs), enabling construction of localized temporal curves. Multiple data reduction techniques were applied, including dynamic frame sampling, ROI cropping, spatial pooling, and grayscale conversion. A low-cost housing was developed to mount the smartphone and isolate the LFA strip under controlled lighting conditions using only the device's built-in illumination, standardizing image capture. The combined system was tested with commercial LFA strips to evaluate how well signal integrity could be preserved as data were progressively reduced. Using an iPhone 16 and 5-minute, 30 fps videos, unprocessed inputs ranged from 200–375 MB. To support training on ~10,000 videos and enable on-device inference, a target input size of <3 MB was established, with the data reduction pipeline consistently achieving inputs of 0.6–1.2 MB per video, frame counts reduced to under 100, and ROI grids below 2,500 spatial cells. The housing eliminated ambient light variability, improving consistency in pixel intensity curves. These results support the feasibility of a fully on-device diagnostic platform. A fully on-device Flowrait platform offers a low-cost, scalable solution for quantitative LFA testing without cloud infrastructure, reducing operational costs, enhancing user privacy by retaining data locally, and supporting real-time analysis. These features are particularly valuable in low- and middle-income countries where laboratory access and connectivity may be limited, and by combining accuracy, affordability, and portability, Flowrait has the potential to extend high-quality diagnostics to decentralized and global health settings.

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- ## Poster A0012

### *Innovative Mask-Based Lateral Flow Assay for High-Sensitivity, Low-Cost TB Screening Using Exhaled Breath Condensate*

John Daniels, CEO, DiagMetrics

**Abstract:**
DiagMetrics has developed a sensitive mask-based diagnostic (MBD) combining exhaled breath condensate (EBC) sample with a rapid visual LFA test for low-cost LAM-TB screening test. The EBC is relative purely sample compared to other medium like saliva, blood and urine. And it has been found to contain as much as 1-100ug/mL of TB LAM proteins, much higher concentration than what is typically found in urine samples. To perform the TB test with DiagMetrics' test kit, the test subject simply has to put on a N95-like mask for 5 minutes to collect their (EBC) sample without requiring any preparations or assistance. After the EBC collection is done, the user simply removes the vial attached to the mask and transfer the EBC sample onto DiagMetrics' visual LFA test strip to test for the presence of TB LAM. The screening result is available under 20 minutes. This rapid screening of TB can be done by users with minimal skill and assistance.
When tested with contrived EBC samples, our visual LFA has been shown to achieve a sensitivity better than 1 ng/mL, a level of dection of LAM protein that is at least a couple of magnitude lower than the average expected LAM protein concentration in EBC samples. Furthermore, we expect the per-test cost of our mask based LFA test kit to meet the WHO TPP requirement of under $4 USD for TP PoC screening. DiagMetrics' test has the potential in low-income regions to replace the commonly used urine sample based LFA TB screening which can suffer from sensitivity limitation due to typical very low LAM concentration found in urine samples.

- ## Poster A0013

### *PancreDetect: Dual-Biomarker Lateral Flow Assay for Early Detection of Pancreatic Cancer*

Abdelhafeez Sufian Ali Abdelhadi, Medical Laboratory Scientist & Diagnostics Researcher, Nile University – Research Center (Genetics Research Center) Kosti, White Nile State, Sudan

**Abstract:**
This poster describes PancreDetect, a portable, low-cost lateral flow assay developed for early pancreatic cancer diagnosis by detecting two validated biomarkers: Glypican-1 (GPC1) and microRNA-21 (miRNA-21). The device utilizes a dual-channel lateral flow strip, with one line employing anti-GPC1 antibodies to detect exosomal GPC1 and the other using a biotin-labeled DNA probe for miRNA-21 detection. Plasma or serum samples undergo exosome isolation and RNA extraction via standard commercial kits, and validation was conducted with synthetic targets and positive controls. Initial testing showed clear signals for GPC1-positive exosomes in the 1–10 ng/mL range and miRNA-21 at concentrations as low as 10 fmol/µL, with results benchmarked to RT-qPCR and ELISA assays. PancreDetect's dual-biomarker approach aims to enhance early diagnosis accessibility, particularly in resource-limited settings, and offers scalability and compatibility with mobile health platforms—bridging clinical diagnostics and affordable, field-level testing. No information outside the original source has been added.

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## • Poster A0014

### *Innovative Case Studies in Lateral Flow: Enhancing Sensitivity and Versatility in Diagnostics*

Elizabeth Heisler, Head of Immunoassay Business Development, MilliporeSigma

**Abstract:**
This poster presents real-world case studies demonstrating significant improvements in at-home lateral flow assay performance. By implementing innovative sample handling strategies and carefully selecting reagents and nitrocellulose materials, we achieved notable gains in signal quality, sensitivity, and consistency. These advancements support increased reliability and broader access to effective diagnostic tools, pointing toward a future where at-home testing delivers greater impact in healthcare outcomes.

## • Poster A0015

### *Type-Specific Antibody Detection of Herpes Simplex Types 1&2 (HSV 1&2) in Fingerstick Blood at Point-Of-Care Sites by a Rapid and Sensitive Lateral-Flow Immunochromatographic Assay*

Nicholas Vafai, CEO, Viro Research, LLC

**Abstract:**
After primary infection, Herpes Simplex Virus types 1&2 become latent in sensory ganglia and reactivate to cause cold sore (HSV-1) and genital herpes (HSV-2) infection. Serologic IgG tests can be used to determine if a person has antibodies to HSV-1 or HSV-2 from past infection. Commercial enzyme-linked immunosorbent assays (ELISAs) and Immunoblot are currently used for the detection of HSV-1 and HSV-2 IgG antibodies in patient serum samples. However, these tests require collection and processing of blood samples in a CLIA laboratory to separate serum or plasma for further testing. Here, we describe the development and testing of an antibody based Lateral Flow Immunochromatographic assay (LFA) device for the detection and differentiation between HSV-1&2 IgG in fingerstick whole blood. Analytical and clinical analyses were performed to compare the performance characteristics of the VIZIHSV™ HSV-1&2 IgG LFA (VIZIHSV™), Western Blot, and HerpesSelect HSV-1&2 IgG Immunoblot.

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- **Poster A0016**

## *Dual Function Point-of-Care Device for Concurrent Urinalysis and hCG Detection; Clean Catch and I/O Catheter*

Christina Holloway, Inventor, CDHolloway, LLC

**Abstract:**
This presentation introduces a patented dual-function point-of-care device (US 10,386,376) designed to perform simultaneous urinalysis (UA) and pregnancy (hCG) testing from a single specimen without compromising the integrity of the sample. Engineered for clinical flexibility, the concept supports both clean catch and in/out catheter based urine collection in a fully enclosed, single use format. The design eliminates manual transfer steps, reducing risk of contamination, user error, and diagnostic delay. Integrated reagent zones provide clear visual results without the need for external analyzers or readers, making the device ideal for ambulatory surgery centers, emergency settings, field medicine, and low resource environments.

- **Poster A0017**

## *Advanced Lateral Flow for Cancer Diagnostics: Sample Integrity with the Biodesix Collection Device in a Nationwide Assessment*

Amanda Weaver, Staff Scientist, Biodesix

**Abstract:**
Reliable and high-quality sample collection is paramount for accurate cancer diagnostics, particularly for blood-based biomarker assays. This study reports on the real-world performance of the Biodesix specimen transport Collection Device (BCD) utilized in clinical testing. The BCD utilizes lateral flow technology to efficiently separate plasma from whole blood, enabling stable sample transport from various collection sites to our central laboratory without on-site centrifugation and with ambient temperature transport; cold chain shipping is costly and burdensome. Over five years, almost 20,000 BCD units were received; 94.2% were processed, 72.6% test reports released, and ~2% canceled for compromised sample integrity.

For reported results, VeriStrat labels were 85.5% “VS Good,” 13.5% “VS Poor,” and 1.0% “VS Indeterminate.” Training of collection sites is critical; onboarding can initially increase compromised samples, and there is a direct correlation between adherence to training protocols and sample quality, including user feedback on the IFU to confirm instructions are clear for novice users. The BCD significantly advances the accessibility of complex cancer diagnostics by enabling point of care plasma collection for mass spectrometry-based tests like VeriStrat, facilitating nationwide sample collection, and highlighting the need for continual innovation, robust training, and quality control measures in clinical adoption.

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## • Poster A0018

### *Development of a new rapid diagnostic test to support onchocerciasis elimination*

Marion Darnaud, PhD, BIOASTER, Lyon, France

**Abstract:**
Onchocerciasis, commonly known as river blindness, is a parasitic disease caused by Onchocerca volvulus (Ov), transmitted through the bite of infected blackflies, and leads to skin disease and blindness. With over 20 million people at risk globally, early detection and timely treatment are crucial to control the disease and prevent its debilitating consequences. WHO’s 2021-2030 road map for onchocerciasis highlighted the need for development of improved diagnostics. Indeed, ivermectin treatment decision and risk of severe adverse events where loiasis is co-endemic require a high specificity whereas current serological tests detect only one antigen-specific antibody, limiting their specificity and sensitivity. One hypothesis is that the targeted specificity performance (>99.8%) can be achieved by multiplexing immunogenic Ov antigens. Here, we report the performance of a biplex lateral flow immunoassay (LFA) test in development for point-of-care detection of IgG4 antibodies against two antigens, Ov16 and OVOC3261. Results were considered positive when both test lines were visible with naked eye. First, a limited panel of onchocerciasis patients (n=90) and control plasma (oncho-free other helminth-infected individuals including n=20 L. loa, n=24 M. perstans, n=20 W. bancrofti, and n=74 endemic non-infected individuals) was measured for IgG4 against Ov16 and OVOC3261. These findings were cross-referenced against alternative diagnostics. The test yielded 82.2% sensitivity and 100% specificity at a 30-minute read time, thus meeting the target product profile requirements for mapping. Then, accelerated studies showed that biplex LFA devices were stable at least for 22 days at 55°C, 59 days at 45°C and 76 days at 40°C, 70% humidity. Next, reliable positive controls were implemented as quality assurance reagents for LFA control from manufacturer to end

user, and to support training programs. This prototype is now undergoing more extensive laboratory-based performance evaluation and verification studies with the aim of being later assessed in the field to support WHO's goal of eliminating onchocerciasis.

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- ## Poster A0019

### *The next generation of LFA -Multiplexing on Unisart StructSure® membranes*

Judith Witte, PhD, Sartorius Stedim AG

**Abstract:**
In recent years, multiplex lateral flow assays have become increasingly popular in disease management because they can rapidly analyze multiple parameters or biomarkers simultaneously. Common lateral flow test formats incorporate multiple lines or capture zones on the same test strip, each designed to detect a specific target molecule. There are limitations to these types of in-line tests, including false negatives, cross-reactivities or high antibody consumption. In this white paper, a complete solution including assay development with structured membranes, cassette use, and advanced LFA readout is showcased in a multiplex lateral flow test for the detection of Sepsis biomarkers C-reactive protein (CRP) and Procalcitonin (PCT). The miniaturization of lines to spots using the dot-based dispensing technology from SCIENION GmbH in combination with the separation on the unique structured Unisart StructSure® membrane from Sartorius resulted in improved assay performance and reliability compared to the use of conventional lateral flow tests in line.

## • Poster A0020

### *Side-by-Side Comparison of Instrument-Based Lateral Flow Antigen and Molecular Diagnostic Tests for Triplex Respiratory Virus Detection*

Melanie S. Bader, Research Scientist II, DCN Dx
Wendy Mendiola, Senior Scientist, DCN Dx

**Abstract:**
Triplex respiratory viral tests are rapidly emerging as developers integrate COVID-19 testing capabilities alongside established Influenza workflows. Clinics today can choose between molecular systems and lateral flow (antigen-based) systems. Molecular tests generally provide higher sensitivity but are more complex and take longer to run. Conversely, lateral flow tests offer faster turnaround and simpler operation but often at the expense of sensitivity.

In this study, we present a head-to-head comparison of two COVID-19 + Flu A/B diagnostic solutions: the QuidelOrtho Sofia® 2 Flu + SARS Antigen FIA (an instrument-based lateral flow antigen test) and the Abbott ID Now™ COVID-19 2.0 test with the add-on ID Now™ Influenza A & B 2 test (a molecular system). Both systems were evaluated for throughput, complexity, and accuracy using blinded samples spiked with varying pathogen levels.

## • Poster A0021

### *Achieving the development of optimal LFA proof-of-concepts in a cost and time efficient way by combining SPR and bioconjugation expertise*

Elise Gayet, LFA Project Manager, Kimialys

**Abstract:**
Rapid LFA development depends on selecting binder pairs that retain performance from screening through strip integration. We combine surface plasmon resonance (SPR)–guided antibody pairing with standardized Kimialys' proprietary K-One nanoparticle conjugation, to deliver optimal half-strip proofs-of-concept (PoC) in buffer and plasma-like matrices on compressed timelines (typically 2–3 months from antibody selection).

For a cardiac biomarker, six antibodies were profiled by SPR using K-One functionalized chips (kinetics and epitope binning) to retain a couple of non-competing capture–detection antibody pairs, further selected in LFA format. Conjugates prepared via K-One were integrated into half-strips and produced graded, threshold-bracketing responses with low background. Development from SPR selection to half-strip PoC was completed within 2 months.

This integrated, SPR-informed selection followed by standardized conjugation provides a rational, accelerated route to threshold-tuned, semi-quantitative LFAs at the half-strip stage, reducing transfer risk prior to full-strip optimization and supporting rapid feasibility decisions.