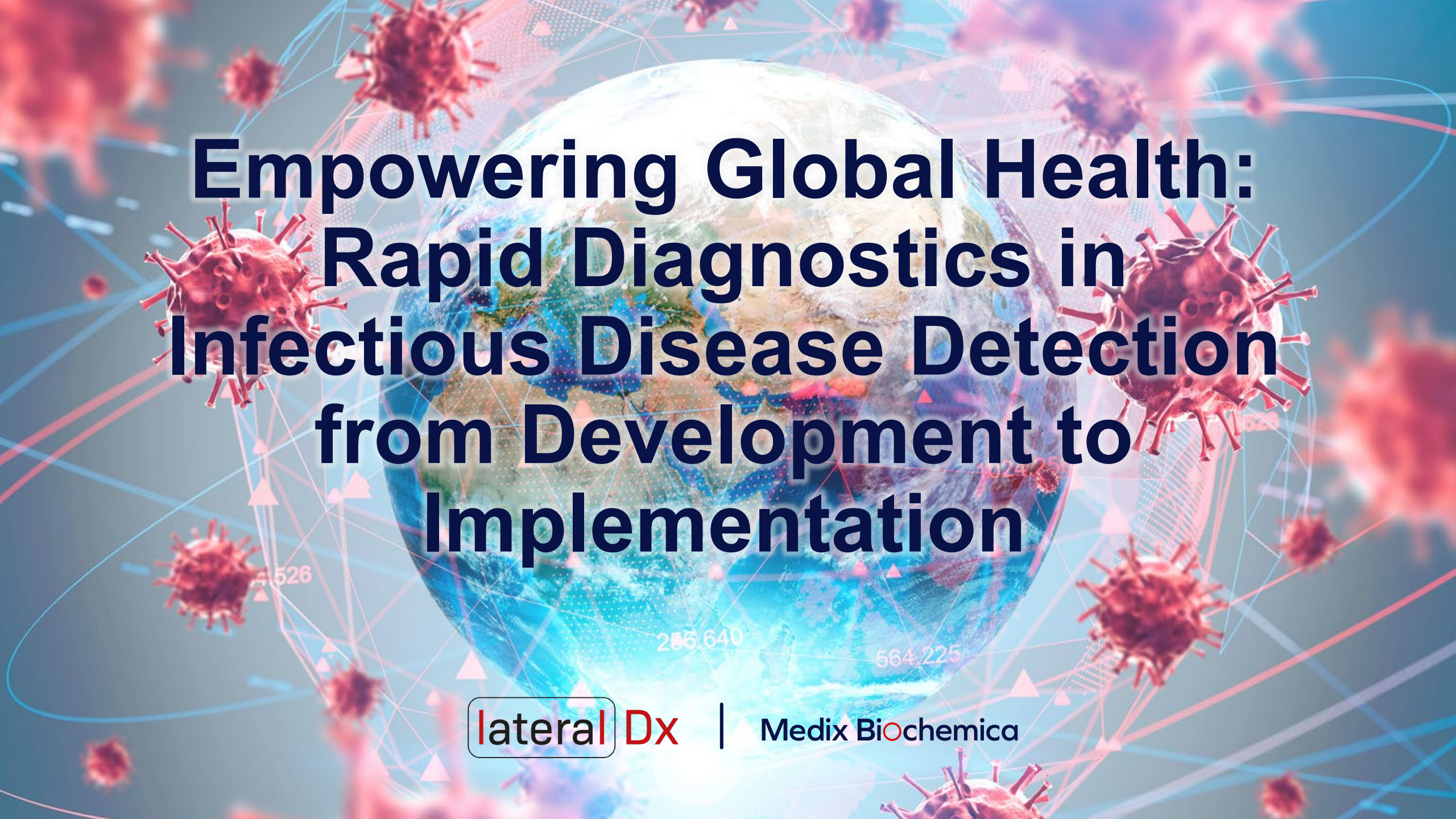




Empowering Global Health: Rapid Diagnostics in Infectious Disease Detection from Development to Implementation

lateral Dx

Medix Biochemica

Before we get started

 Please use the Q&A button at the bottom of your screen to submit any questions.

There will be a Q&A session at the end of this webinar. If we do not have time to answer your questions, we will reach out by email following the webinar.

 This webinar is being recorded. The recording as well as on-demand link will be released following the webinar.

Independent, International, and Industry-Leading Raw Materials Supplier

- Provider of high-quality antibodies, antigens, proteins, enzymes, biospecimens
- Experts in immunoassays, clinical chemistry, molecular diagnostics
- Our portfolio is among the most comprehensive in the IVD industry
- Enabling our customers to develop and manufacture quality IVD tests



Featured Speakers



Richard Campbell

Founder and Managing Director
Lateral Dx



Amy Moore

Global Product Manager
Medix Biochemica



Medix Biochemica



THE LATERAL FLOW EXPERTS

Understanding LFT Test Development Process

Richard Campbell

Founder and Managing Director
Lateral Dx



Providing high quality and cost effective Contract Lateral Flow Solutions



Established in 2019 we are based in Alloa, Scotland and pride ourselves on being the **Lateral Flow Experts**.

Our aim is to provide high quality and cost-effective contract services in the area of lateral flow technology.

With over 25 years' experience in the lateral flow assay industry, we can assist you with every step of your lateral flow test development journey.



Rapid
Antibody
Screening

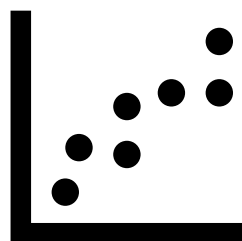
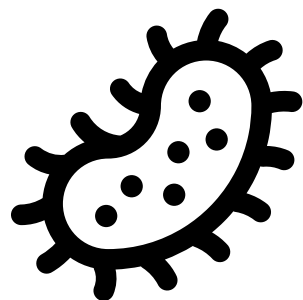
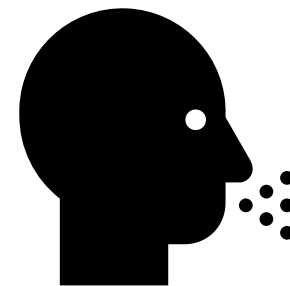
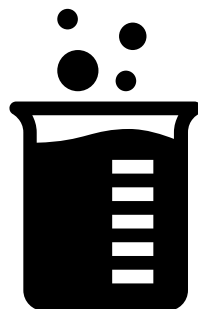
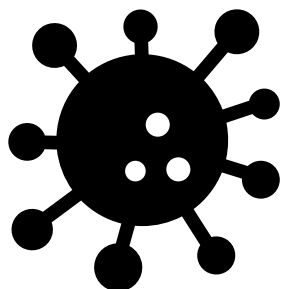
Contract
Development



Contract
Manufacture

Consultancy

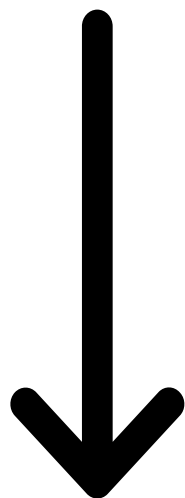




Development Experience

- **Nanoparticle Conjugation:**
 - Gold Colloid, Nanorods, Nanoshells, Polystyrene/latex, Cellulose, Fluorescent, Enzyme precipitate, Carbon
- **Sample Matrix:**
 - Blood, serum/plasma, saliva, NP swab, BAL, water, plant material, urine, milk, soil, fuel, surface swab
- **Test Formats:**
 - Antibody sandwich, antigen sandwich, serological, competitive/inhibition
 - Visually read, Semi-quantitative, fully quantitative
- **Test Development Areas:**
 - Infectious disease, human clinical, hormone panels, biothreat agents, Drugs of abuse, bacteria, virus, fungal pathogens, cardiac markers, inflammation markers
- **Antibody Types:**
 - Polyclonal, Monoclonal, Recombinant, Synthetic (Aptamers)

Phased process



User needs & design inputs from customer to create

- Functional specifications for the assays
- Design risk assessment
- Workplan

Project Plan & Timeline

Feasibility

- Prototype development
- Raw material identification
- Prototype Testing
- Initial R&D stability set up

Feasibility Report

Specification review versus feasibility outputs
Gated Phase Review

Optimisation

- Raw material and process robustness
- Scale up as required
- Development of QC testing regime
- Optimisation batch manufacture & testing
- Stability

Optimisation Report

Specification review versus optimisation outputs
Gated Phase Review

Transfer & Validation

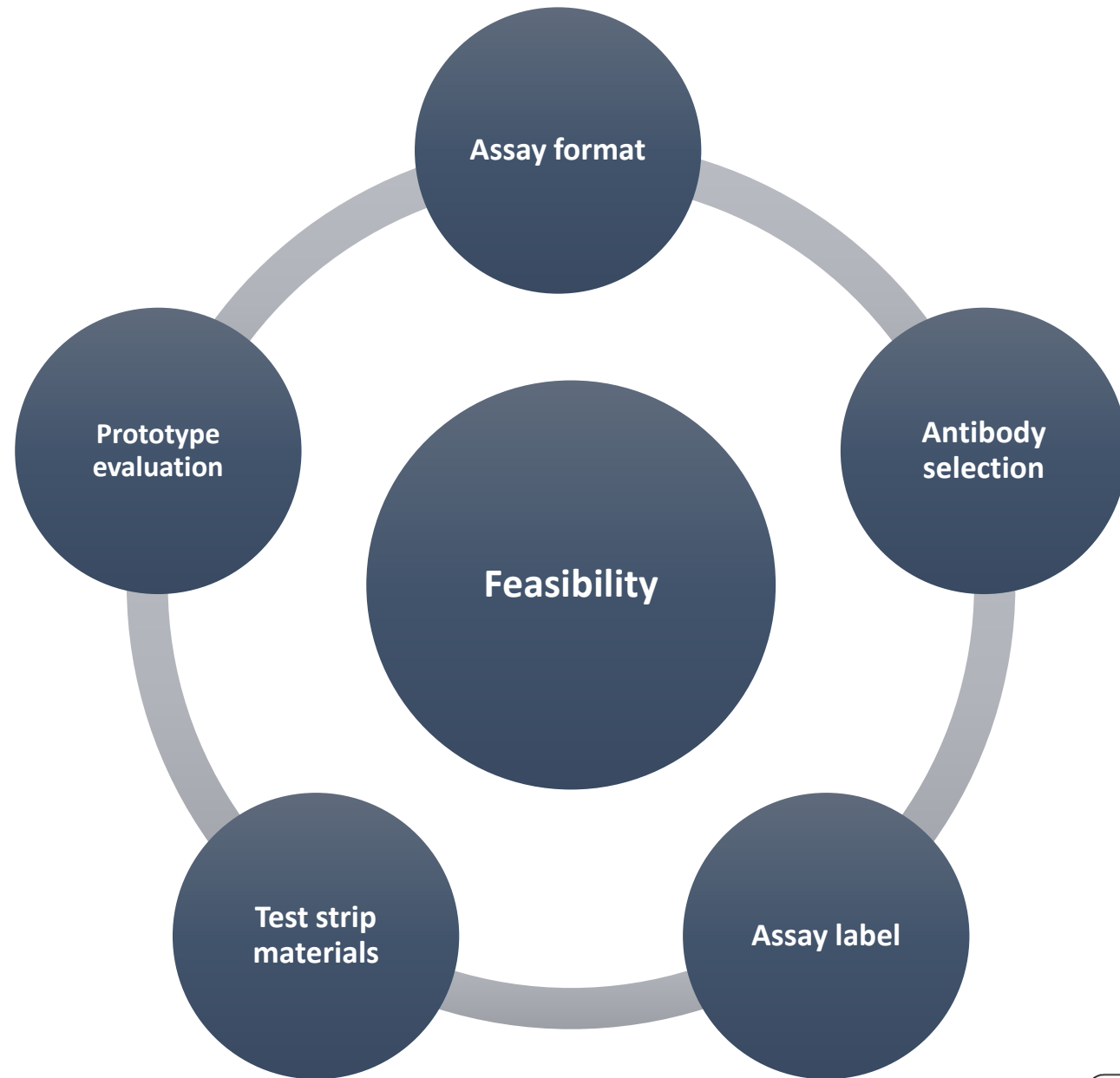
- Transfer checklist activities
- Process risk assessments
- Creation of manufacturing documentation
- Manufacture validation batches
- Execution agreed analytical method validation
- Stability

Approved procedures and manufacturing records
Validation Master Plan and Validation Protocols
Validation Reports & Summary Report
Specification review versus optimisation outputs
Gated Phase Review

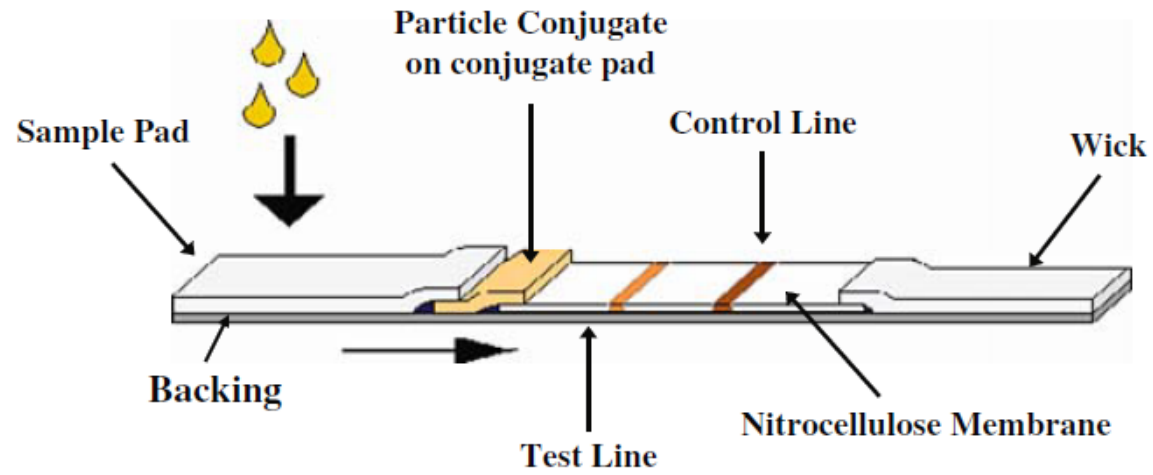
Routine Manufacture

Batch manufacturing records
Trending

Technical Considerations



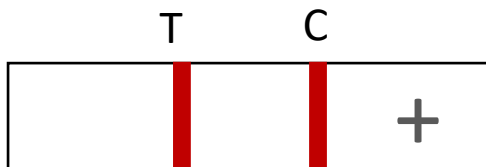
Assay Format



Sandwich

Larger analytes
Multiple binding sites
Test line = Positive

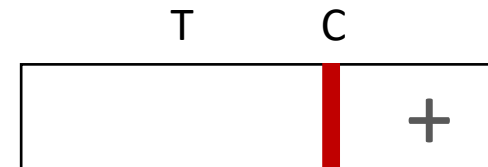
e.g. Proteins /organisms



Competitive

Smaller analytes
Single binding site
Test line = Negative

e.g. Drugs / toxins





Choice of Assay Label

- Colloidal Gold
- Fluorescent nanoparticles
- Cellulose nanobeads
- Dyed microspheres





Colloidal Gold

What it is:

Gold nanoparticles (20-60nm) suspended in solution, creating a distinctive red colloidal system. Generally, 40nm

Conjugation occurs through:

Electrostatic forces, hydrophobic interactions, and dative bonds between gold and sulfur-containing amino acids in proteins

Optimised when:

pH is adjusted to protein's isoelectric point or slightly above, followed by stabilisation with blocking agents like BSA

Why it works for LFAs:

Combines visual detection capabilities with simple chemistry, excellent stability, and minimal interference with biomolecule function

The ideal balance of simplicity, stability and sensitivity makes colloidal gold the industry standard for lateral flow detection systems



Fluorescent nanoparticles

What it is:

Lanthanide-based (especially europium) nanoparticles that emit specific wavelength light when excited, typically 100-300nm in size

Conjugation occurs through:

Carbodiimide chemistry (EDC/NHS), streptavidin-biotin interactions, or surface functionalization with maleimide or NHS-ester groups

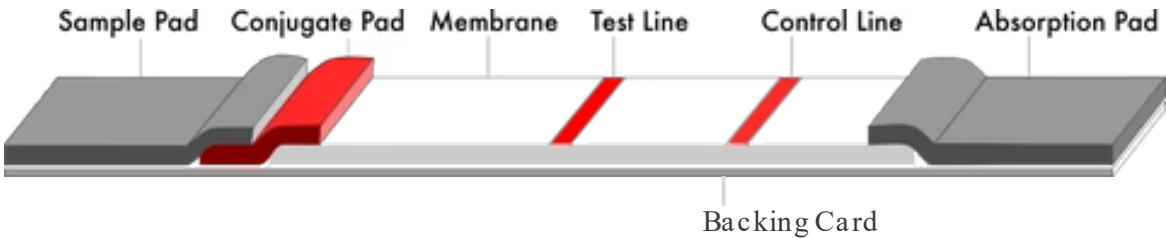
Optimised when:

Particles are properly coated, reaction chemistry is controlled, and conjugation buffers maintain nanoparticle stability

Why it works for LFAs:

Large Stokes shift prevents self-quenching, time-resolved fluorescence eliminates background noise, and exceptional sensitivity enables lower detection limits than colorimetric methods

Europium-based fluorescent nanoparticles deliver superior sensitivity and quantitative capabilities while maintaining the simplicity of lateral flow formats

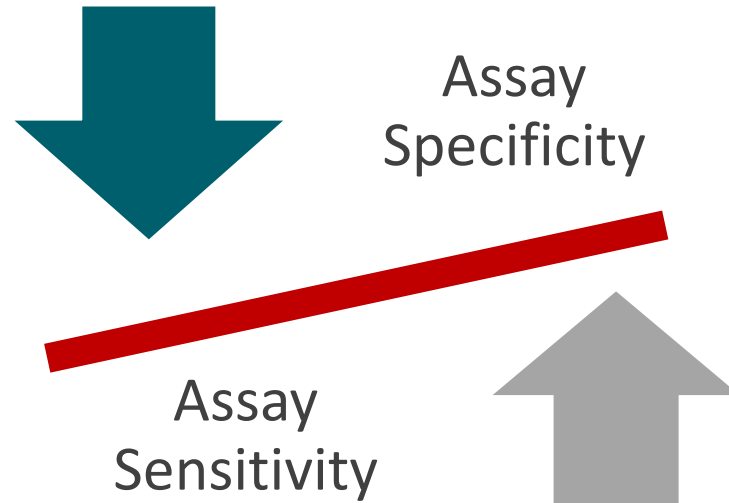


Test Strip Materials

Material	Function in LFT	Common materials
Sample Pad	Separate red blood cells and plasma Filtration of sample Adjust sample pH, buffer environment Lyse virus/ cells, dissociate proteins	Cellulose papers, glass fibre, PTFE
Conjugate Pad	Absorb & release detector reagent consistently Maintain stability of conjugate for shelf-life of test Hydrophilic, low protein binding , tensile strength	Glass fibre, treated polyester
Membrane	Bind Test and Control line reagents Major contributor to speed of test	Nitrocellulose (various flow rates, binding capacity and surfactant treatments)
Absorption Pad / Wick	Absorb sample volume Absorbent capacity relative to sample volume	High density cellulose papers
Backing card	Provides Structure for strip Adhesive quality very important Accurate dimensions	Polystyrene or polyvinyl chloride with pressure sensitive adhesive
Buffer	Adjust LFT running environment (pH, molarity, etc) Allow test to flow	

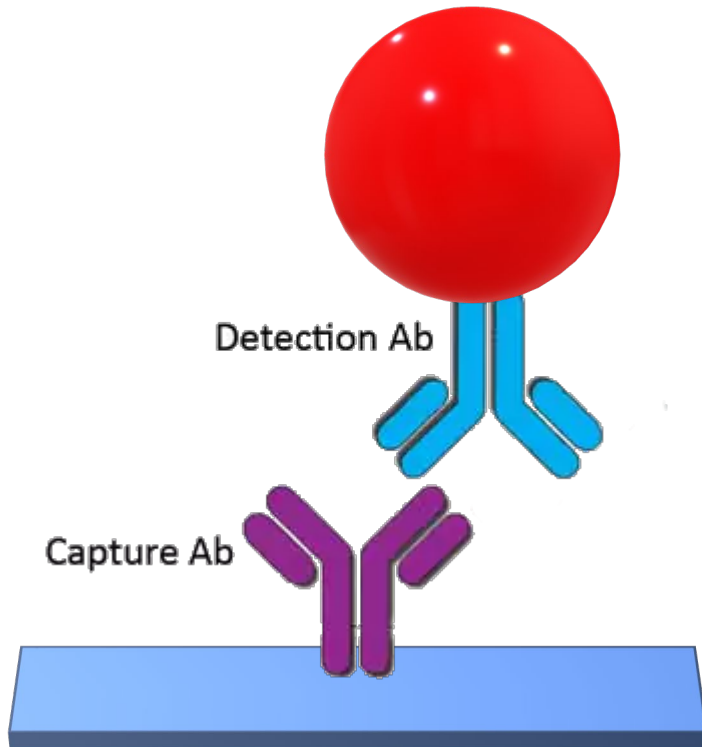
Assay Performance

- Sensitivity and specificity typically exist in an inverse relationship
- Improving one often comes at the expense of the other



- Hundreds of factors interact in one step assay
- All need to be balanced to ensure maximum assay performance
- The optimal balance depends on the **intended use** of the test:
 - Screening tests prioritise sensitivity (minimise missed cases)
 - Confirmatory tests prioritise specificity (minimise false alarms)
 - Point-of-care tests often seek optimal balance for clinical decision-making

Avoiding Non-specific Binding



What it is	Common causes	Minimised through	Critical factors
Unwanted interactions between assay components and non-target molecules , leading to background signal, reduced sensitivity, and potential false positives	Hydrophobic interactions between proteins and membranes, charge-based attractions , denatured antibodies, and matrix effects from complex sample types	Antibody selection , Blocking agents (BSA, casein, serum), surfactants , optimized buffer composition, salts and sample pre-treatment steps	Antibody selection , antibody quality , conjugate stability, membrane selection , and sample matrix characteristics all influence the prevalence and severity of non-specific binding

Controlling non-specific binding is the cornerstone of assay specificity

Antibody Selection

- Commercial or customer developed
- Price / availability / quality / Licencing
- Monoclonal , polyclonal, recombinant
- How many to screen
- How perform screen
 - Recommended pairings vs Full matrix
 - ELISA pre-screen
 - Negative screening
 - Screening matrix
 - Buffer
 - Spiked matrix
 - Characterised sample



Rapid Antibody Screening

Innovative antibody screening method that can **quickly, quantitatively** and **cost-effectively** screen multiple antibodies for their suitability for use in the lateral flow test format.

The system can work with antibody quantities of as little as 0.1mg and results can be generated in 1-2 weeks.

- Up to 20 antibodies
- Any signal particle
- Fast turnaround
- Low antibody quantity
- Fully quantitative data

OUR PROCESS

Select antibodies for screening



Conjugate antibodies to signal particle



Deposit all antibodies onto Nitrocellulose



Matrix testing of all combinations

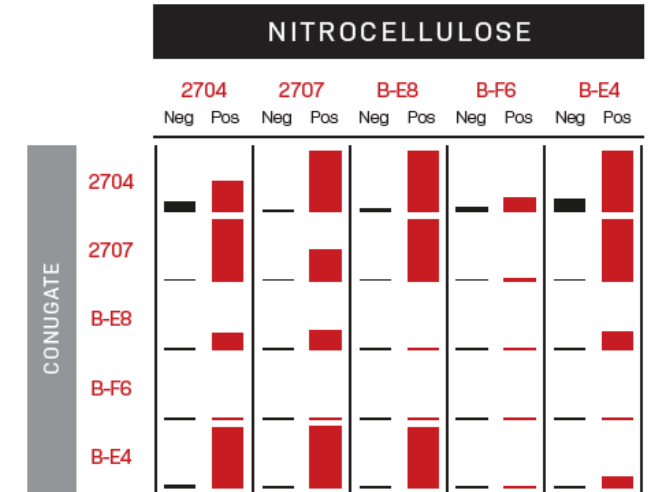


Analysis and selection of best pairings

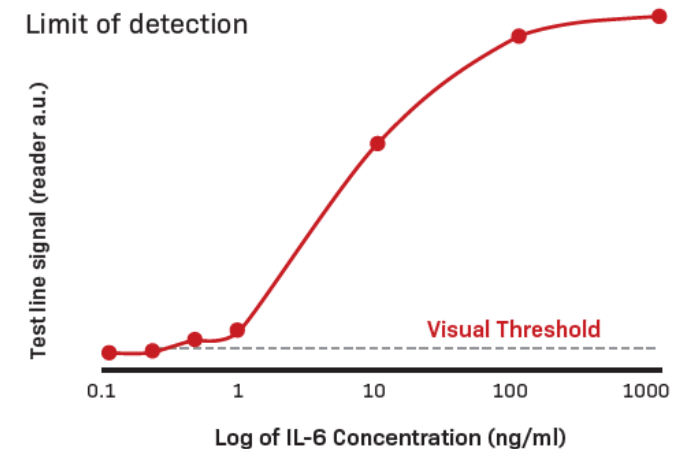


LOD of best pairing

5x5 matrix study



Limit of detection

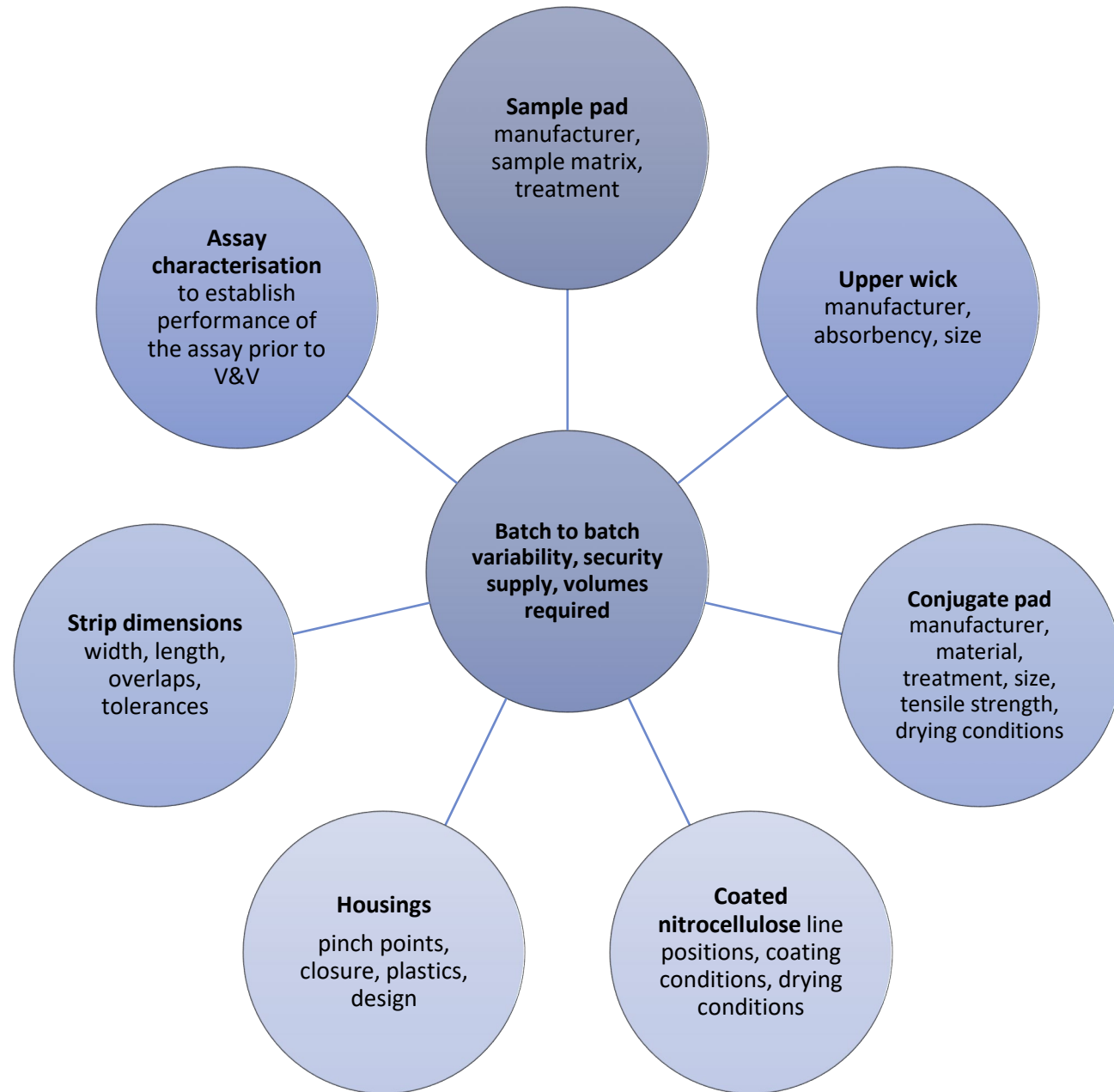
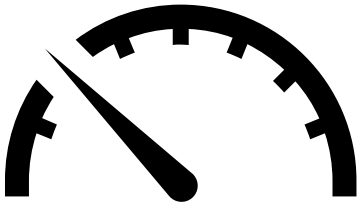


Development Samples

- What to use during the development
- Purified / recombinant analyte
- Spiked buffer
- Spiked matrix
- Characterised sample panel
 - Number
 - Source
 - Characterisation



Optimisation



Optimisation

Assay Optimisation, technical work and final report

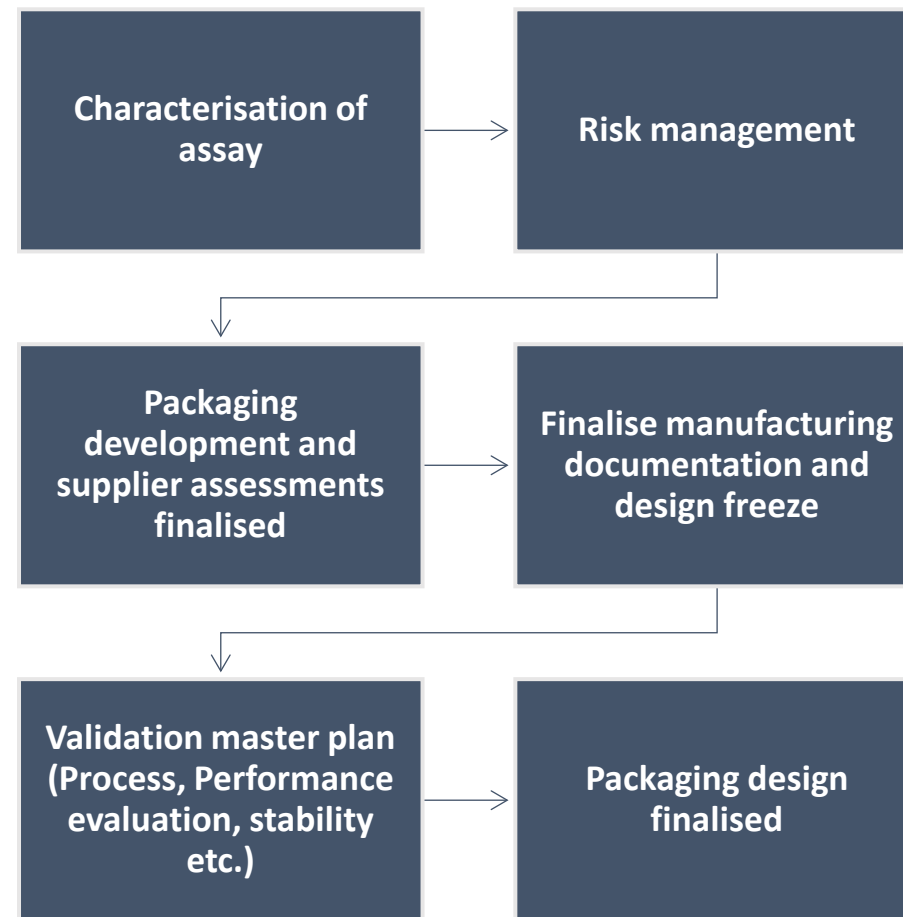
QC panel development, evaluation, stability and draft documented QC process

Equipment, facilities and utilities qualification

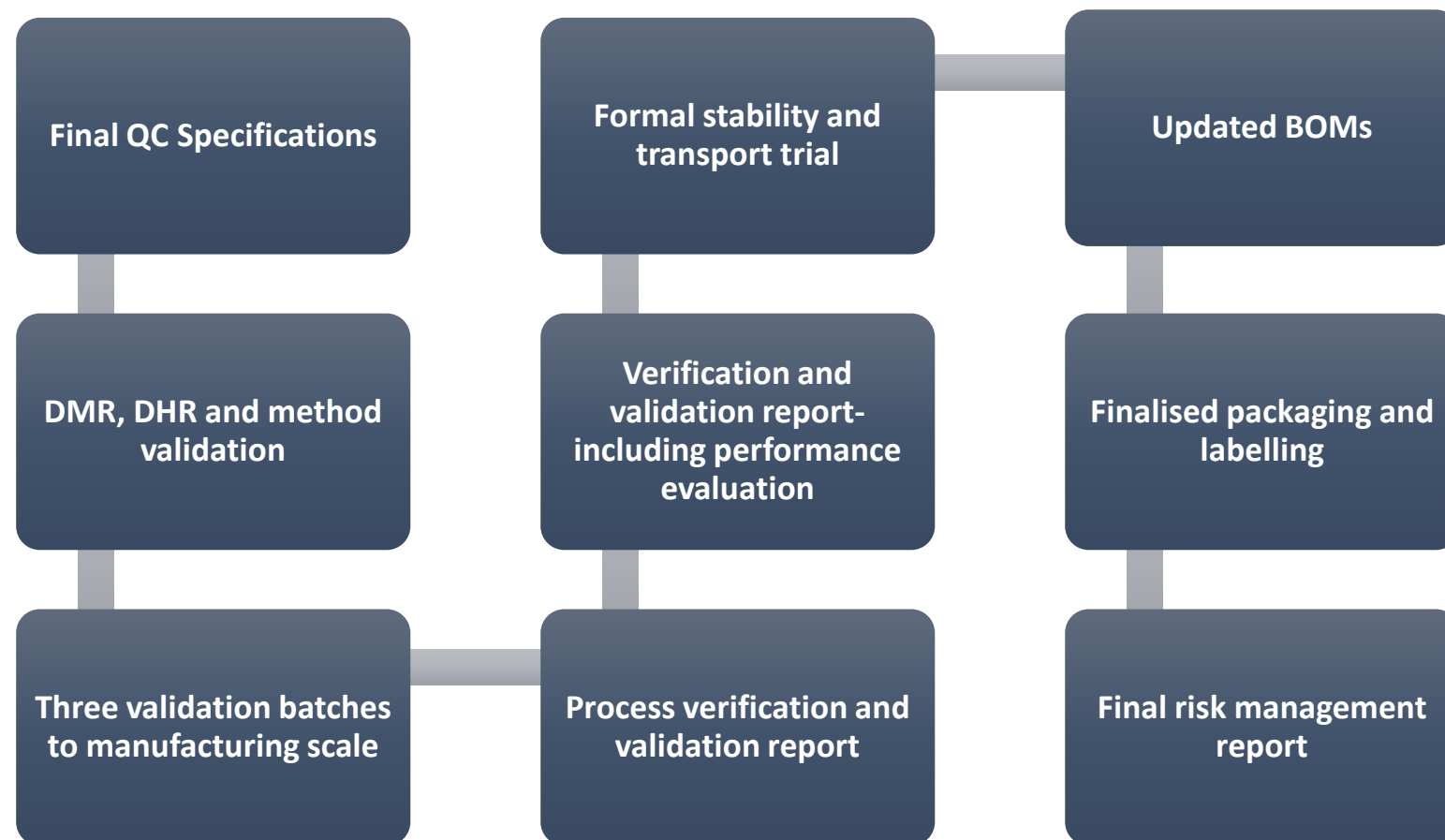
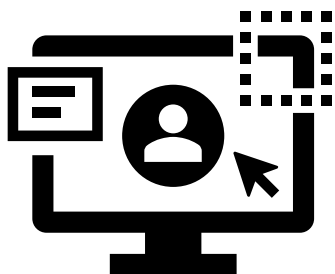
Generation of pilot batches (including material diversity)

Manufacturing specification

Informal stability



Design Verification & Validation





The Lateral Flow Experts

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www.lateraldx.com

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Empowering Global Health: Rapid Diagnostics in Infectious Disease Detection from Development to Implementation

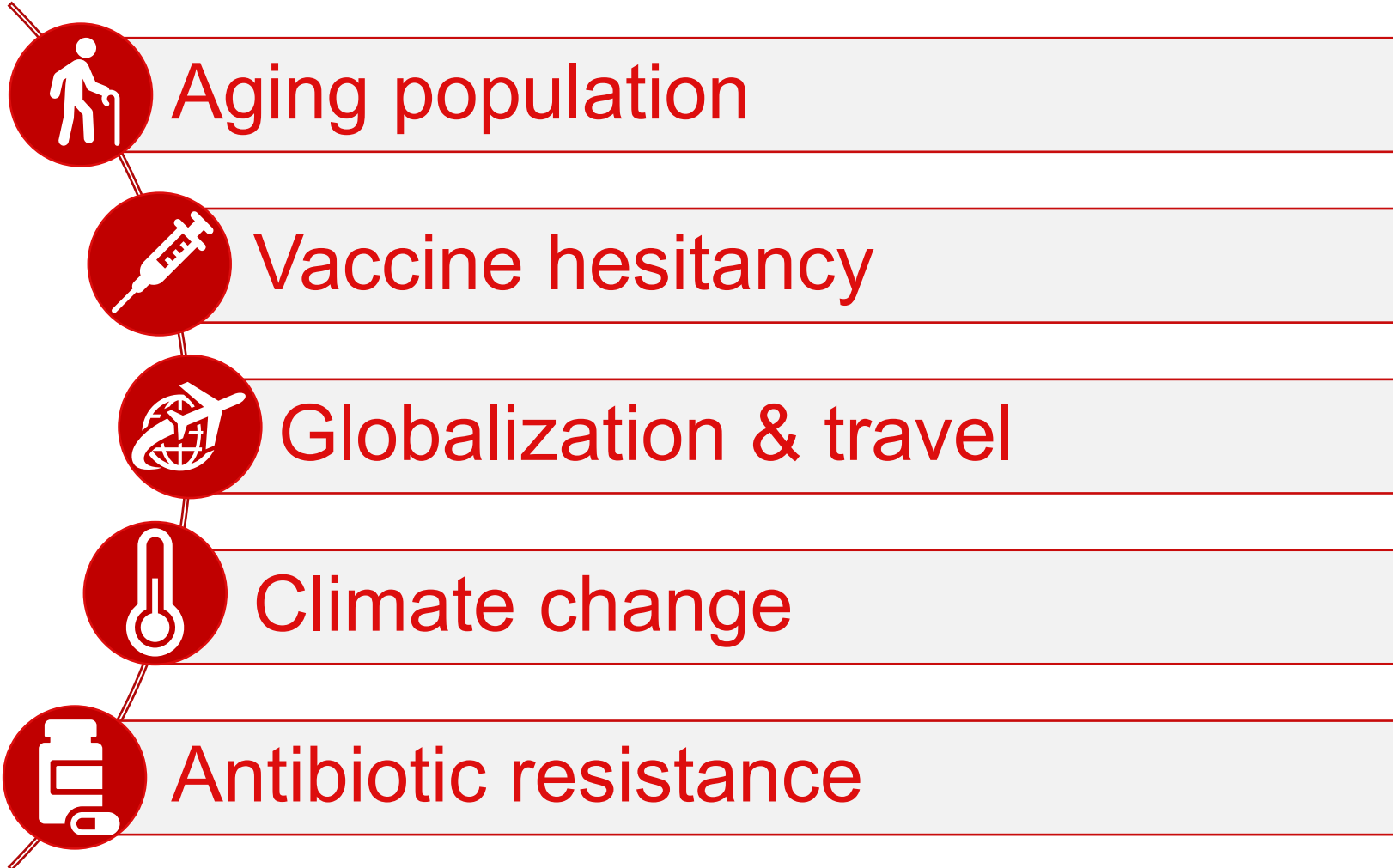
Amy Moore, PhD

Global Product Manager for Infectious Diseases

2025-05-13

Medix Biochemica

Global Infectious Disease Challenges



Diagnostic Testing for Infectious Diseases

Method	Advantage	Disadvantage
Culture	High specificity Gold standard	Time (slow test results) Cost Low sensitivity Labor intensive
Molecular	Optimal sensitivity and specificity for early diagnosis Differentiation of strains & subtypes	Higher cost/reimbursement challenges Specialized lab personal Higher technical requirement
Antibody detection (Serology)	Simple and reliable IgM+ indicates early diagnosis IgG+ indicates late diagnosis/previous exposure	Utility for acute infections limited
Antigen detection	Direct evidence of acute infection Time (fast test results) High positive predictive value Simple to use Lower cost	Lower sensitivity

Rapid Diagnostic Testing at Point of Care

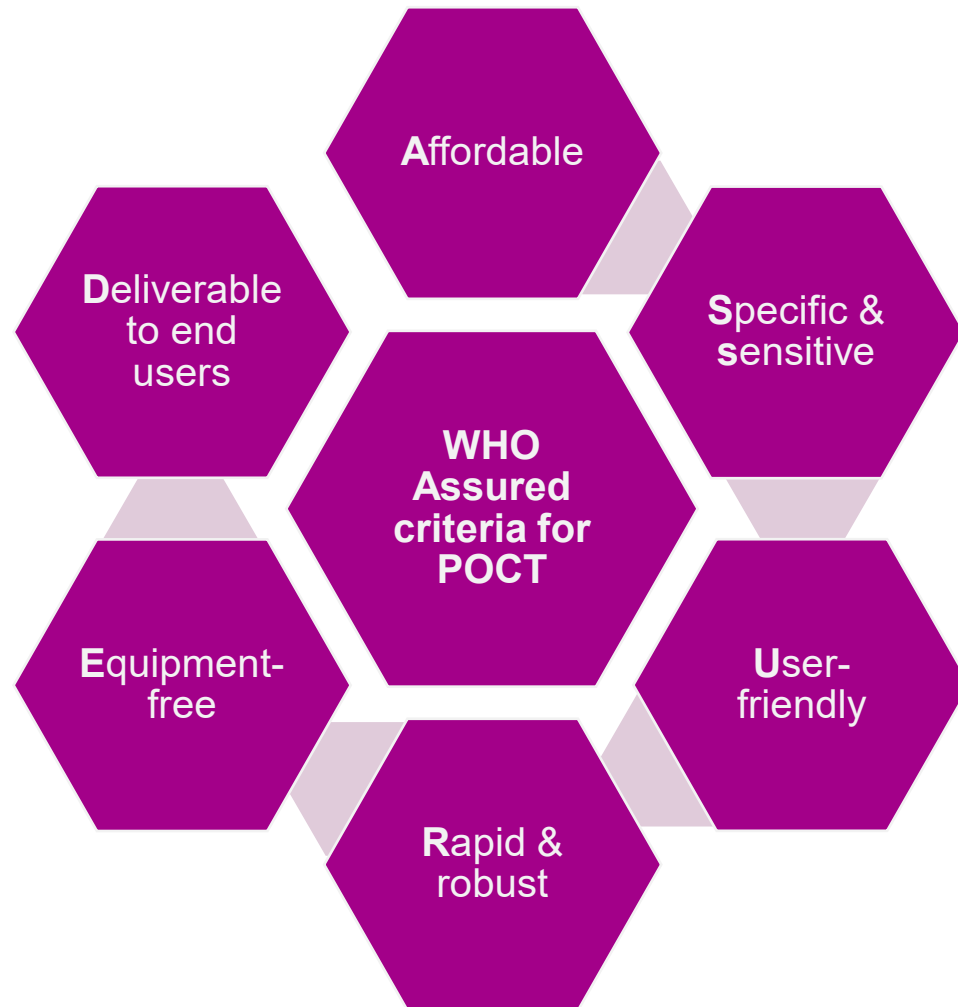
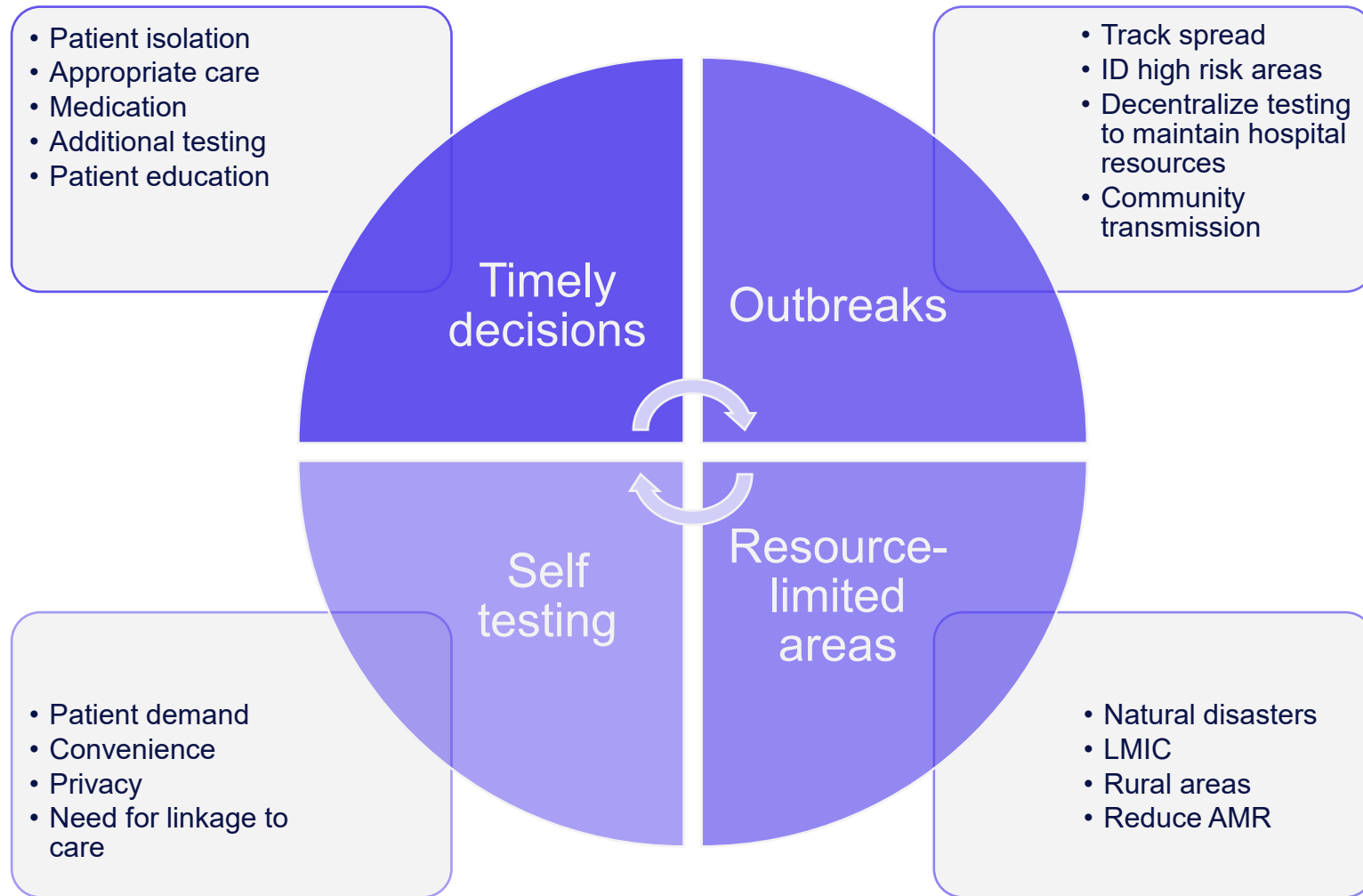


Image source: www.lateraldx.com/services/

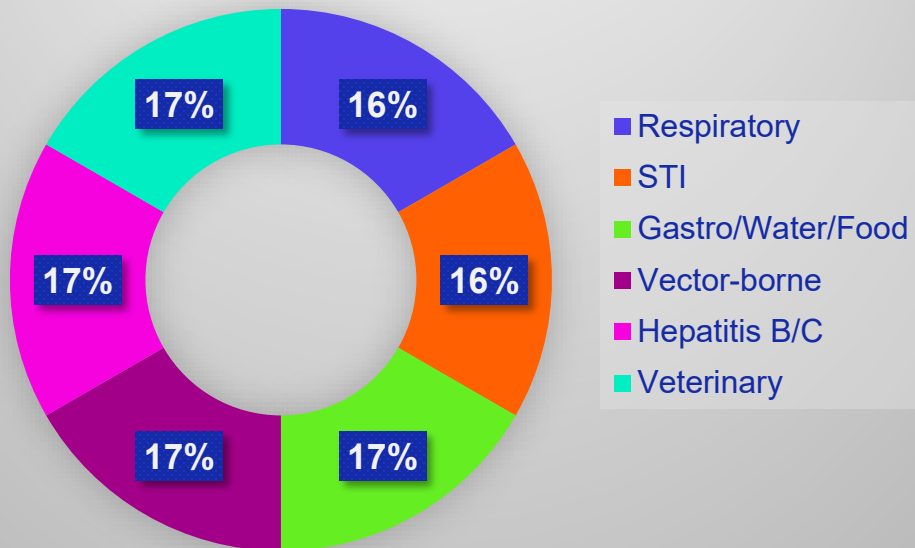
Rapid Diagnostic Testing at Point of Care



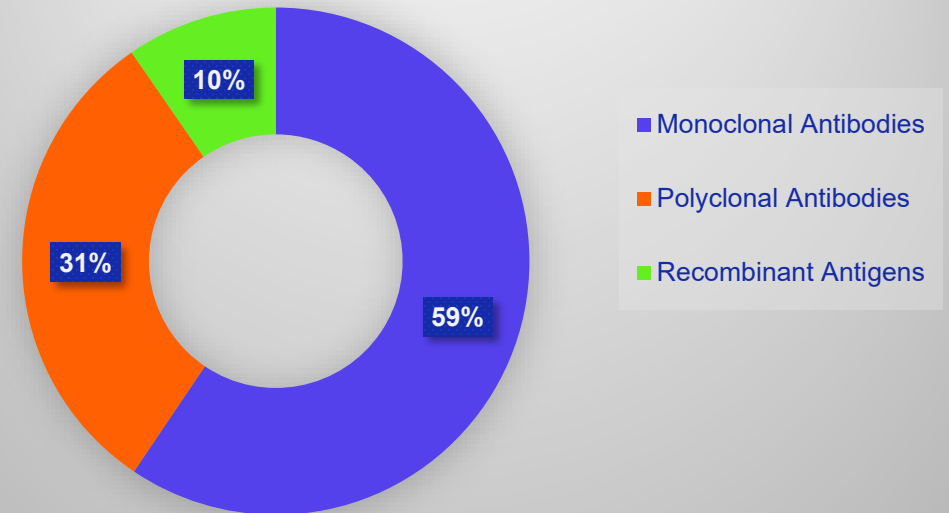
Our Product Selection: Ready to Meet Challenges of Infectious Disease Testing

**>1,000
products**

Focus Areas

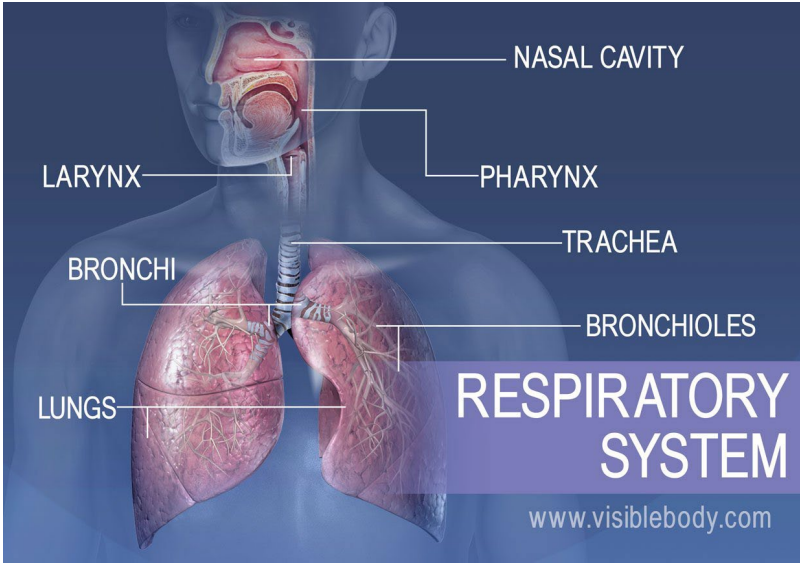


Product Types



Acute Respiratory Infections (ARI)

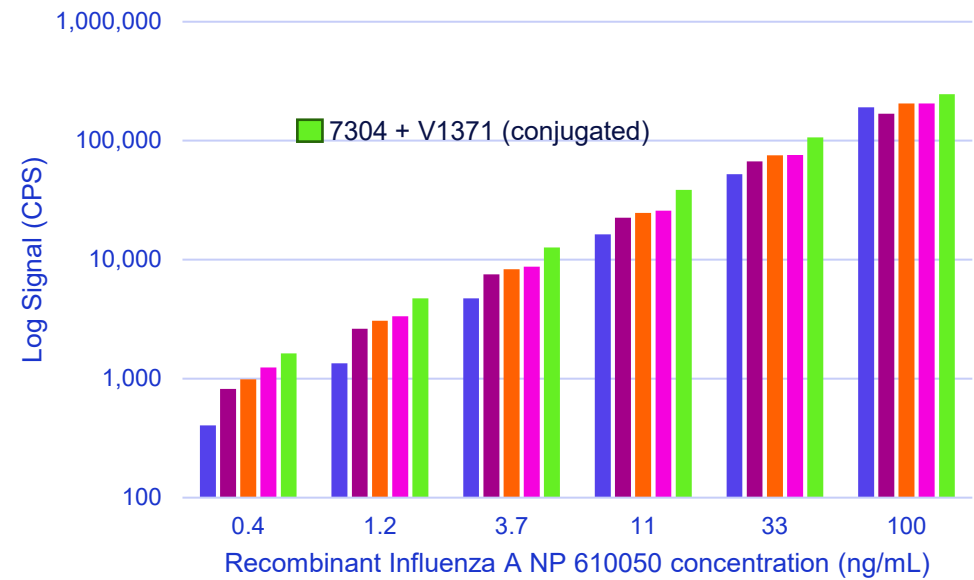
- A leading cause of death globally
- Burden highest for the young and the old
- Accurate diagnosis difficult through clinical presentation
- Most common cause of unnecessary antibiotic usage



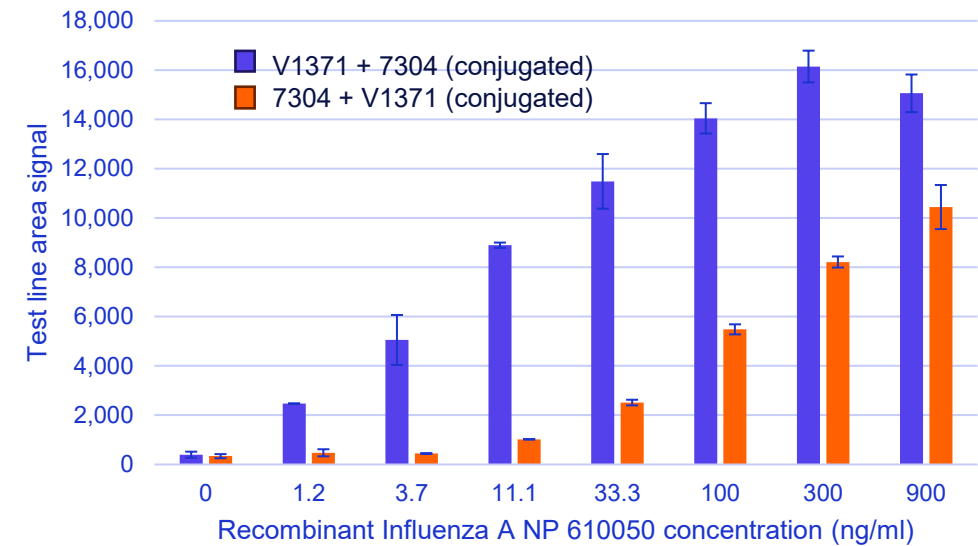
Analyte	Ab	Ag
Adenovirus	■	■
Bocavirus	■	
Bordetella pertussis	■	■
Chlamydia pneumoniae	■	■
Coronavirus (SARS-CoV-2)	■	■
Influenza A	■	■
Influenza B	■	■
Legionella pneumophila	■	■
Metapneumovirus	■	
Mycobacteria (LAM)	■	
Mycobacterium tuberculosis	■	■
Mycoplasma pneumoniae	■	■
Parainfluenza	■	■
Rhinovirus	■	
Respiratory syncytial virus (RSV) fusion	■	■
Respiratory syncytial virus (RSV) NP	■	■
Streptococcus group A	■	■
Streptococcus pneumoniae	■	

Influenza A mAbs: FIA & LF

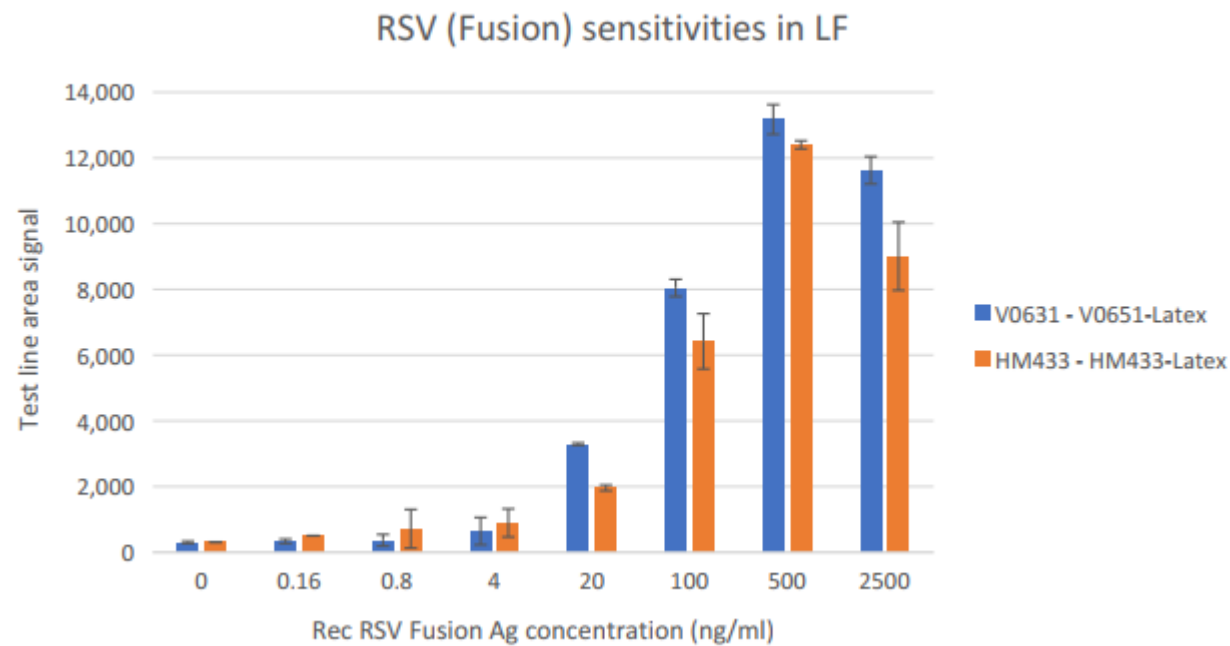
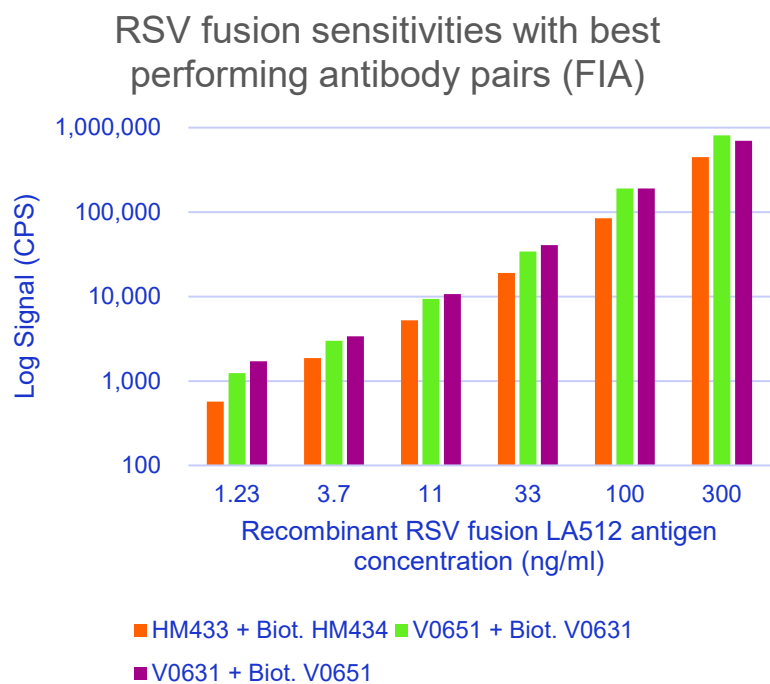
FIA



Lateral flow



Respiratory Syntial Virus (RSV) mAbs: FIA & LF



Scientific Publications and Additional Resources



Explore more: medixbiochemica.com/resources

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Sexually Transmitted Infections (STI) and Viral Hepatitis

Incident cases of four curable STIs among adults (15–49 years old), by WHO region, 2020

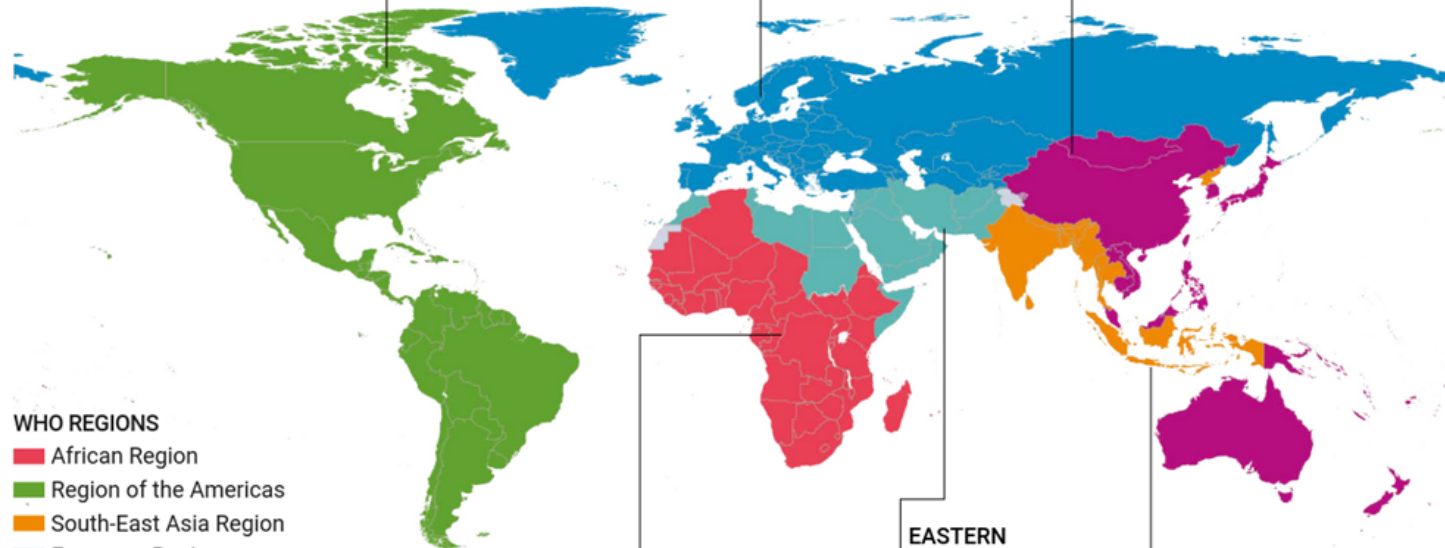
Syphilis (*Treponema pallidum*), gonorrhoea (*Neisseria gonorrhoeae*), chlamydia (*Chlamydia trachomatis*) and trichomoniasis (*Trichomonas vaginalis*)

GLOBAL
374 million
[286 million–481 million]

REGION OF THE AMERICAS
74 million
[53 million–104 million]

EUROPEAN REGION
23 million
[16 million–31 million]

WESTERN PACIFIC REGION
86 million
[61 million–117 million]



AFRICAN REGION
96 million
[66 million–134 million]

EASTERN MEDITERRANEAN REGION
36 million
[22 million–56 million]

SOUTH-EAST ASIA REGION
60 million
[32 million–107 million]

Source: WHO, 2021.

- >1 million STIs per year worldwide
- 304 million people with chronic hepatitis B and C worldwide
- 1.3 million deaths from chronic hepatitis B and C worldwide

STIs and Viral Hepatitis Product Selection



Analyte	Ab	Ag
Chlamydia trachomatis	■	■
Gardnerella vaginalis	■	
Herpes simplex virus 1 (HSV-1)	■	■
Herpes simplex virus 2 (HSV-2)	■	■
Human immunodeficiency virus (HIV)	■	■
Human papillomavirus (HPV)	■	■
Mycoplasma genitalium	■	
Mycoplasma hominis	■	
Neisseria gonorrhoeae	■	
Treponema pallidum	■	■
Trichomonas	■	



Analyte	Ab	Ag
Hepatitis A virus (HAV)	■	■
Hepatitis B core antigen (HBcAg)	■	■
Hepatitis Be antigen (HBeAg)	■	■
Hepatitis B surface antigen (HBsAg)	■	■
Hepatitis Bx		
Hepatitis C virus (HCV)	■	■
Hepatitis C virus core	■	■
Hepatitis C virus E1 & E2	■	■
Hepatitis NS3	■	■
Hepatitis C NS4	■	■
Hepatitis NS5	■	■
Hepatitis E virus		■

**New Anti-HIV-1
p24 monoclonals
prelaunch
samples available
soon!**

Vector-Borne and Gastrointestinal Product Selection



Analyte	Ab	Ag
Chikungunya	■	
Dengue	■	■
Japanese encephalitis	■	
Malaria	■	■
Rickettsia	■	
Oropouche virus	■	
Saint Louis encephalitis	■	
Trypanosoma cruzi		■
West Nile virus	■	■
Yellow fever	■	
Zika virus	■	■



Analyte	Ab	Ag
Campylobacter	■	■
Clostridium difficile	■	■
Cryptosporidium	■	■
E. coli	■	■
Giardia lamblia	■	
Helicobacter pylori	■	■
Norovirus	■	■
Salmonella	■	■
Shigella	■	
Vibrio cholera	■	



Base Matrices, Biologicals, & Biospecimens Infectious Disease-Related Offerings

Base Matrices, Processed Plasma & Serum

Product Code	Description
H1091	Normalized human serum *
H2000	BioCon II, defibrinated plasma *
H2001	Human control base matrix *
H2420	Universal negative base matrix *
H2550	BioCon II CD, charcoal stripped plasma *
H2700	BioCon II D, defibrinated, delipidated plasma *
D1072	Anti-HBs positive plasma unit **
N1072	Anti-HBs negative plasma unit **
D1039	Anti-HBc positive plasma unit **
N1039	Anti-HBc negative plasma unit **
N1090	Anti-HBs and Anti-HBc negative plasma unit **
D1097	Anti-TPO positive plasma unit **
D1098	Anti-TG positive plasma unit **
Coming soon!	Ferritin depleted plasma D-Dimer depleted plasma



- Available in a sample starter kit
- New products - evaluation samples available

Biologicals & Biospecimens

Product Code	Description
991-03	Urine
991-19	Cerebrospinal fluid
991-25	Vaginal swabs
991-10	Vaginal fluid
991-05	Saliva
991-13	Nasal fluid
991-26	Nasal wash
991-17	Sputum
991-18	Fecal/stool
991-43	Rectal swab
991-31	Nasal swab
991-63	Lesion swab
991-24	Serum (small volume)
991-58	Plasma (small volume)



Biologicals, Biospecimens, Base Matrices Catalog and Customization Matrix available through the Resources Hub: medixbiochemica.com/resources or by request at biologicals@medixbiochemica.com

Medix Biochemica

The Qualified Supplier to the IVD Industry

IVD test manufacturers across the globe trust Medix Biochemica as their partner of choice for IVD raw materials

Medix Biochemica's critical IVD raw materials enable our partners to manufacture diagnostic tests that support global health.

**Limited time offer for FREE
samples of selected
infectious disease products**



Quality



Supply Reliability



Scientific Innovation

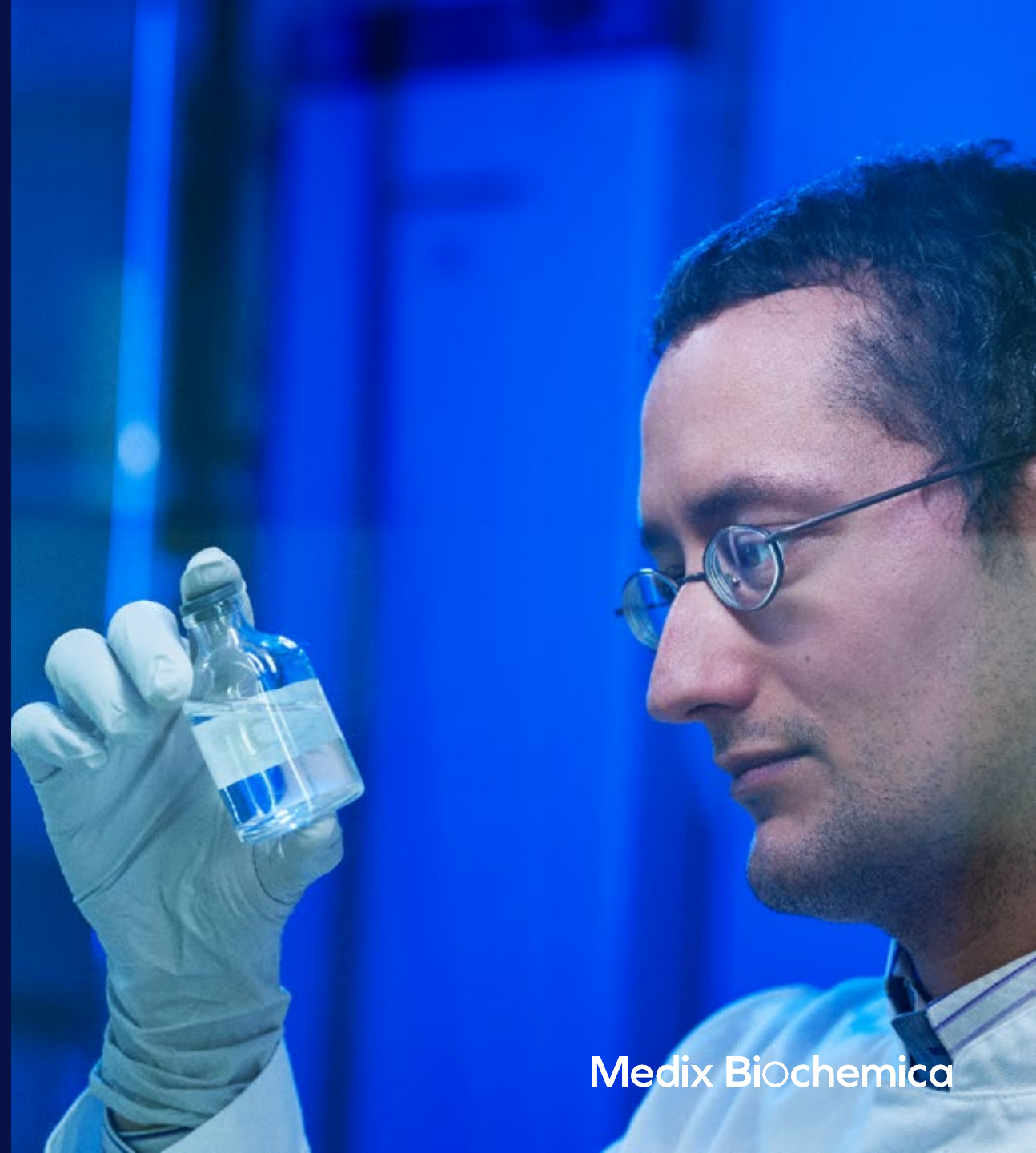


Comprehensive Portfolio



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Share your feedback:



Medix Biochemica

Questions and Answers



Richard Campbell

Founder and Managing Director
Lateral Dx



Amy Moore

Global Product Manager
Medix Biochemica



Thank you

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