

**The right test
at the right time**





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Healthcare challenges and solutions



Today, challenges in healthcare are **more acute** than ever before



Reimbursement
challenges



Rising cost



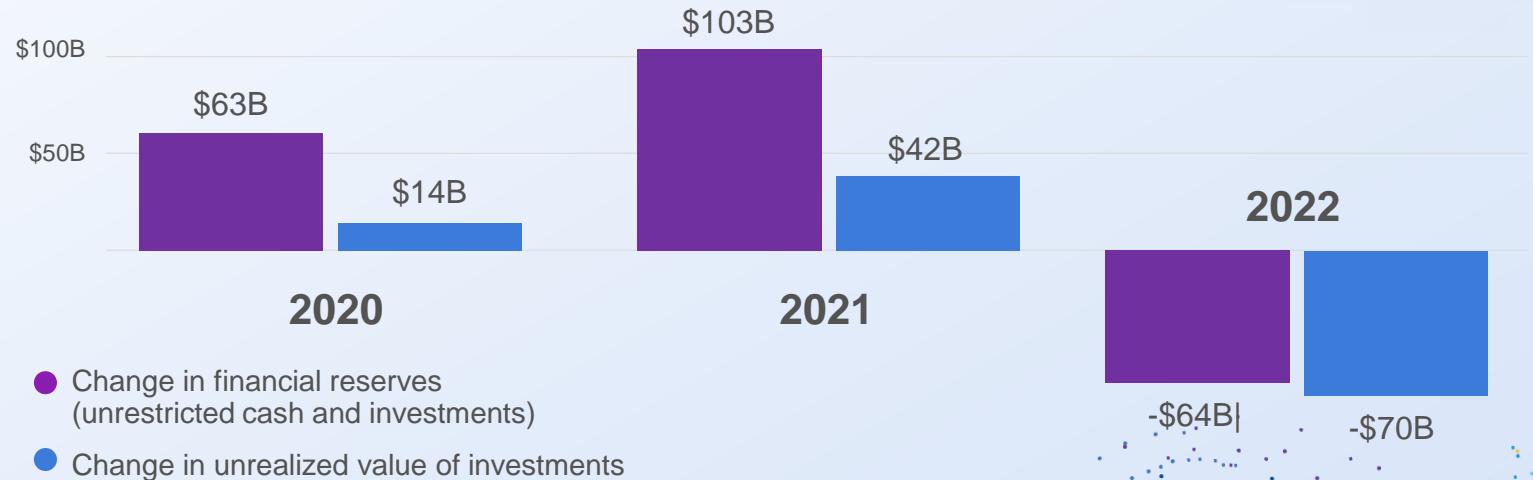
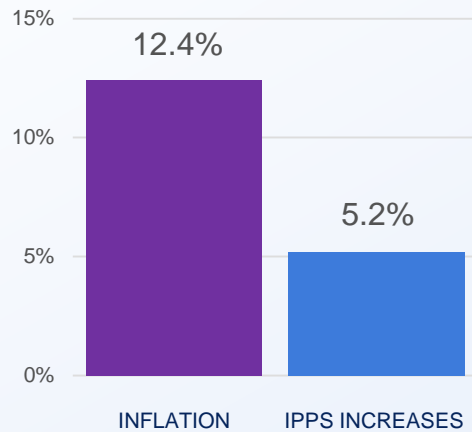
Staff
shortages

Massive growth in expenses and rising inflation fuel continued financial challenges for America's Hospitals and Health Systems*



Economy-wide inflation grew by 12.4% between 2021 and 2023 - more than 2X faster than Medicare reimbursement for hospital inpatient care*

Financial reserves for nonprofit hospitals and health systems analyzed fell with the value of stocks and other investments in 2022 that have likely stabilized or increased with 2023 market improvements. **

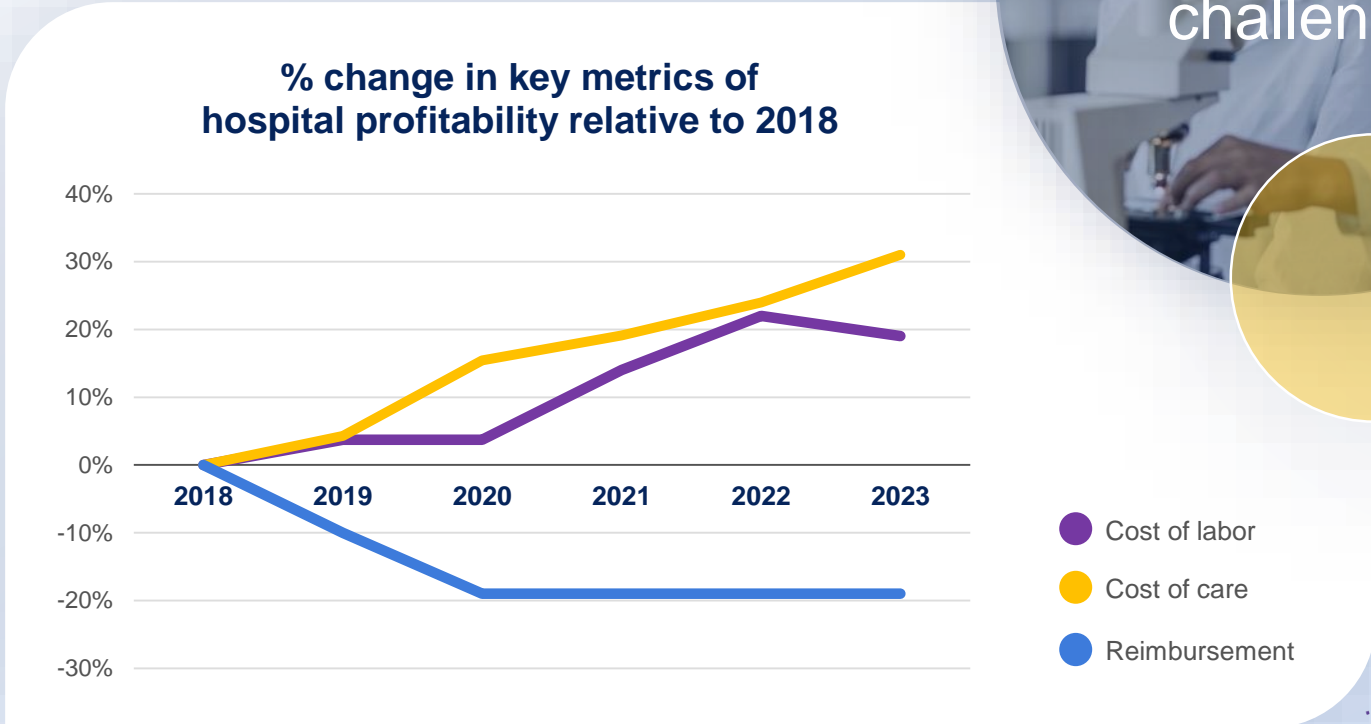


*Costs of Caring | AHA

**KFF Analysis of S&P Global RatingsDirect Data, 2019-2022

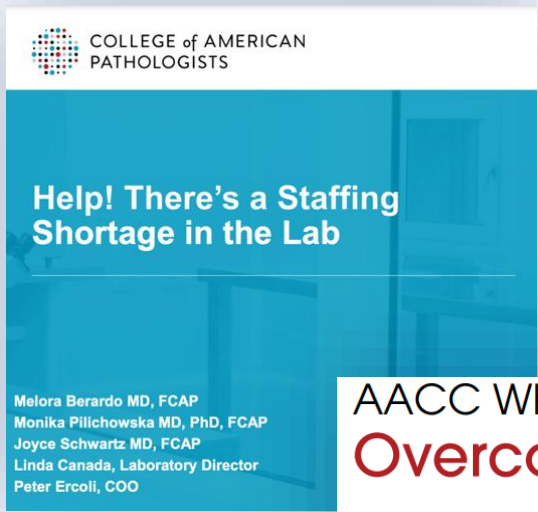
Respiratory Panels coverage is limited to when targeted testing is not appropriate and according to the patient condition

LCD - MoIDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39038) (cms.gov)



All data normalized compared to 2018 to align on the same scale

Volume of testing and test menus continue to grow, but the workforce is aging and is retiring at a rate that outpaces annual growth



AACC Whitepaper on **Overcoming Lab Staffing Shortages**

Developed for AACC by the Policy & External Affairs Core Committee and Clinical Laboratory Scientists Council

Authors: Erika Deaton-Mohney MT(ASCP), CPP; Sharon Ehrmeyer, PhD, MT(ASCP); Christopher Farnsworth, PhD, DABCC; Theresa Kunzler, MS, MT(ASCP); Frederick Strathmann, PhD, DABCC; & Monica Thomas, MPA, CLS(ASCP)

ASCP STRONGERTOGETHER

The Medical Laboratory Personnel Shortage
(Policy Number 04-04)

Policy Statement

ASCP believes that the severity of the medical laboratory personnel shortage requires the creation and development of federal policy initiatives such as grant programs, service learning, continuing education, and public service announcements.

AACC Whitepaper on Overcoming Lab Staffing Shortages | myadlm.org

Laboratories define strategies to face the challenges

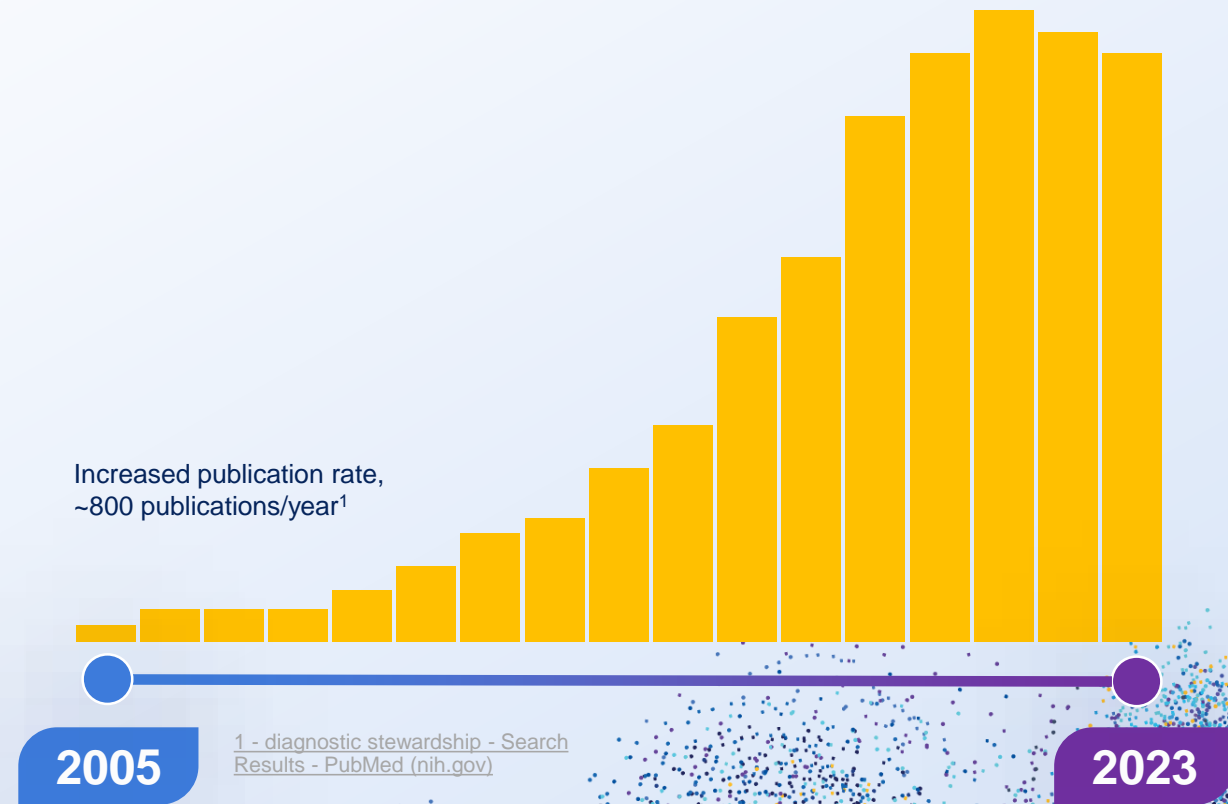
Focus on cost optimization, reducing redundant testing

Choose tests that are automated, easy, flexible

Optimize for best clinical value

Strategies are executed by implementing diagnostic stewardship initiatives

Diagnostic stewardship aims to ensure that the correct test is ordered for the right patient at the right time, and to prompt the right action



Why is it advocated?

Practice **testing appropriateness** for the patient's condition and the pre-test probability of the suspected disease **to prevent unnecessary testing and reduce healthcare costs and make informed decisions that lead to better patient outcome**¹

Choosing Wisely[®]

An initiative of the ABIM Foundation

IDSA
Infectious Diseases Society of America



AMERICAN
SOCIETY FOR
MICROBIOLOGY



*Diagnostic stewardship interventions that **make a difference***



1 - American Society for Microbiology

Algorithms (workflow) are the outcome of diagnostic stewardship initiatives

Institutions design algorithms (workflow) that provide **best clinical value, optimizing costs and increasing staff efficiencies**

Diasorin's answer to molecular stewardship



*currently in development. Not available for sales

Combination of several variables determines the best testing approach

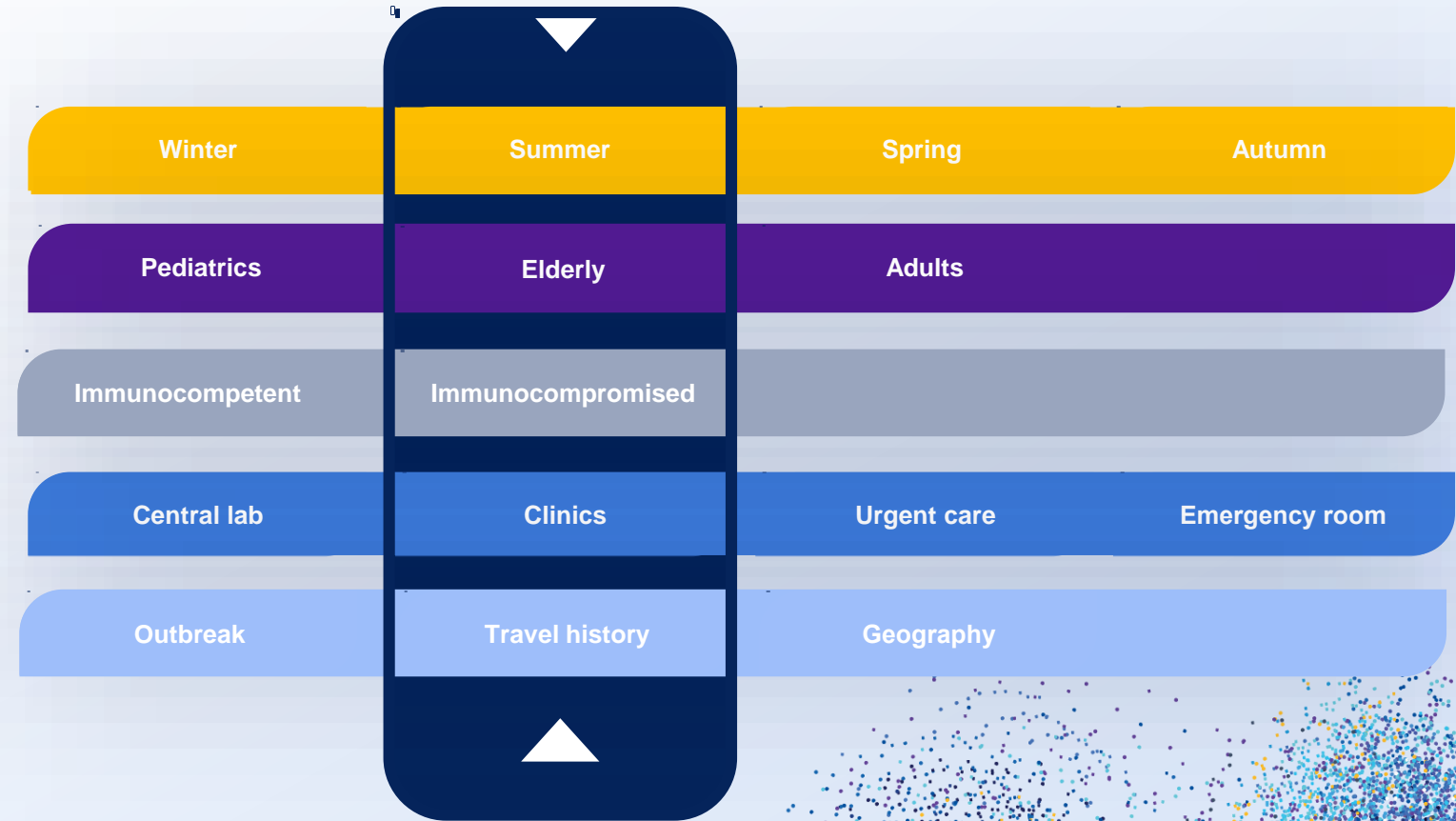
Seasonality: winter, summer, spring, autumn

Patient profile: pediatrics, elderly, adults

Immunesystem: immunocompetent, immunocompromised

Setting: central lab, clinics, urgent care, emergency room

Prevalence: outbreak, travel history, geography



Current **solutions** utilize the tools available on the market to answer the **challenges** in the best possible way...

... but there is room for improvement to accomplish the mission in an optimal way

Customization

Ease of use,
automation

Ability to
adapt to the
specific case

Flexibility

Optimal diagnostic stewardship



Molecular market landscape and our strategy



Diasorin's answer to molecular stewardship



*currently in development. Not available for sales

LIAISON PLEX®

LIAISON PLEX®

Random access

Scalable

Touchscreen interface

Room temperature storage

Sample-to-answer workflow

Flex Testing



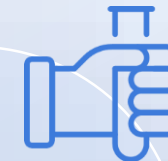
LIAISON PLEX[®]



Fully Integrated Cartridge



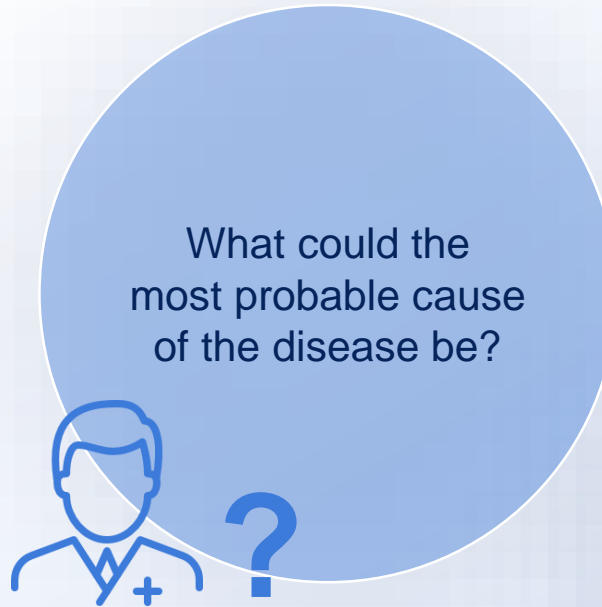
Proven NanoGrid Technology



Ambient Storage

Flexibility

Finding the positive pathogen with **minimal financial burden**

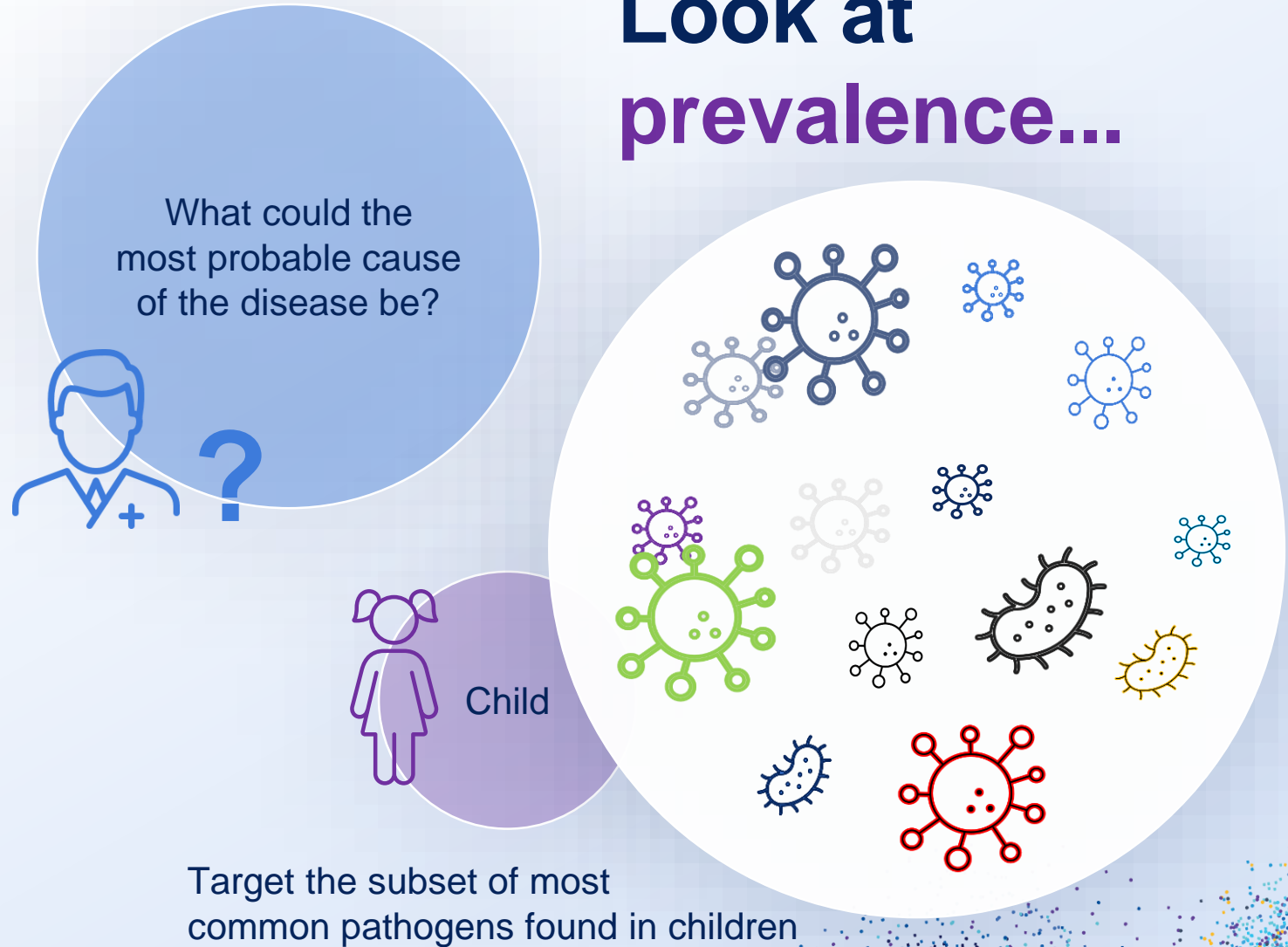


Look at prevalence...



Flexibility

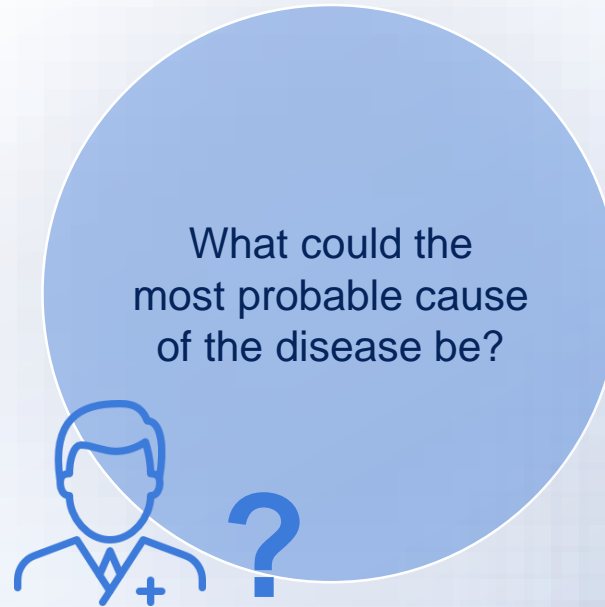
Finding the positive pathogen with **minimal financial burden**



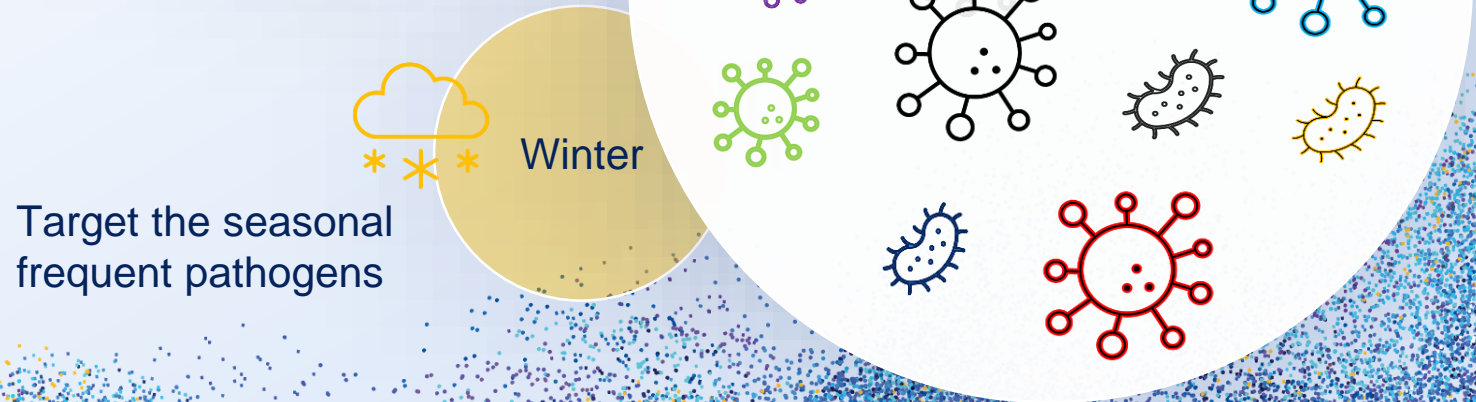
Look at prevalence...

Flexibility

Finding the positive pathogen with **minimal financial burden**

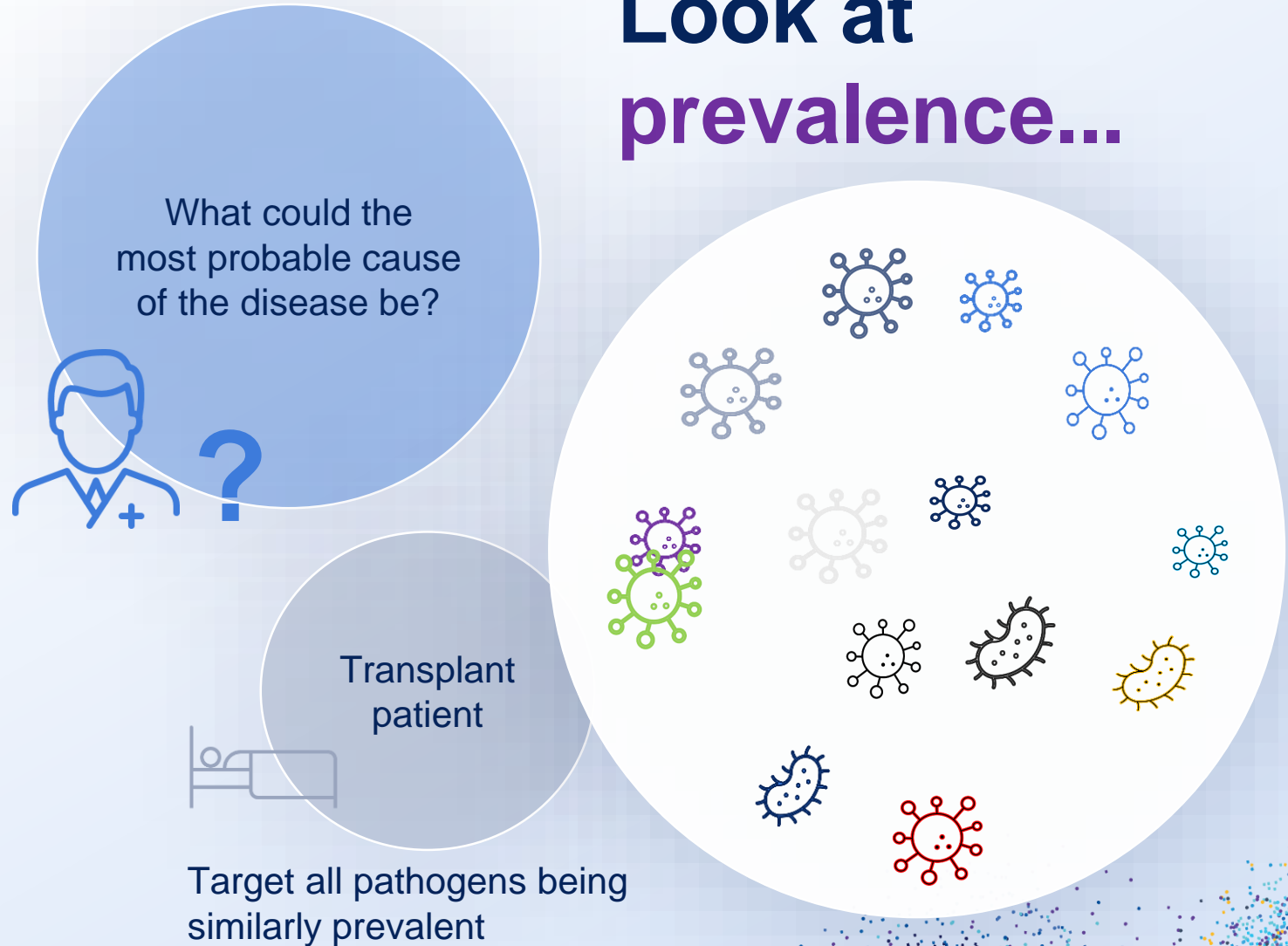


Look at prevalence...



Flexibility

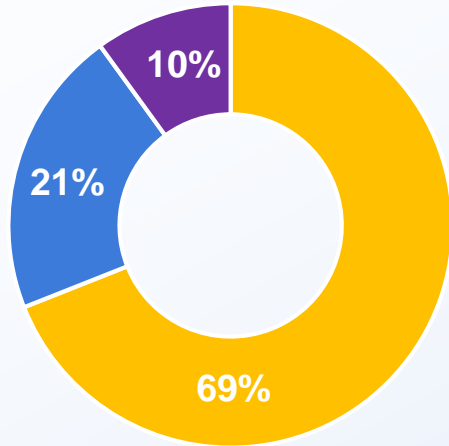
Finding the positive pathogen with **minimal financial burden**



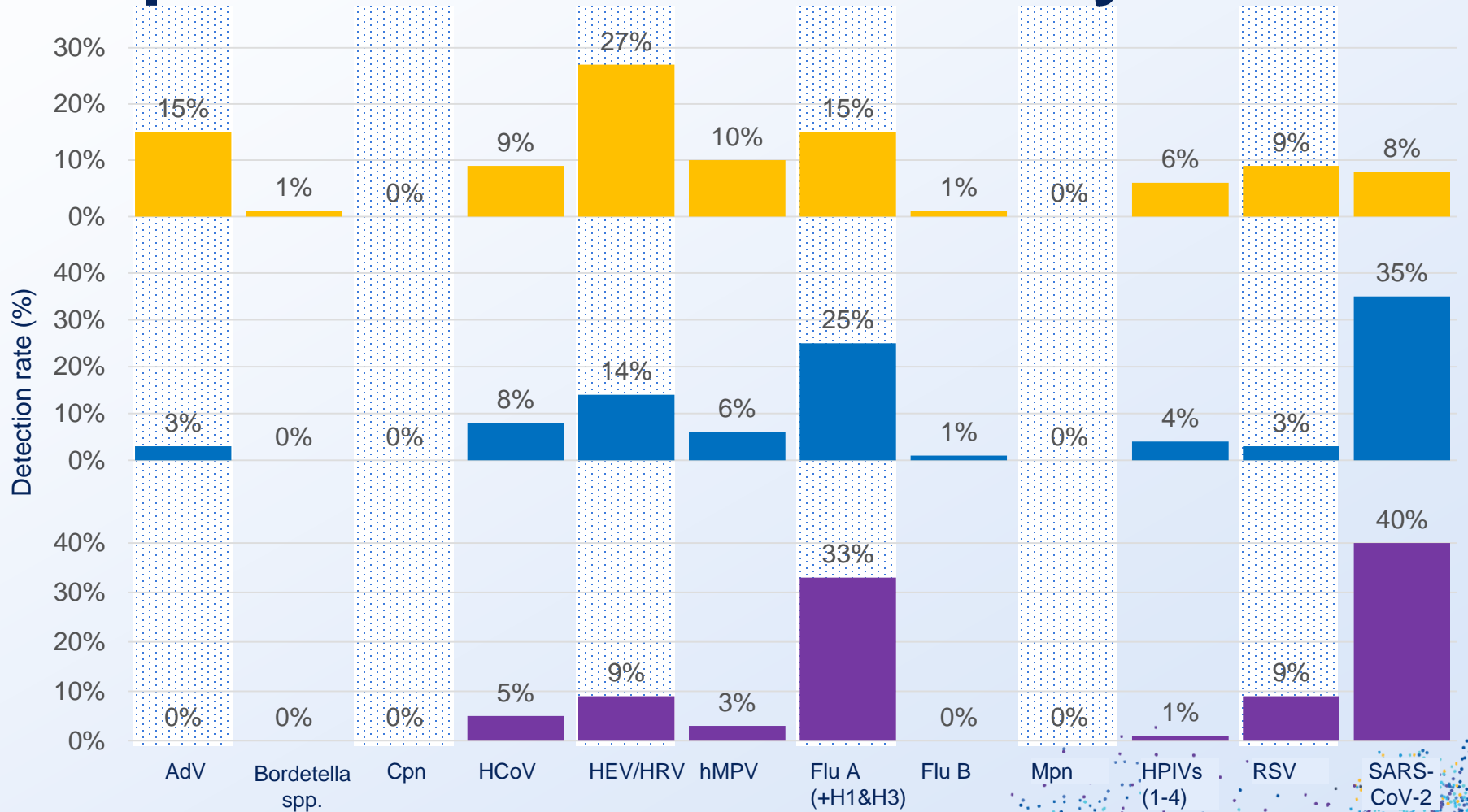
Look at prevalence...

PLEX RSP Prospective Clinical Data Analysis

The probability of infection by respiratory pathogens varies by age



- Young (0 - 21y)
- Adult (21 - 65y)
- Elderly (> 65y)



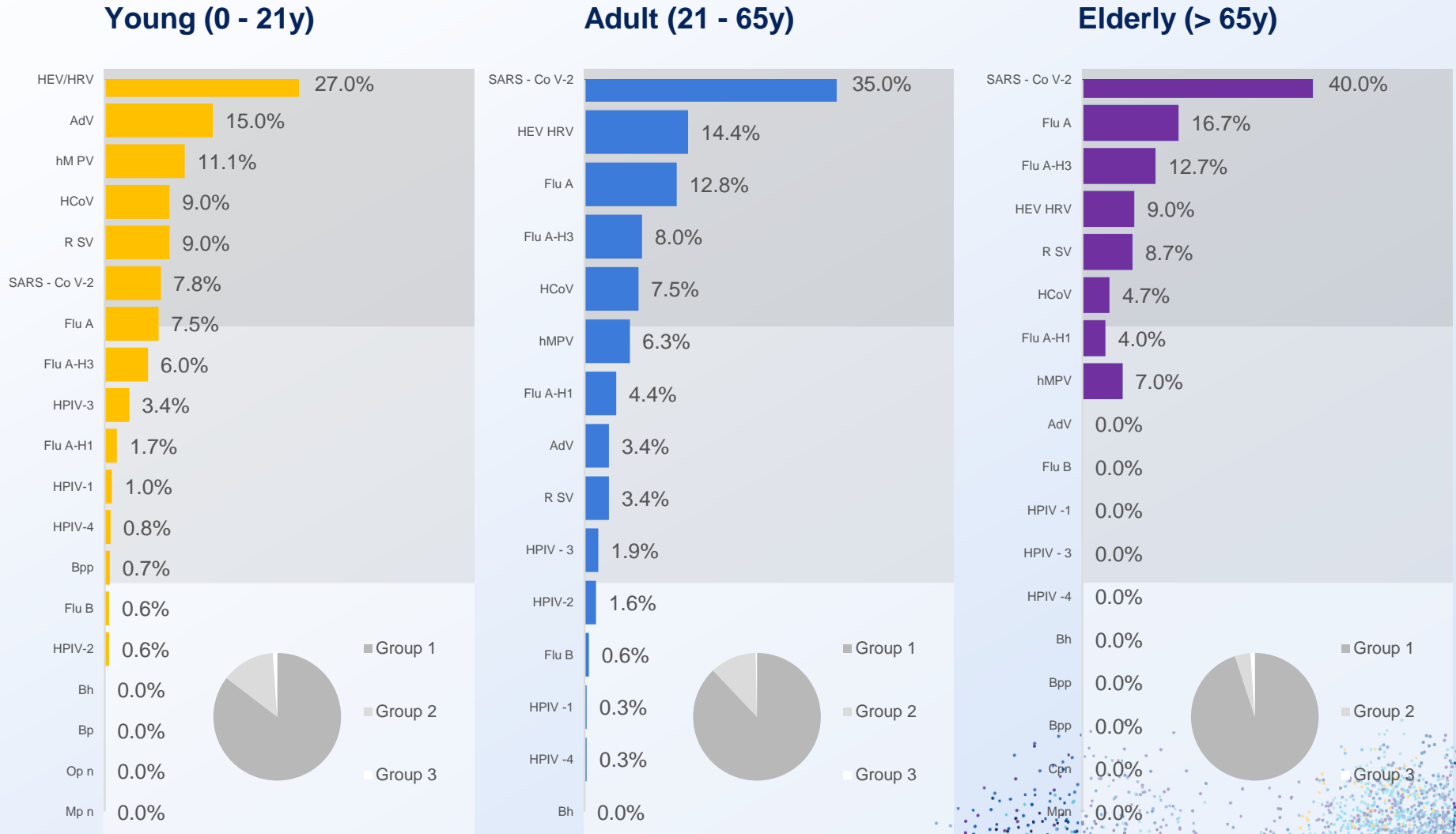
PLEX RSP – 510(k) Prospective Clinical Data Analysis

Prospective Clinical Data Analysis

There is a common set of 7 panel targets that can serve as a base for each age group.

Beyond that, target selection may vary depending on age, prevalence & other factors.

Detection rate (%)



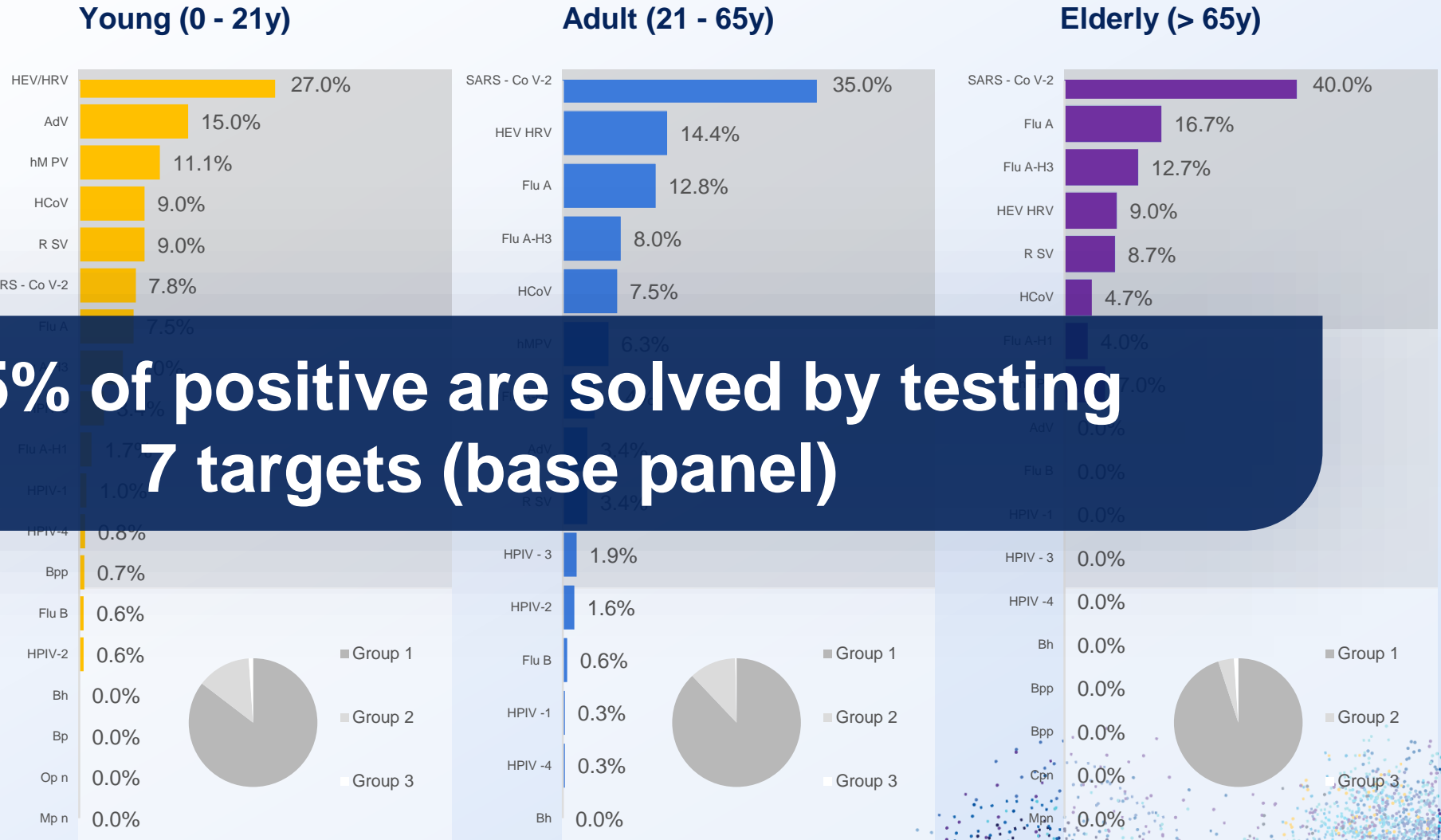
Prospective Clinical Data Analysis

There is a common set of 7 panel targets that can serve as a base for each age group.

Beyond that, target selection may vary depending on age, prevalence & other factors.

85-95% of positive are solved by testing 7 targets (base panel)

Detection rate (%)



ADLM guidance on lab diagnosis of respiratory viruses

“**The fixed nature of the multiplex PCR panels raises the concern** that they might include pathogens that the clinician does not want to test for. Ideally, common pathogens should be tested first followed by testing for uncommon pathogens.”

"Besides influenza, RSV, and SARS-CoV-2 NAATs, clinicians are currently unable to order targeted PCR for any other respiratory viral pathogen except possibly using LDTs; hence, **there is no choice left but to order the multiplex PCR panels**. To prevent overutilization of rapid multiplex viral panels by clinicians in low-impact situations, indication selection using restrictive or guided test ordering built into the electronic medical records can be used.”

"Diagnostic stewardship aims to select the right test for the right patient, generating accurate, clinically relevant results at the right time to guide appropriate clinical behavior, while conserving healthcare resources (167). Selection of the right test involves the evaluation of test performance, testing volume, laboratory feasibility, **cost vs value**, and the overall impact on clinical outcomes."

Source: ADLM Guidance Document on Laboratory Diagnosis of Respiratory Viruses, May 2024 | 09:03 | 599–628 | JALM

FIXED and FLEX approach

Fixed approach - TRADITIONAL

When all targets are needed every time

Less control over ordering patterns and algorithms

When patient is highly critical

When patient population is largely immunocompromised

Offered by
COMPETITORS and PLEX



Flex approach - NOVEL APPROACH

When customers implement diagnostic stewardship initiatives – algorithms

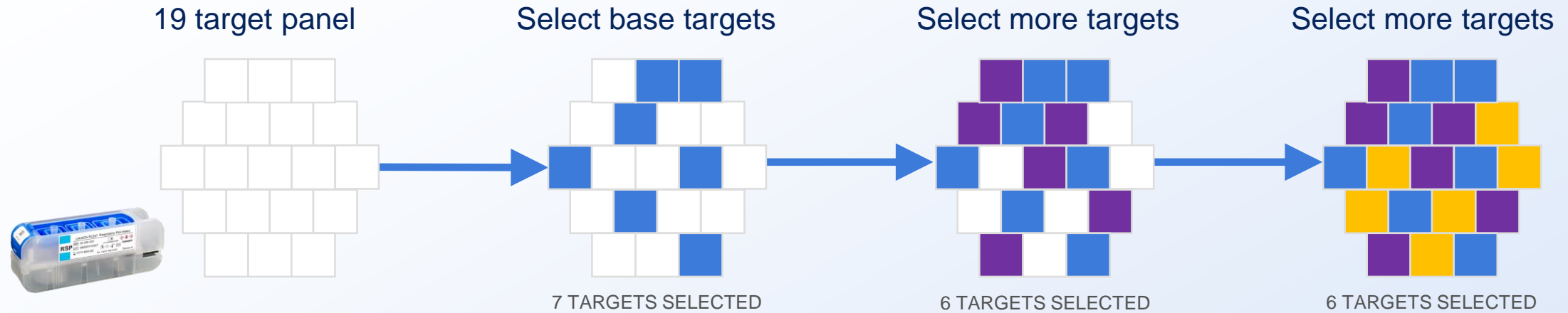
When customers want to have more control over rising costs

Instantaneous reflex to provide a strategic approach to syndromic testing

When operations need to be streamlined (digital sample)

Offered
ONLY by PLEX

Flex Testing Explained



Flex credits

100

Buy kits (@base price)
Buy credits

Flex credits

100

7 results
(included in base price)

Flex credits

95

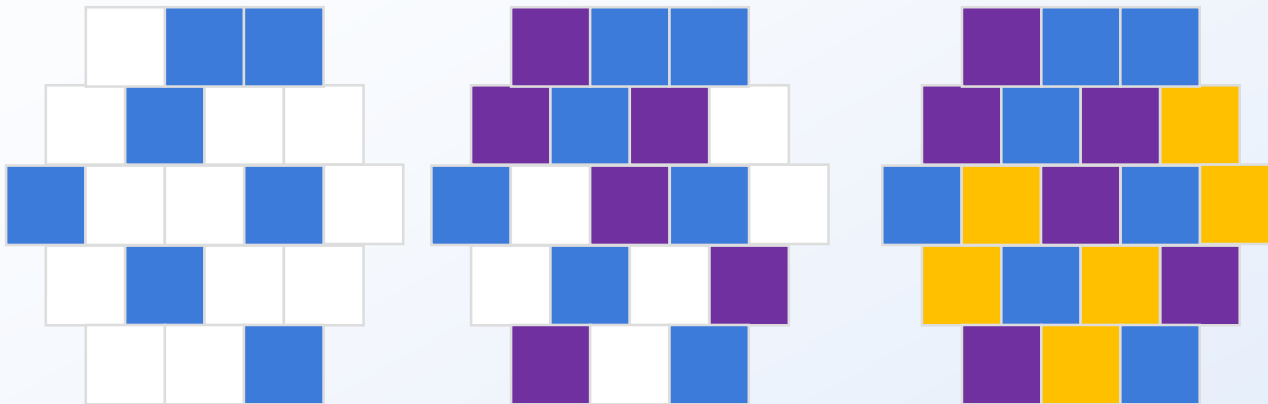
+6 results
(using 5 credits)

Flex credits

90

+6 results
(using 5 credits)

Flex Testing Explained



Flex testing is applicable to:

Number of targets

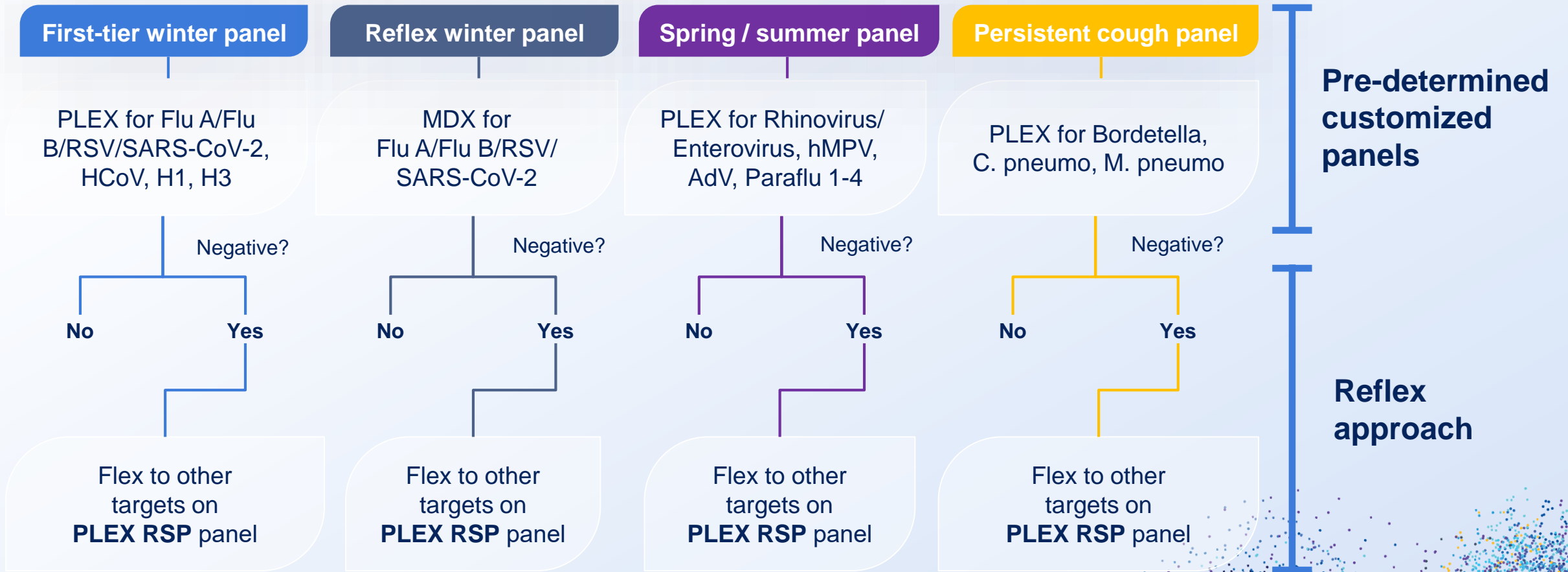
Type of targets

Flexible testing can be leveraged in different ways

Selecting high probability targets and **reflex** to subsequent tiers

Pre-determined **customized** panels based on algorithms

Examples of how LIAISON PLEX[®] Respiratory Flex can be used to maximize clinical utility



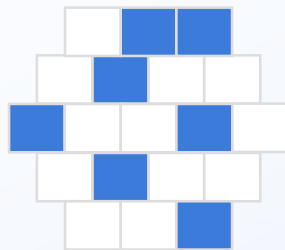
Cost optimization

Simulation based on Clinical Study Data (LIAISON PLEX RSP *Flex* IFU)

PLEX

1000 positive patients

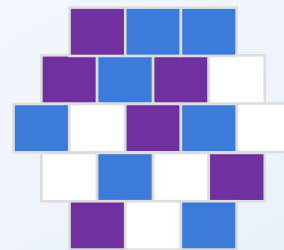
Select 7 most prevalent targets



\$

10% negative (instant reflex)

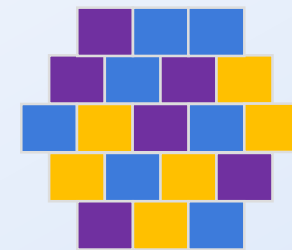
Select additional 6 targets



\$\$

0.5% negative (instant reflex)

Select additional 6 targets

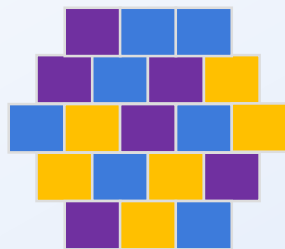


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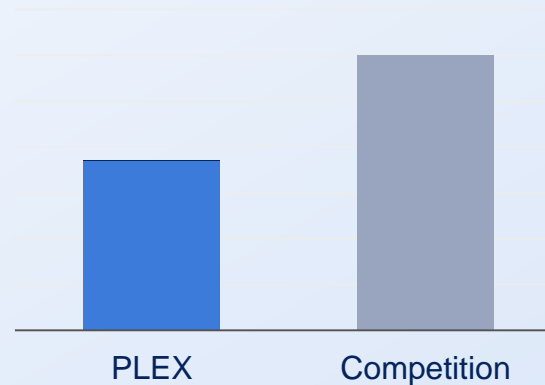
COMPETITION

1000 positive patients

Run full panel (all targets)



\$\$\$

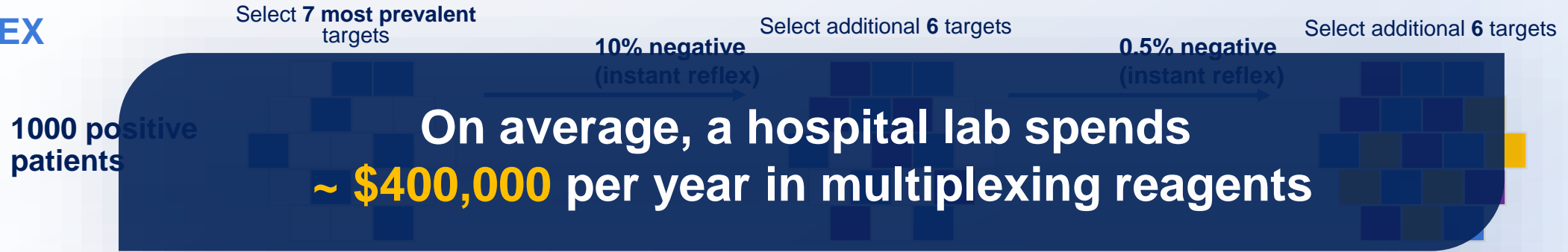


~40% cost saving using LIAISON PLEX[®] flexible approach

Cost optimization

Simulation based on Clinical Study Data (LIAISON PLEX RSP Flex IFU)

PLEX



COMPETITION



Impact on reimbursement

OUTPATIENT



Not admitted to the Hospital
Not hospitalized overnight

~50%¹ of testing

Test is **REIMBURSED** based on **CPT codes**



INPATIENT



Admitted to the Hospital
Spend at least one night in the hospital

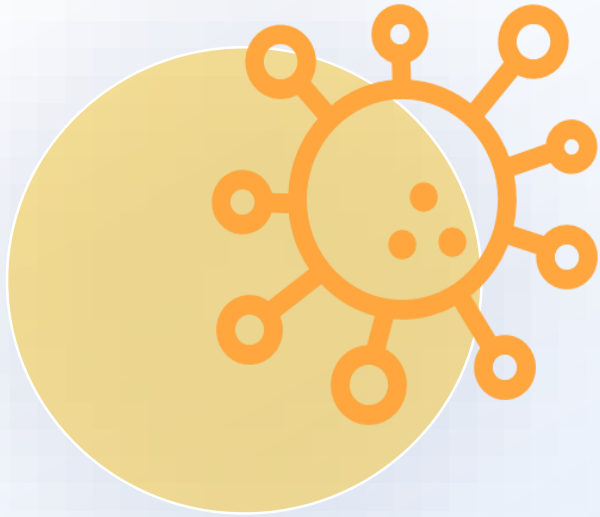
~50%² of testing

Test is not reimbursed, but **COVERED UNDER DRG***

1. Definitive Healthcare Market Procedure Overview 2023
2. DeciBio ID Dx Book 2023

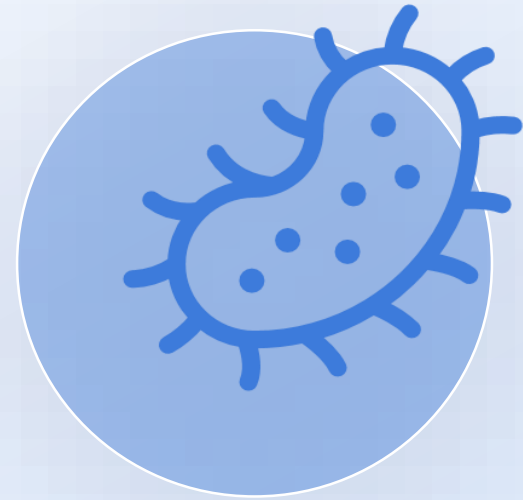
*Diagnosis-Related-group

Reimbursement (outpatient)



VIRUS

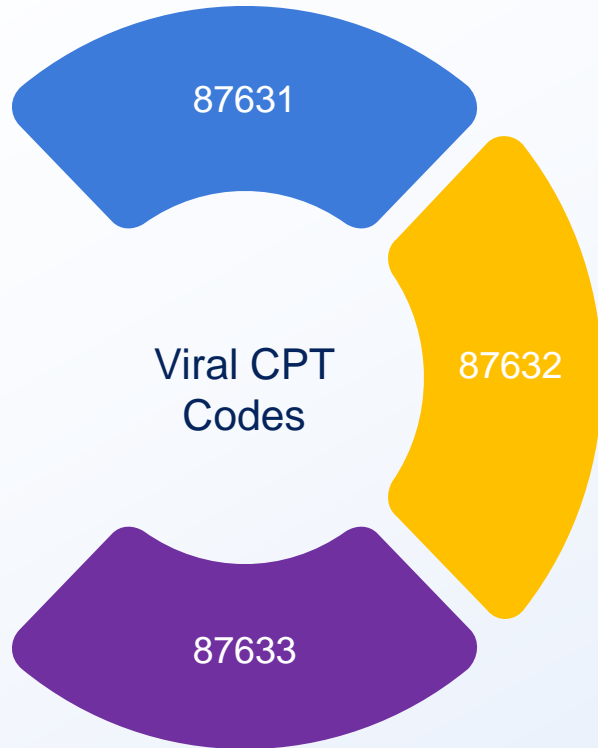
VS.



BACTERIA



Reimbursement (outpatient)



87631

- 3-5 Respiratory Viral Targets
 - \$ 142.63
- Covered for ~90% of patients**

87632

- 6-11 Respiratory Viral Targets
 - \$ 262.99
- Covered for <10% of patients**

87633

- 12-25 Respiratory Viral Targets
 - \$ 416.78
- Covered for <10% of patients**

Medicare database

Panel coverage limitations:

Can be used when targeted testing is not appropriate

Immunocompromised patients

When requested by an ID specialist

The value is also beyond respiratory

Hospitals are waiting for customizable GI options

#targets (viruses/Bacteria)



LIAISON PLEX®

Gastrointestinal Flex
Assay (*)

24 Targets
11 bacteria
5 viruses
8 parasites

Flexible

Key differentiative value of PLEX

- Flexibility and customization
- Wide parasites coverage

(*) in development

Hospitals are waiting for customizable GI options



A perfect Midwest GI panel...

+ Appropriate risk factors (travel/exposure)

- + *Vibrio* spp
- + *Plesiomonas shigelloides*
- + *Cryptosporidium* spp
- + *Giardia lamblia*
- + *Entamoeba histolytica*
- + *Cyclospora cayatanensis*
- + *Strongyloides stercoralis*

"Default panel"

- Salmonella* spp
- Shigella* spp
- Campylobacter* spp
- Yersinia enterocolitica*
- Escherichia coli* O157:H7/STEC
- Aeromonas* spp
- Norovirus
- Rotavirus
- Vibrio* spp
- Plesiomonas shigelloides*
- Cryptosporidium* spp
- Giardia lamblia*
- Entamoeba histolytica*
- Cyclospora cayatanensis*
- Strongyloides stercoralis*

C. difficile

+ Pediatric population

- + Adenovirus 40/41
- + Astrovirus
- + Sapovirus
- + Shiga toxin 1
- + Shiga toxin 2

+ Immunocompromised population

- + Microsporidium
- + *Cryptosporidium*, *Cyclospora*, *Cystoisospora*
- + *Mycobacterium avium* complex
- + Cytomegalovirus
- + *Strongyloides stercoralis*

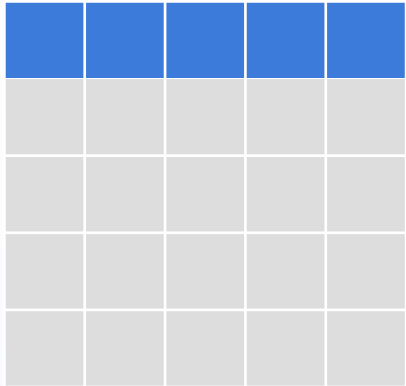
Haessler S, Granowitz EV. N Engl J Med. 2013
Shane, AL et al, Clinical Infectious Diseases, 2017.
European guidelines

“How do we come to consensus on the right number and makeup of panels for specific patient populations. We can’t – so please give us the option to customize”

Presentation by R. Dumm at PASCV.
(Pan American Society for Clinical Virology) May 2024.

Flex testing in GI

Viruses



Summer



Winter



Travel history



Children



Food exposure

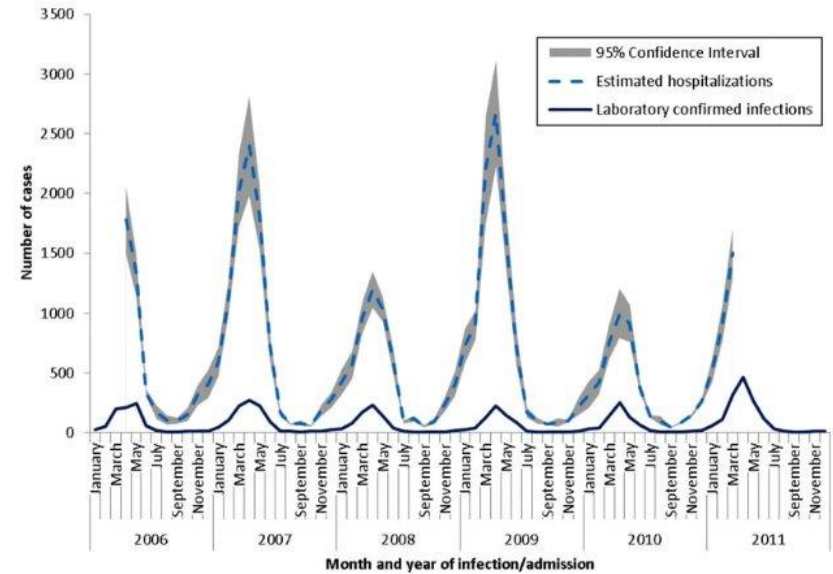
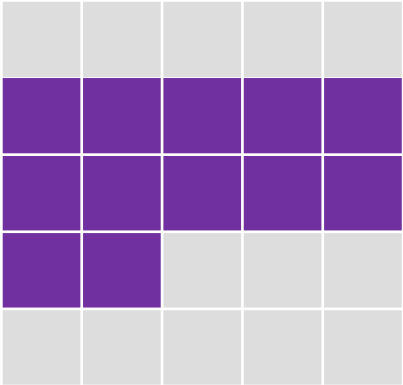


Fig. 3. Seasonal distribution of laboratory-confirmed rotavirus infections reported to the National Enteric Surveillance Program (NESP) and estimated rotavirus hospitalizations by month and year of admission, 2006–2011.

Flex testing in GI

Bacteria



Summer



Winter



Travel history

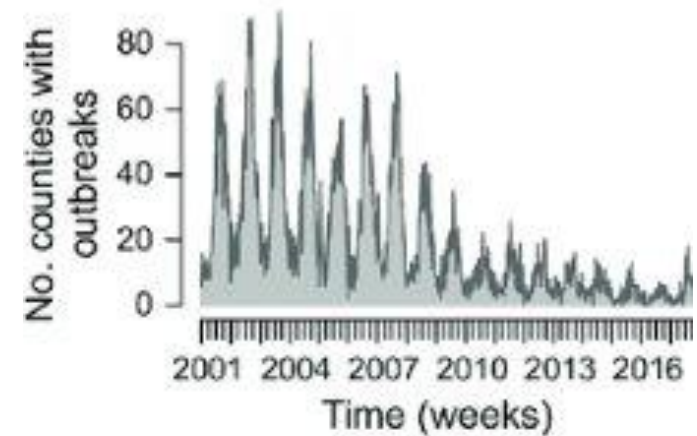


Children



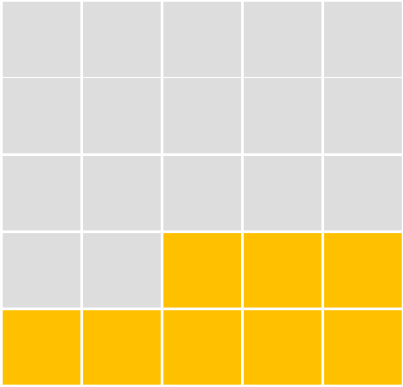
Food exposure

Salmonella



Flex testing in GI

Parasites



Summer



Winter



Travel history



Children



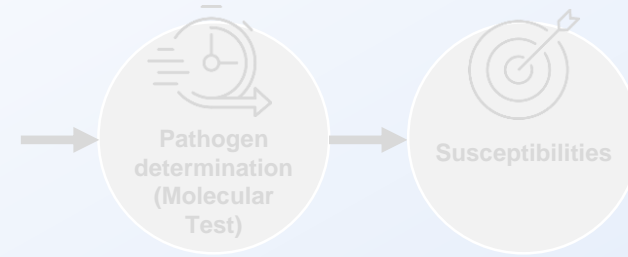
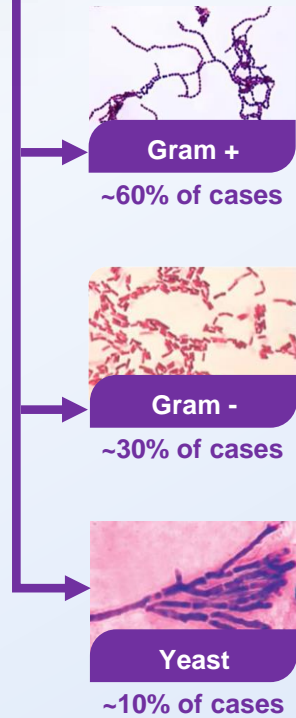
Food exposure

Blood culture

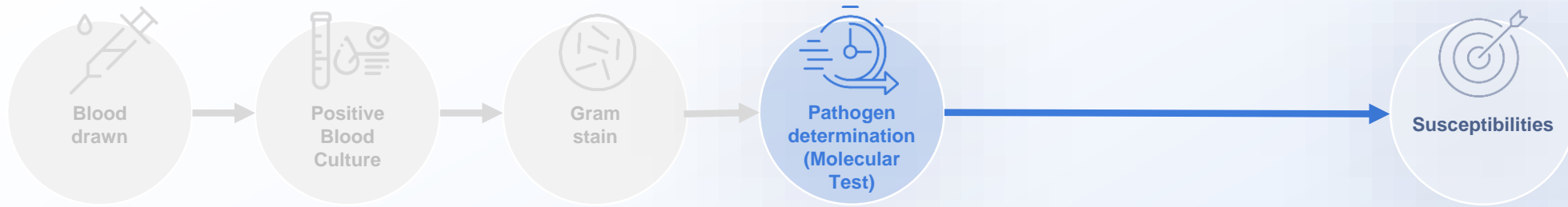
Blood Stream Infections









Gram Stain to determine the most appropriate clinical choice



Blood Stream Infections



 <p>Gram + ~60% of cases</p>	 <p>LIAISON PLEX® BC Gram+ Assay*</p>
 <p>Gram - ~30% of cases</p>	 <p>LIAISON PLEX® BC Gram- Assay*</p>
 <p>Yeast ~10% of cases</p>	 <p>LIAISON PLEX® BC Yeast Assay</p>

3 independent panels
for the most appropriate clinical choice

60 targets



Diasorin LIAISON PLEX®

* In clinical trials

The right time for the right technology: LIAISON PLEX®

Diagnostic Stewardship



Operational Efficiency

Fiscal Responsibility

PLEX but not only PLEX for stewardship

The most flexible solution on market

To achieve the best outcome, diagnostics have to be optimized based on:

- Patient
- Season
- Setting

And the tests available should cover both established clinical areas and more niche **specialty ones**



*currently in development. Not available for sales

LIAISON[®] MDX & LIAISON[®] MDX Plus

LIAISON[®] MDX and LIAISON[®] MDX Plus*: the specialty boxes



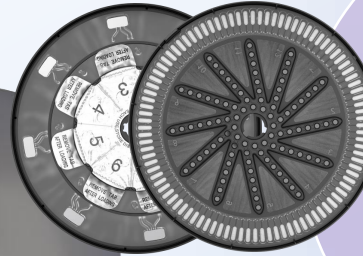
Scalable



Sample-to-answer



CLIA moderate



Open mode capabilities



No need for extraction



Differentiated Menu

*currently in development. Not available for sales

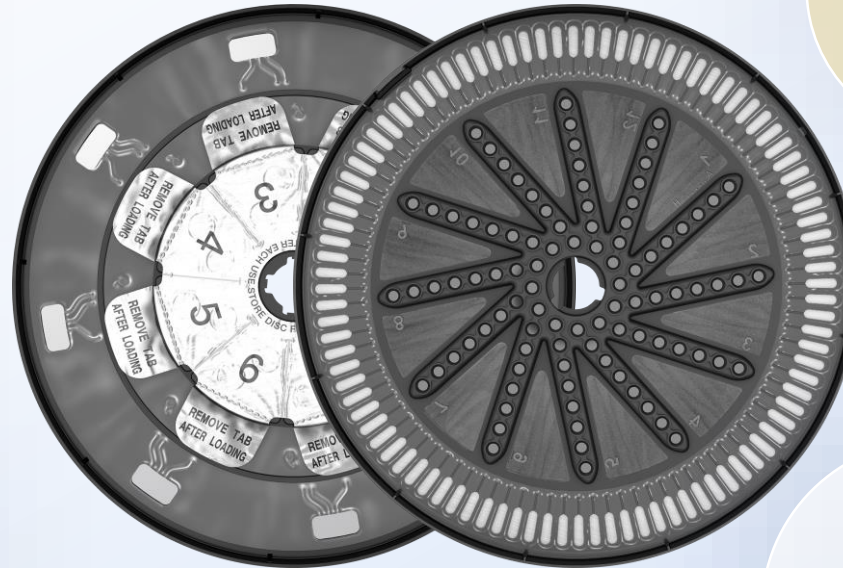
LIAISON[®] MDX assays: targeted specialty menu

Respiratory

Bordetella Direct
COVID-19 Direct FDA cleared
SARS-CoV-2 Variants Direct (RUO)
COVID-19 & Flu A/B Direct
Flu A/B & RSV Direct Gen II
Group A Strep
COVID-19/Flu A/B & RSV Direct (*)
Atypical *Pneumoniae* (*)

Hospital Acquired Infection

C. difficile Direct
C. auris Direct
GBS Direct
Congenital CMV Direct
MRSA/SA Direct (*)



Herpes Viruses

HSV1 & 2 Direct (Swab)
VZV Swab Direct

Meningitis/Encephalitis

HSV1 & 2 Direct (CSF)
VZV Direct (CSF)

Tick Borne Diseases (*)

* Future developments

Candida auris is an urgent threat

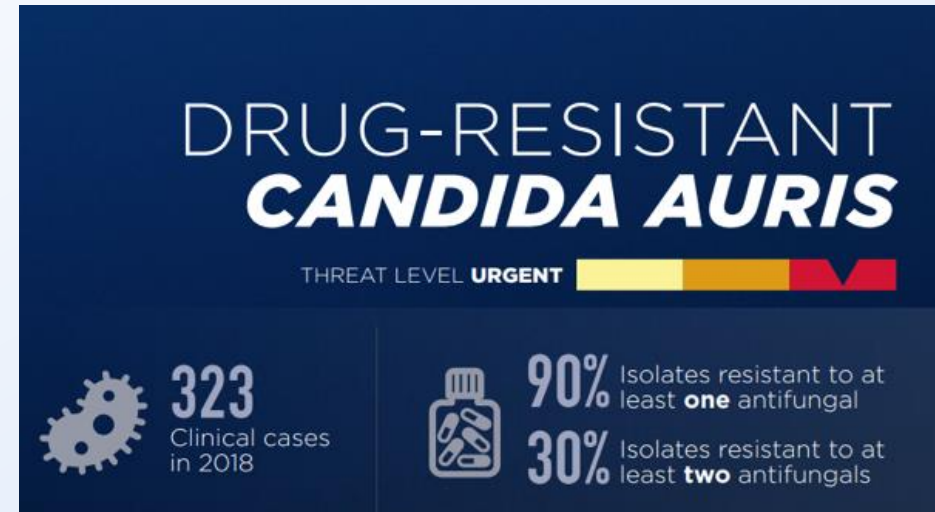
Emerging multidrug-resistant fungus causing life-threatening health-care associated outbreaks.

Rated as an urgent threat by CDC and WHO.

To control the rapidly spreading infections caused by *C. auris*, laboratories must implement identification methods for its diagnosis⁽¹⁾.

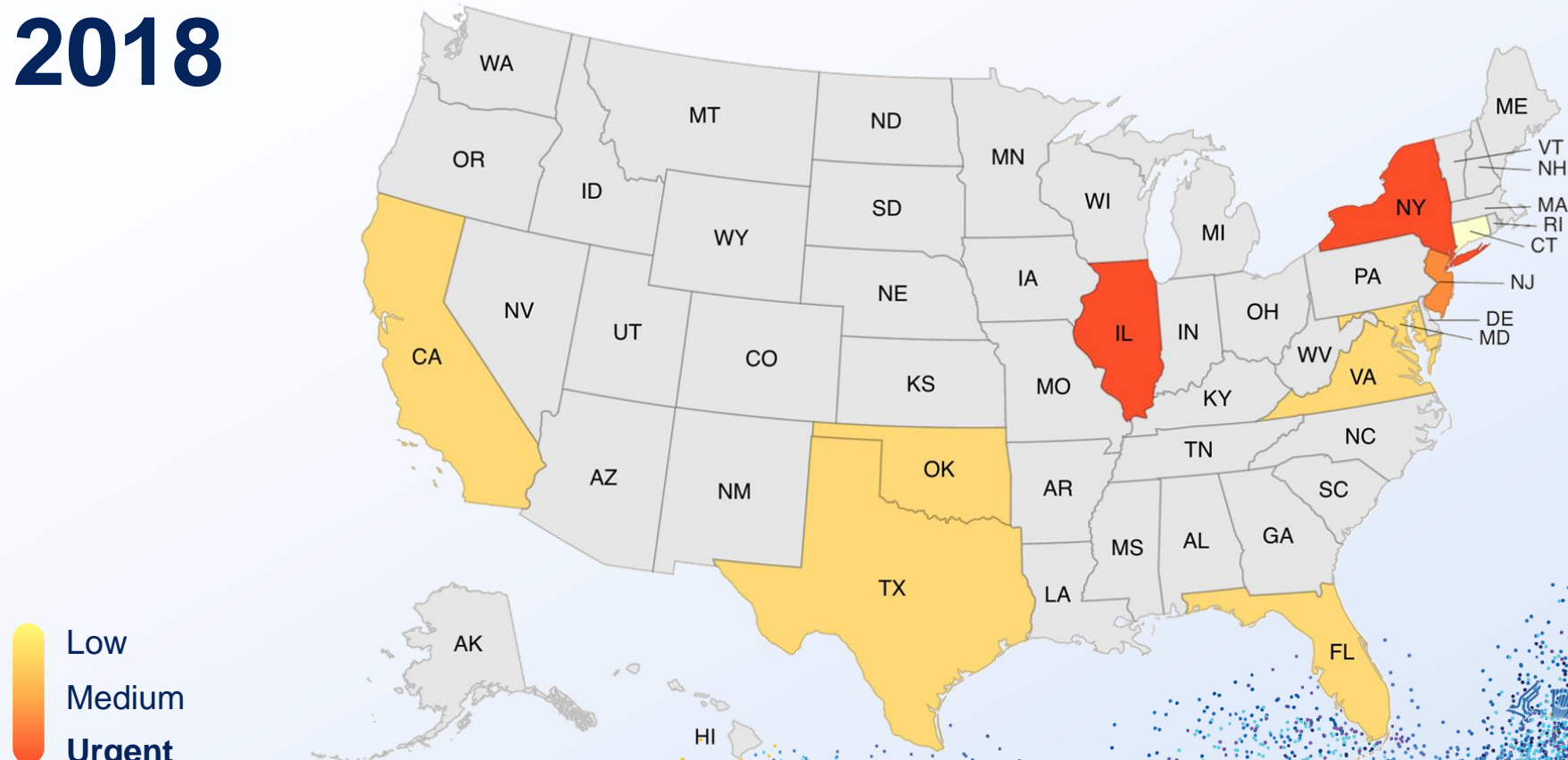
We have **the first FDA cleared molecular assay** on the market for *C. auris* identification

(1) [www.thelancet.com/microbe Vol 4 July 2023](https://doi.org/10.1016/S2666-5247(23)00114-3) [https://doi.org/10.1016/S2666-5247\(23\)00114-3](https://doi.org/10.1016/S2666-5247(23)00114-3)



Candida auris is an urgent threat

2018



10

States

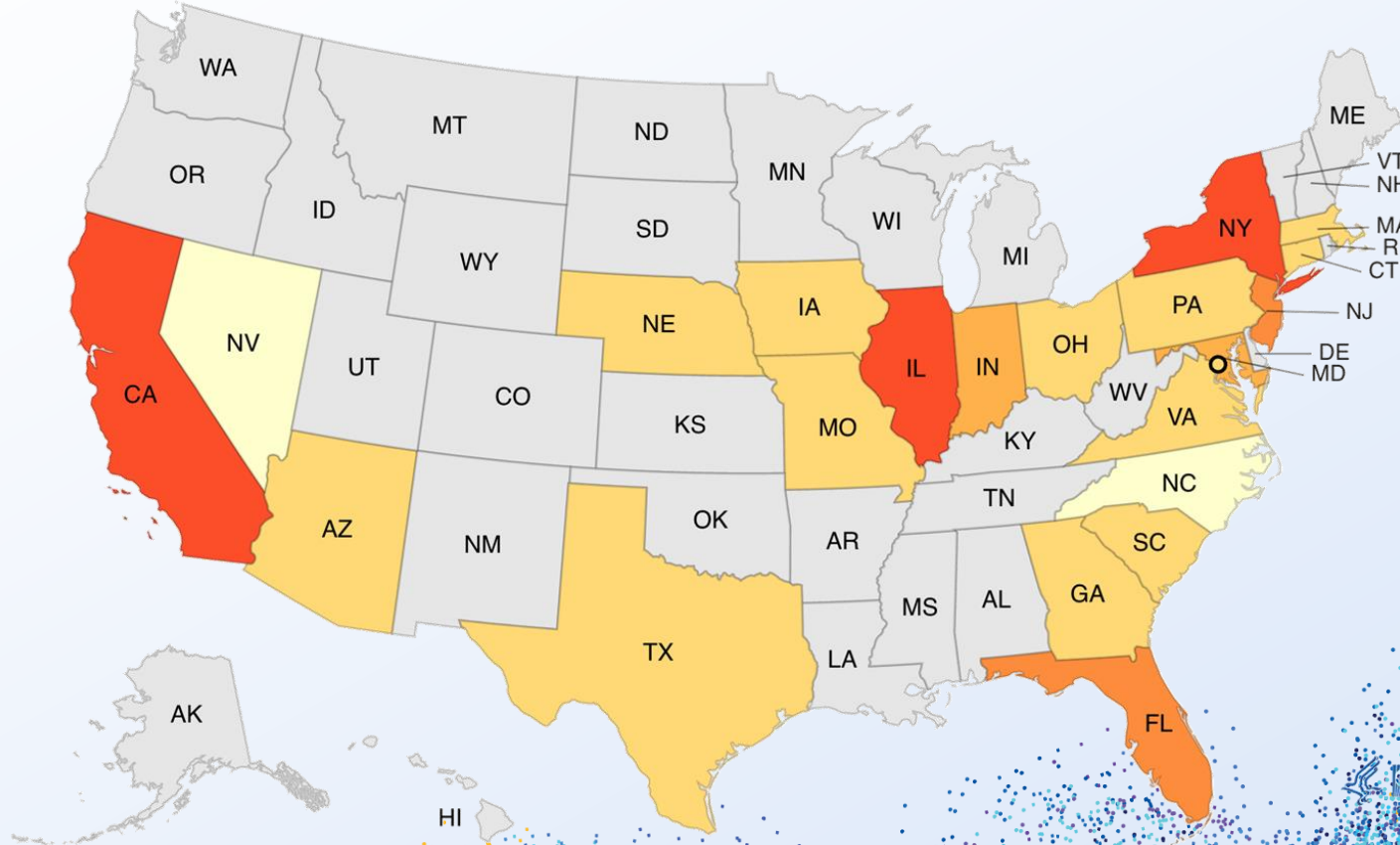
33

Clinical cases



Candida auris is an urgent threat

2020



22

States

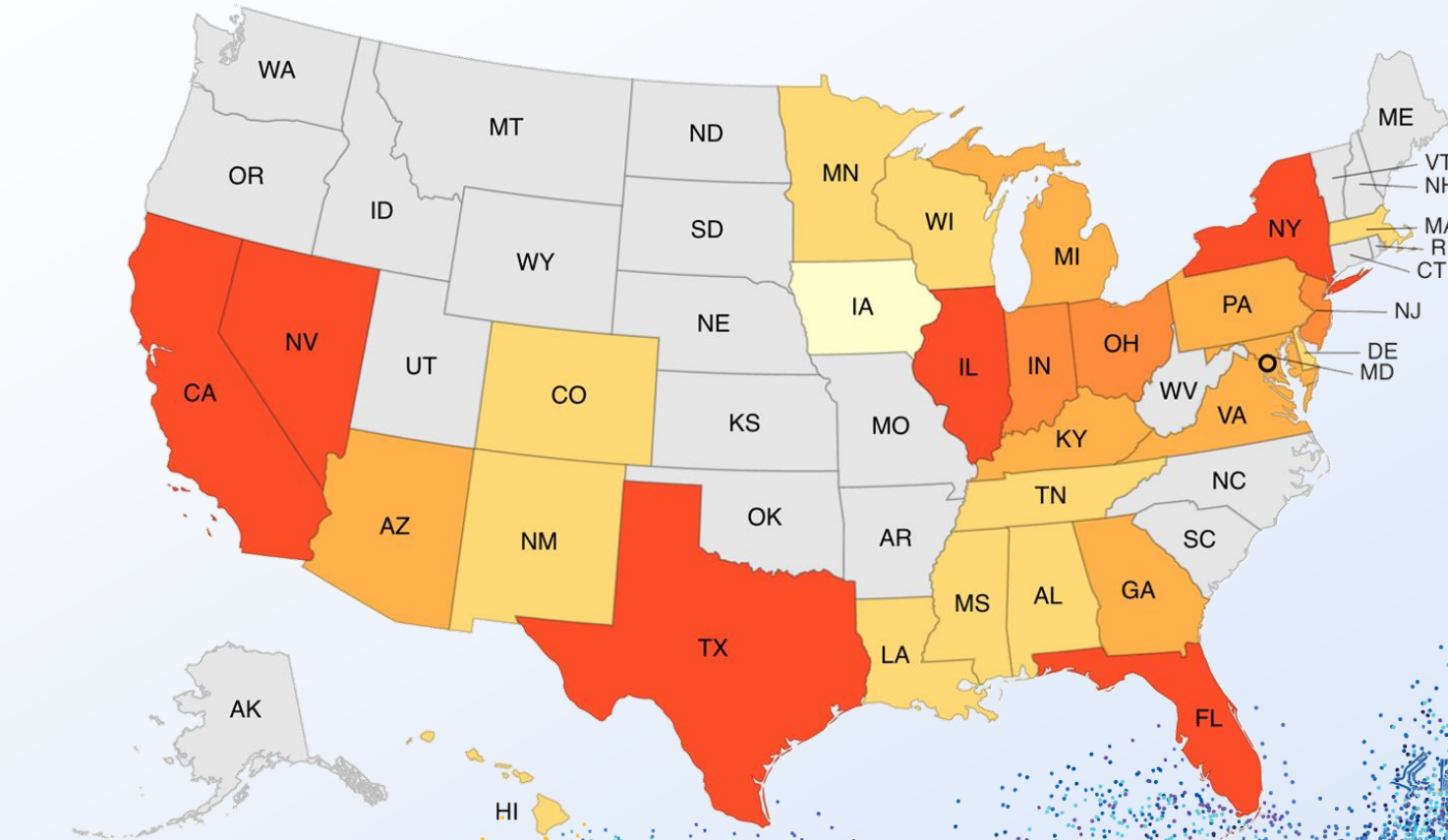
757

Clinical cases



Candida auris is an urgent threat

2022



29

States

2377

Clinical cases



The most flexible solution on the market

To achieve the best outcome, diagnostics have to be optimized based on:

- Patient
- Season
- Setting

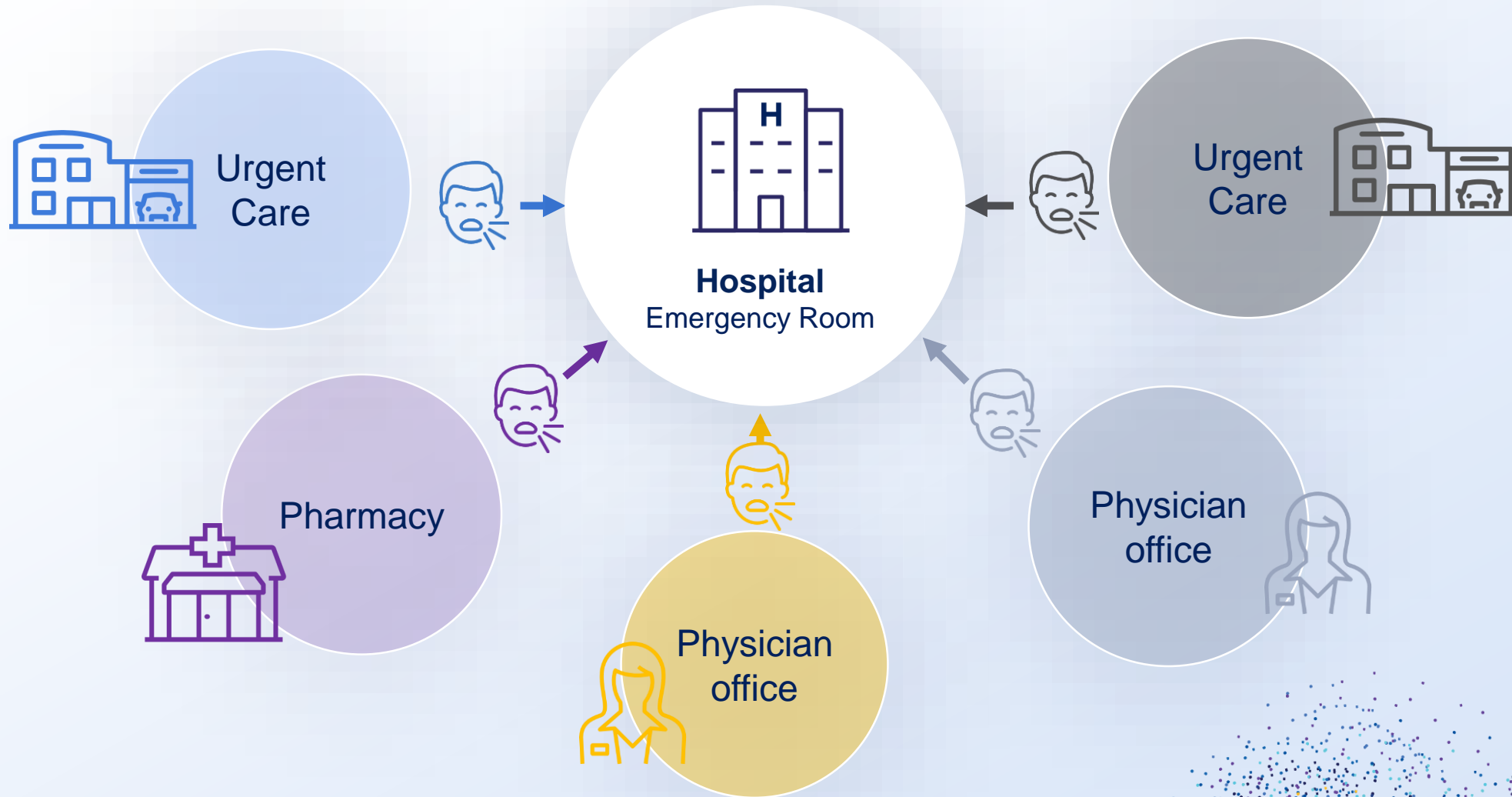
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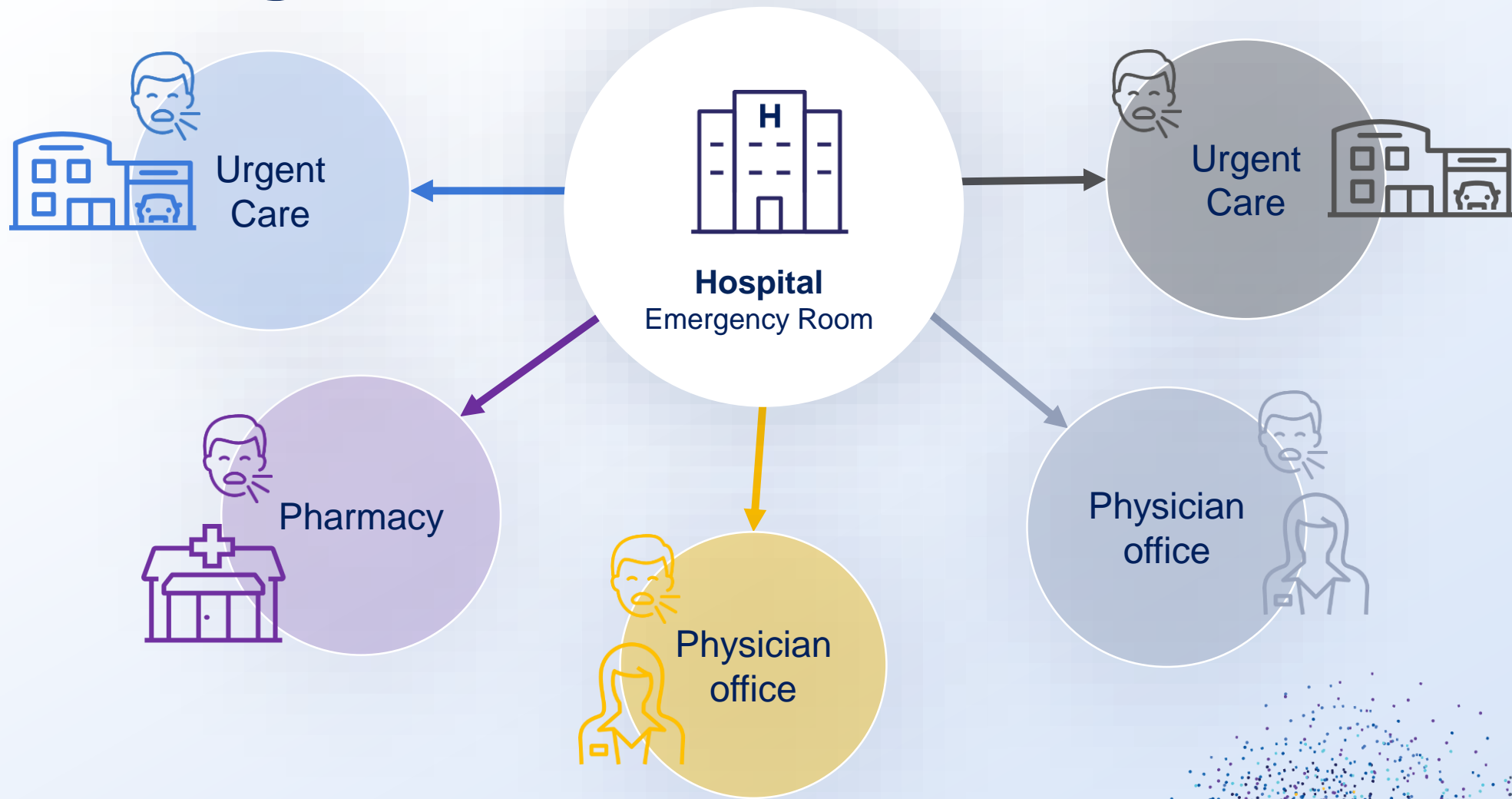
*currently in development. Not available for sales

LIAISON[®] NES

From "sending to a lab"....



...to testing onsite

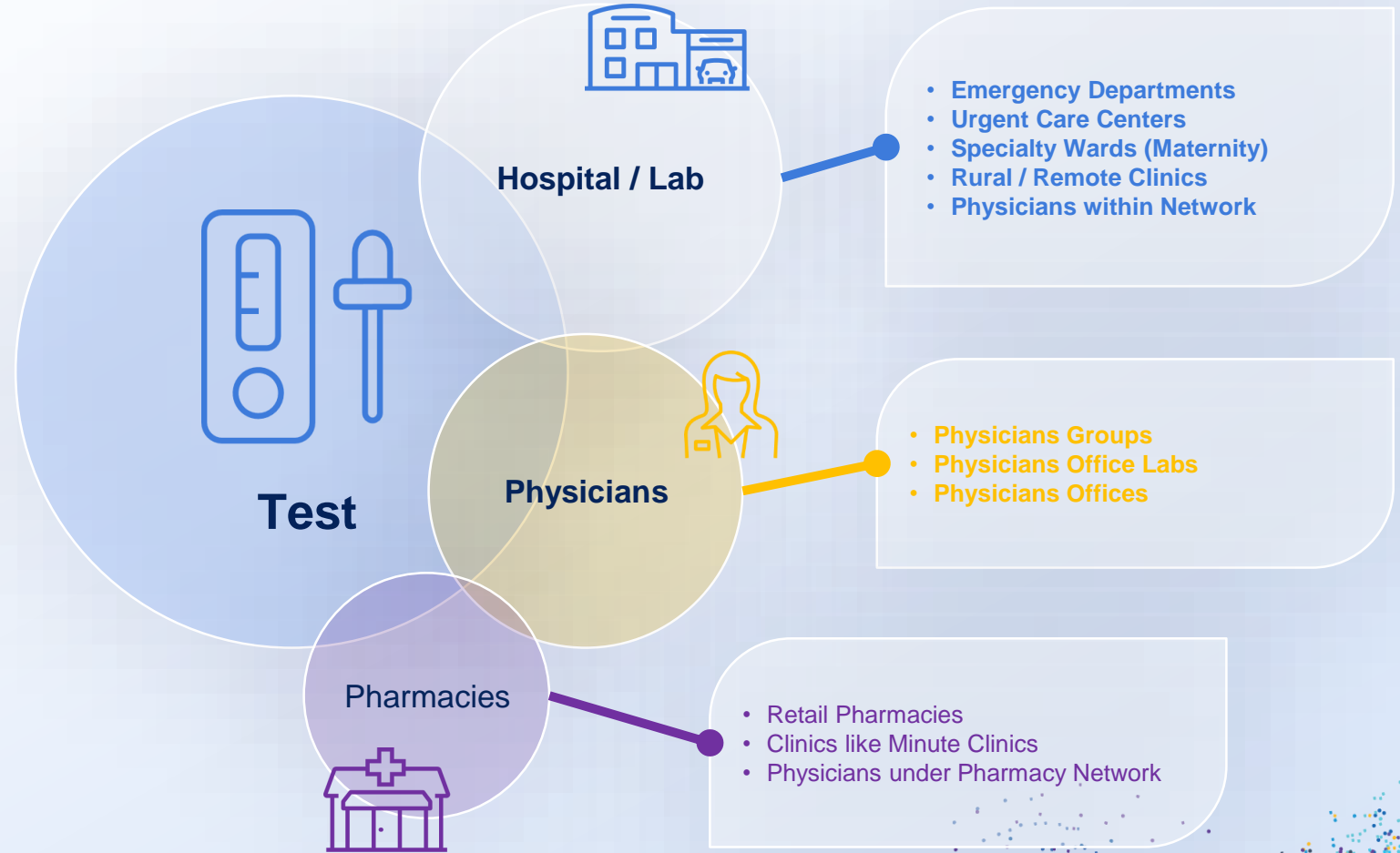


Shift of testing by locations

Trends that emerged from 2015-2019, which then accelerated by the pandemic.

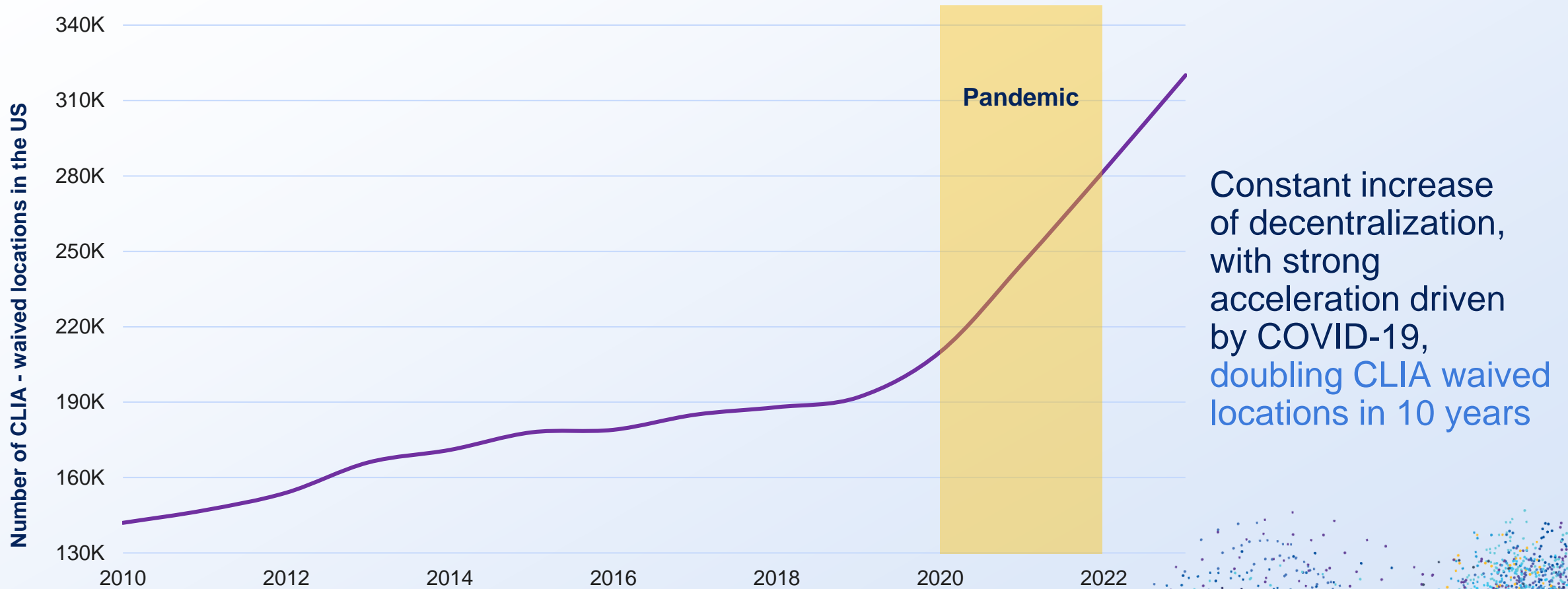
Key reasons for the shifts:

- Ease of Use and simpler molecular testing technology
- Financial Gains to Physicians rather than send-out
- Better patient care and customer satisfaction
- Value Based Care Model



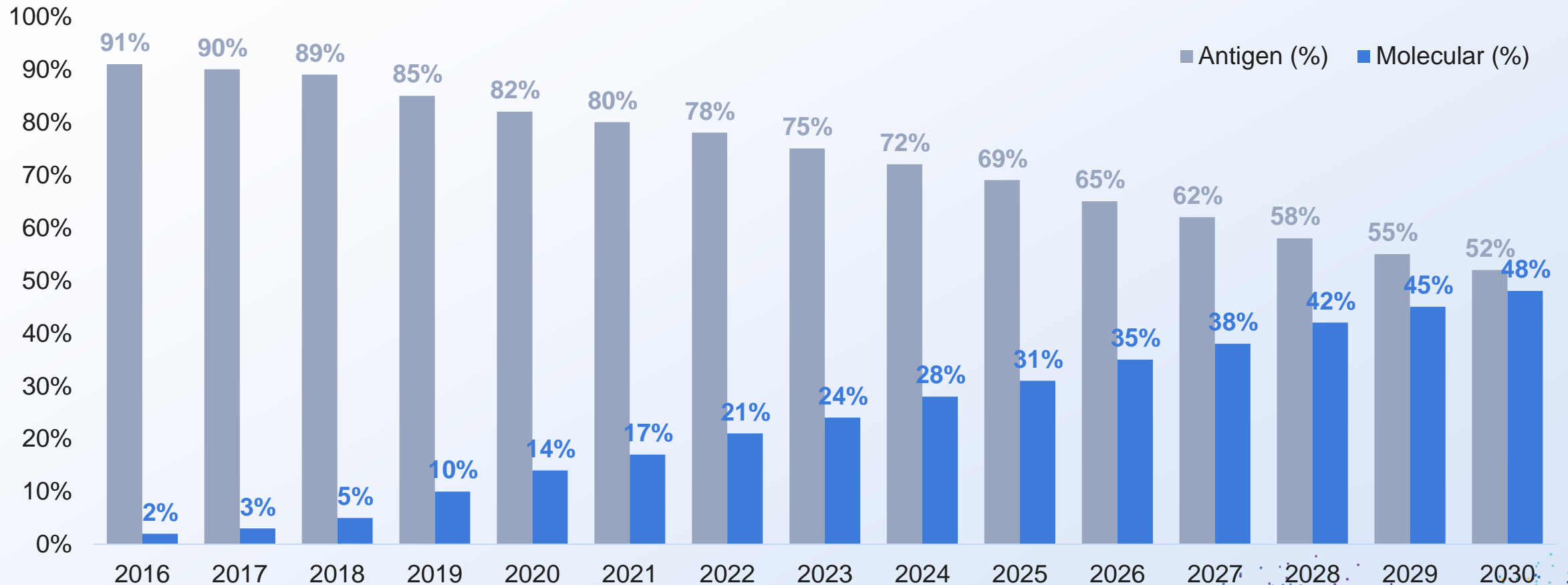
CDC CLIA Laboratory Data for location growth:
<https://www.cdc.gov/clia/LabSearch.html> for testing locations, filtered and categorized where NES or any other molecular solution would be beneficial

Increase number of CLIA-waived locations in the US



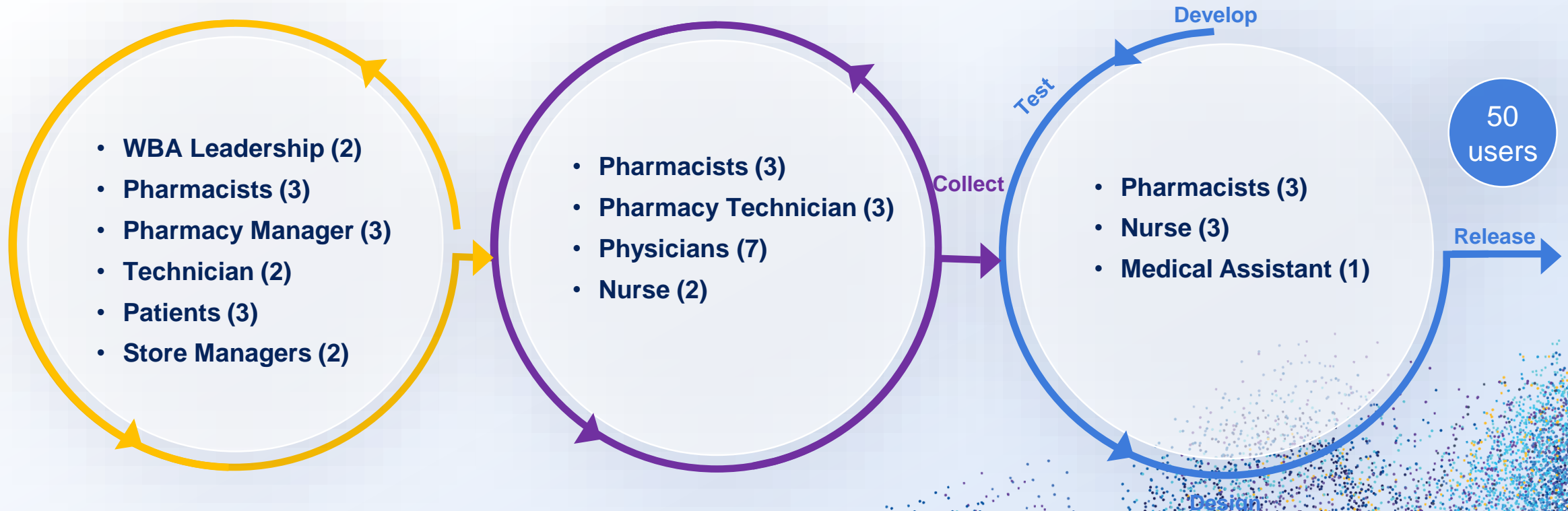
[https://www.sciencedirect.com/science/article/abs/pii/S1551741124000895#:~:text=Results,51.6%25\)%20locations%20in%20in%202023](https://www.sciencedirect.com/science/article/abs/pii/S1551741124000895#:~:text=Results,51.6%25)%20locations%20in%20in%202023)

Antigen vs. Molecular



Data from Definitive Health Care, CPT for GAS and Flu tests were used. Both CPTs show similar breakdown between Antigen v. Molecular. The Absolute numbers for Flu is much higher than GAS. Also, when other methods of testing is included example culture for GAS, the % shifts by 5% in 2016 and 2% in 2022.

LIAISON[®] NES: Designed for uncompromised use



LIAISON[®] NES* is designed to fit the Point of Care segment

Made to Multitask

Error Proof

Platform Benefits

Rapid Results

Plug and Play



Notification

Disease Monitoring

Digital Benefits

Connectivity

Inventory Management

*currently in development. Not available for sales



Technology supporting molecular innovation



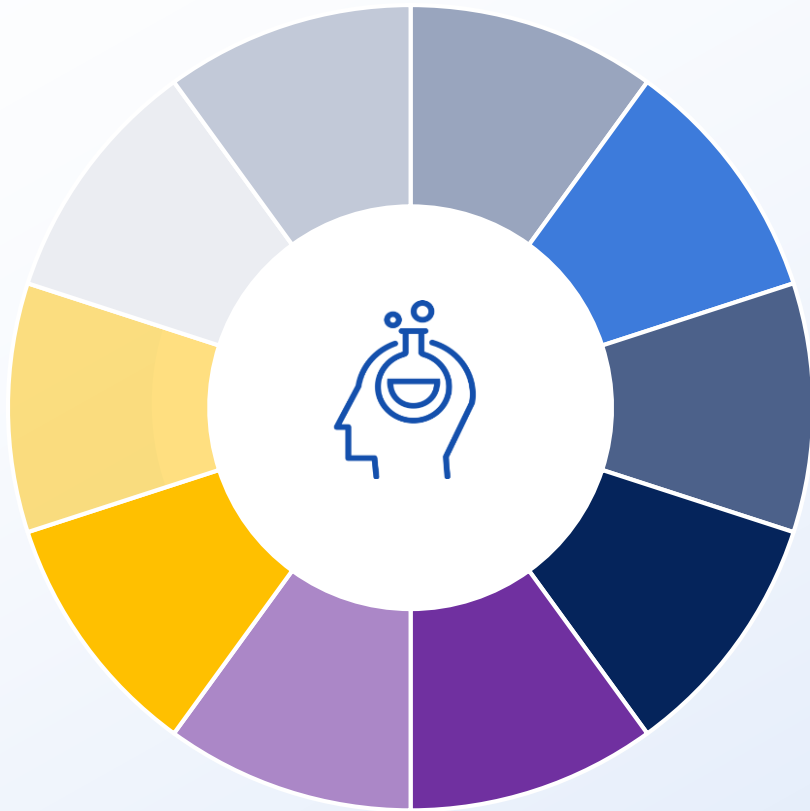
Fueling Innovation: Our Molecular Diagnostics R&D Team and Investments



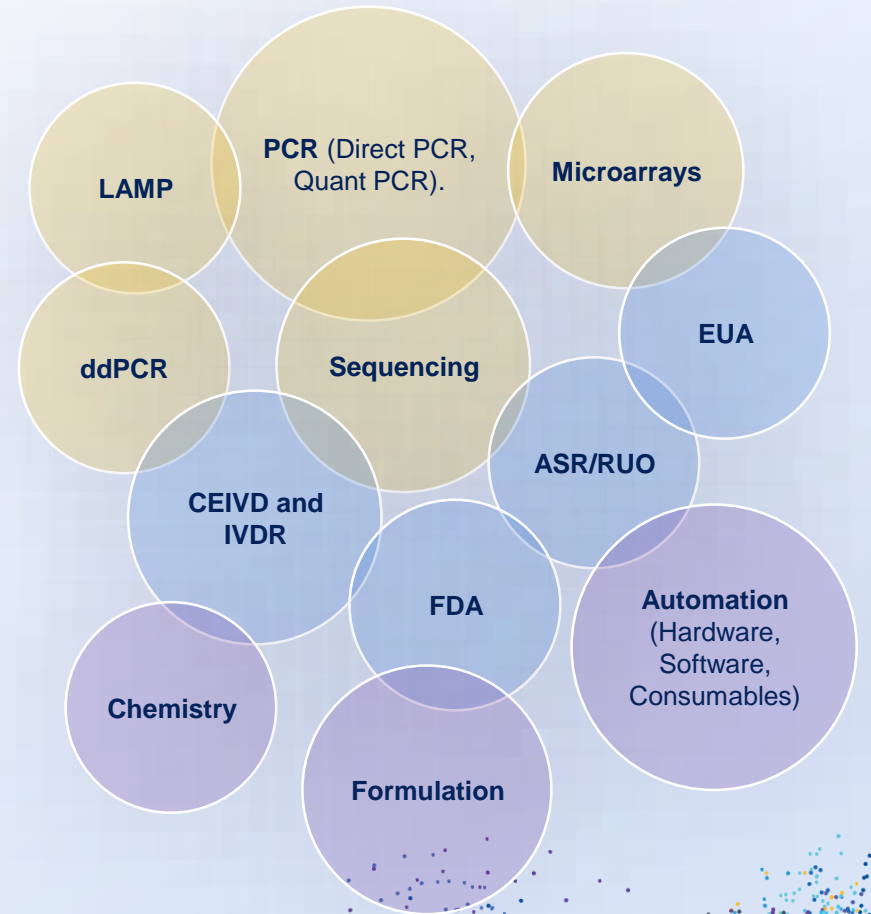
250

Molecular Diagnostic
Researchers
working worldwide

Team Competencies Enable Effective Execution and Support Future Growth



- Bioinformatics
- DNA/RNA Extraction
- Amplification Technologies
- Highly Multiplex Assays
- Ultrafast Assays
- Lyophilization
- Product Validations
- Clinical Operations
- Advanced Genomics
- Data Science



The Technology and Team Enable Diasorin Strategy

Molecular Diagnostics customers have unique requirements for systems and tests depending on

- Indication or Disease Diagnosed
- Laboratory Setting/Location

The Diasorin approach to meeting the customer needs differs from our competitors:

- No 'one size fits all approach'
- Each product is designed from the 'ground up' to meet specific customer needs

LIAISON PLEX® and LIAISON® NES*, bring next level of automation and ease of use to address critical market needs

LIAISON MDX/MDX Plus* and MAGPIX address specialty diagnostics and high throughput/high multiplexing product needs



*currently in development. Not available for sales

LIAISON PLEX[®]: Powered by Innovative and Proprietary Technologies

Unique Technology

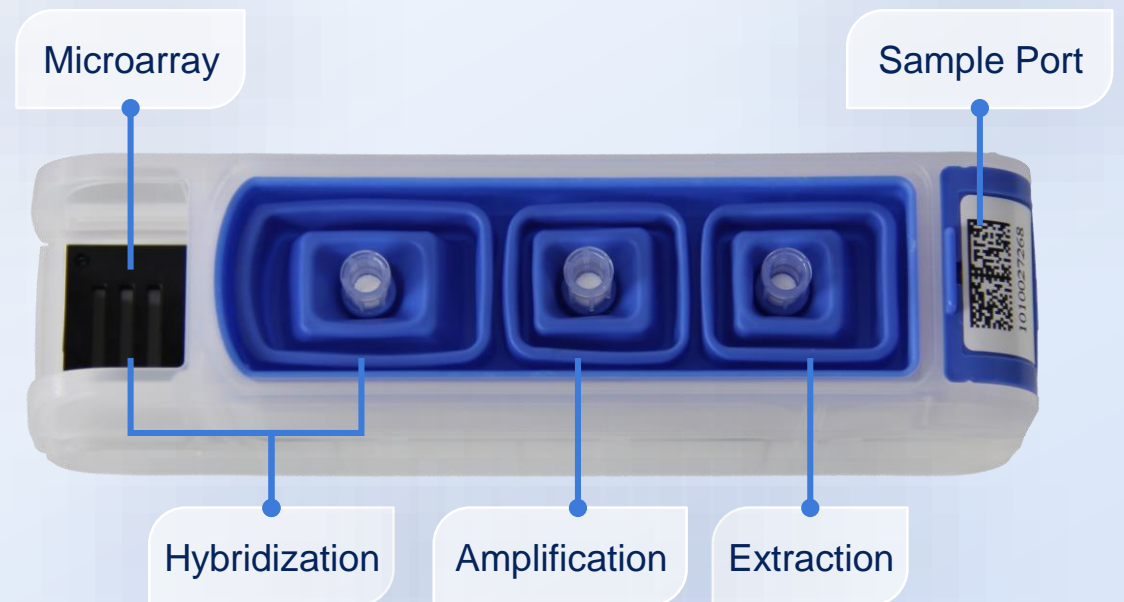
Proprietary NanoGrid technology delivers sensitive and highly specific multiplex detection

Ambient Storage

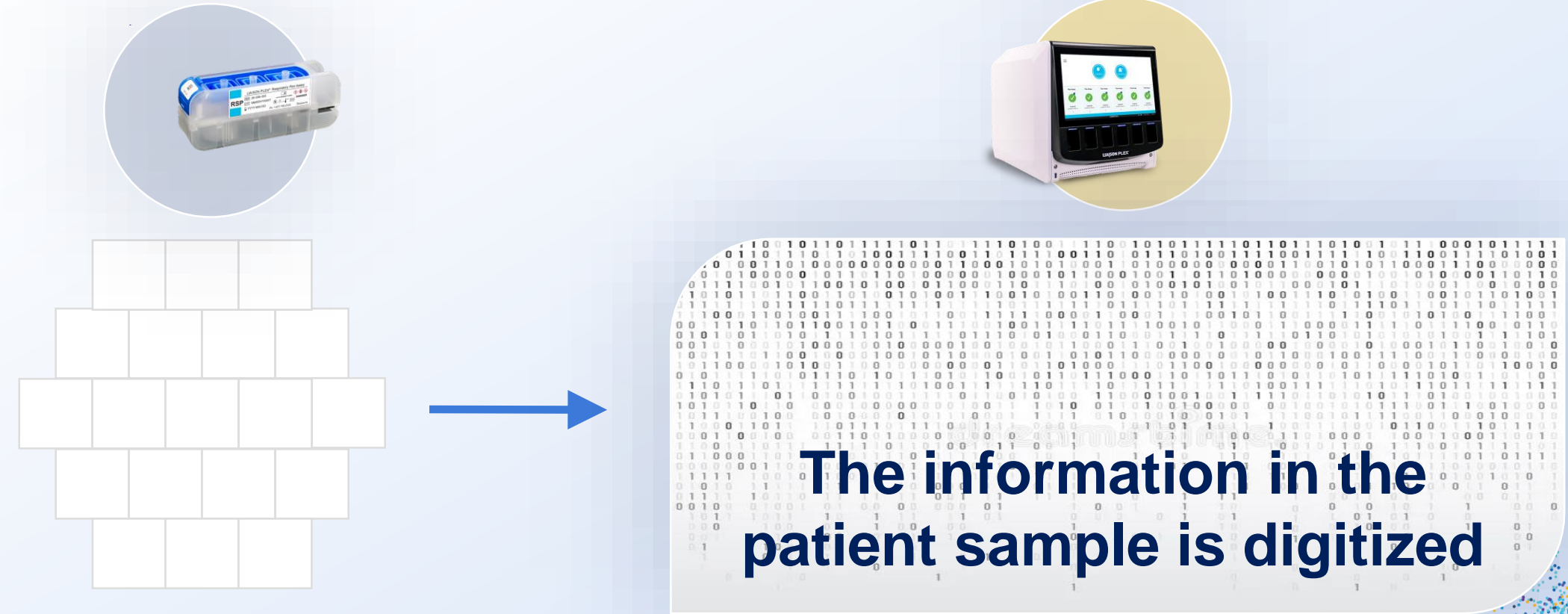
Eliminates the need for cold storage with a room temperature-stable cartridge

Integrated Cartridge

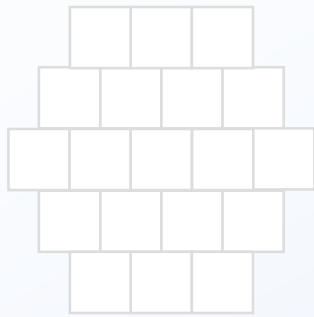
Incorporates DNA/RNA Extraction, Multiplex PCR and Microarray Detection in seamless manner



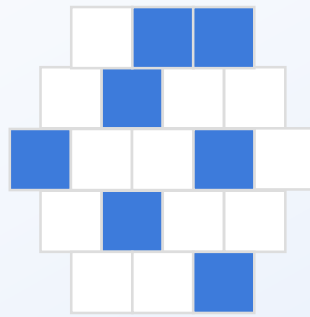
LIAISON PLEX®: Innovation Demonstrated by Digital Sample Technology



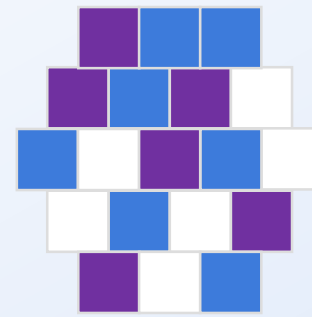
LIAISON PLEX[®]: Innovation Demonstrated by Digital Sample Technology



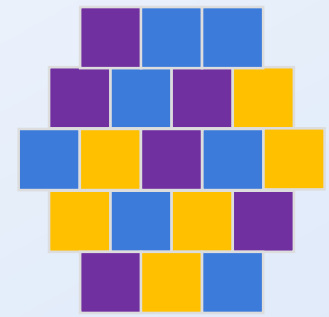
Digital Sample



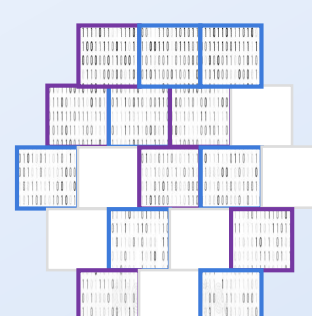
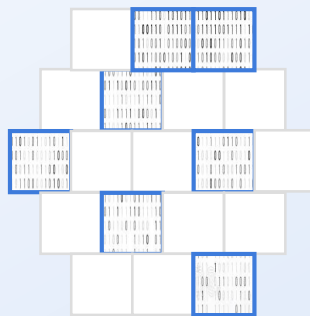
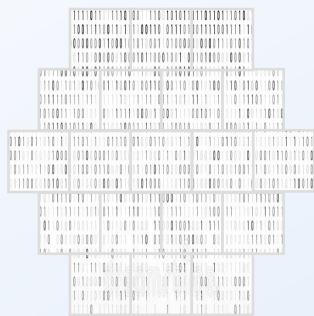
Base Panel



1st Tier



2nd Tier



LIAISON PLEX®: Demonstrating Track Record

Completed development and obtained 510(k)
clearance for LIAISON PLEX® in March 2024



RSP FLEX ASSAY

Obtained 510(k) clearance in March 2024

First assay clearance set the stage for optimized 510(k)
clearance path for follow-on assays

BCY ASSAY

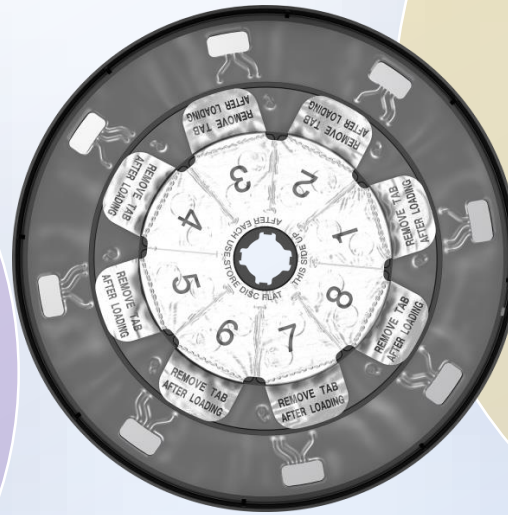
Obtained 510(k) clearance in June 2024

Completed development of blood culture fungal
panel assay in parallel with Plex RSP development

LIAISON MDX: Demonstrated Track Record (24 months)

Products
addressing critical
post-pandemic needs

Simplexa COVID-19 Direct 510(k)
Simplexa Covid-Flu 510(k)



Pioneering products
addressing
critical clinical needs

Simplexa cCMV 510(k)

Only cleared product for congenital CMV diagnosis with saliva swab and urine specimen indication

Simplexa *Candida auris* (*de novo* 510(k))

First product cleared for emerging critical infection

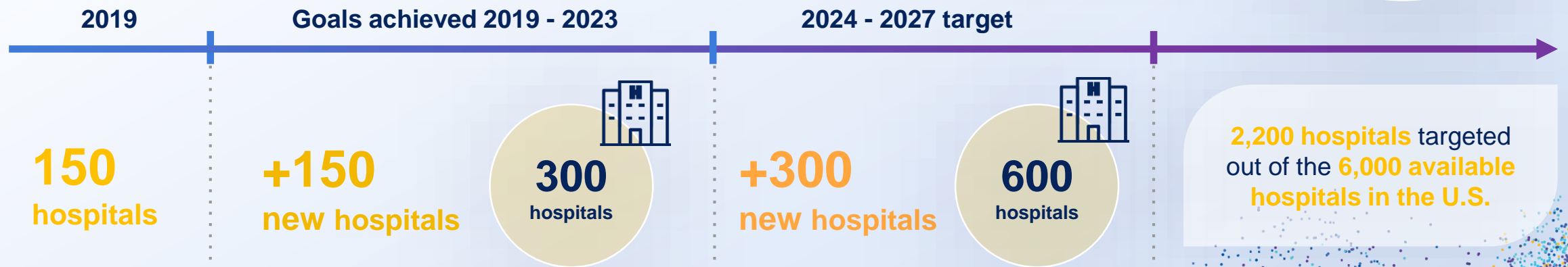
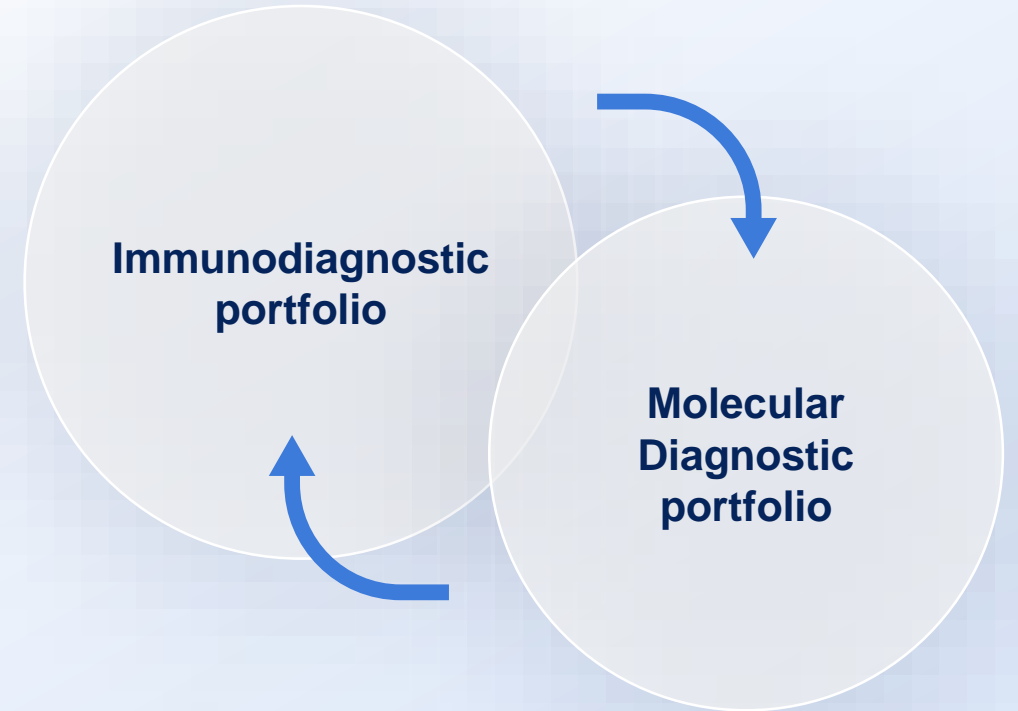
Commercial execution



U.S. Hospital Strategy

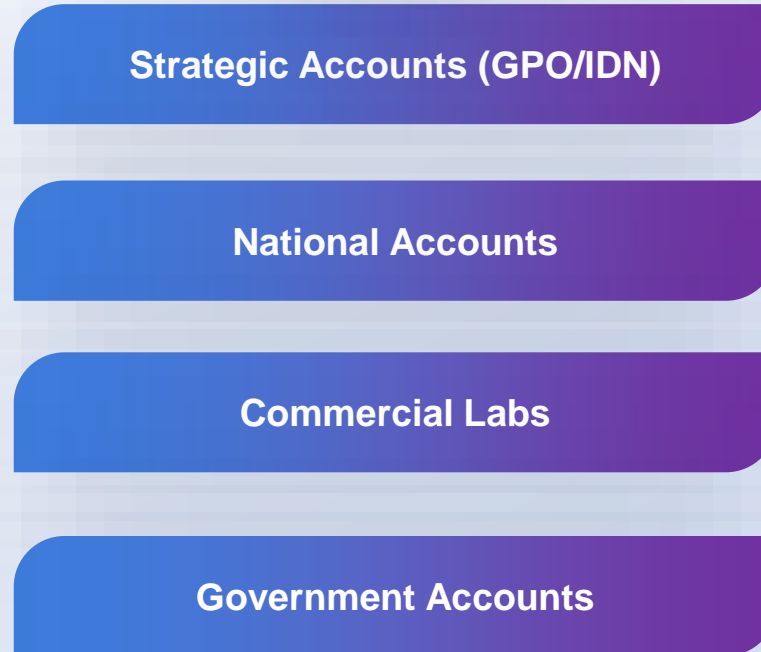
Strategic initiative

- Segmented the market and created teams to address each segment
- Mapped our core assays by Hospital System
- Set new strategy of accelerating our sales by decentralizing specialty testing into key Hospitals consisting of Integrated Health Networks, Major Medical Centers and Teaching Hospitals
- Leveraged on cross-selling opportunities with our IVD technologies
- Keep investing in new commercial resources



U.S. Diagnostic sales organization

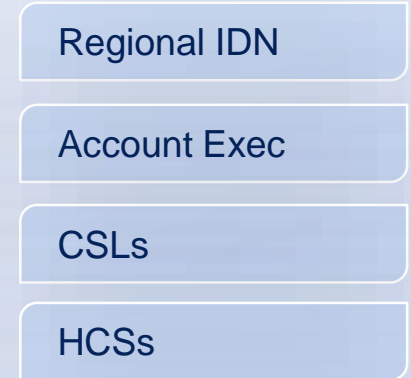
Unique combination of specialists
with one face to the customer



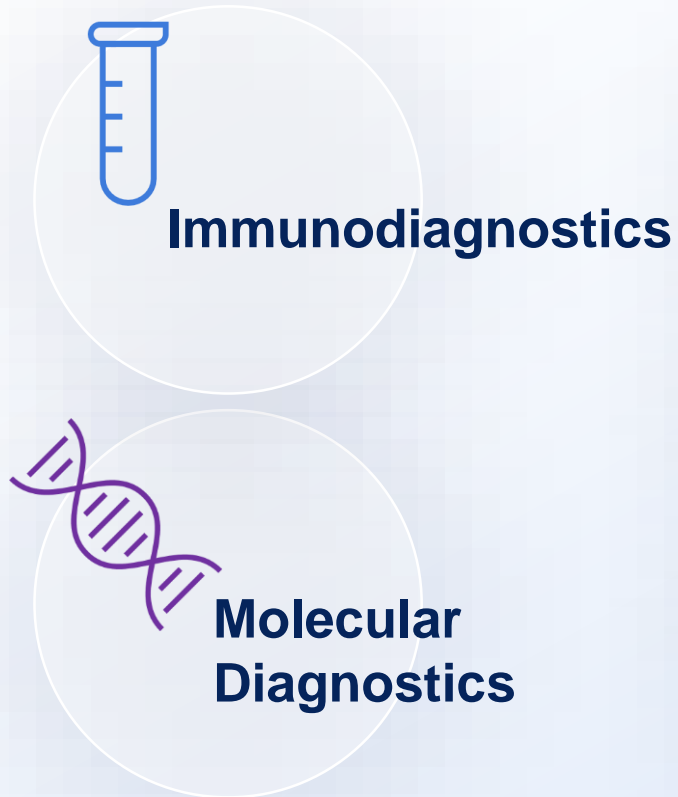
Hospital segment focus



Hospital Strategy



Hospital Strategy



U.S. Diagnostic sales organization

Unique combination of specialists
with one face to the customer



Hospital segment focus



Immunodiagnositics



Molecular
Diagnostics

Strategic Accounts (GPO/IDN)

National Accounts

Commercial Labs

Government Accounts



Hospital
Strategy

Regional IDN

Account Exec

CSLs

HCSs

Diasorin IVD strategy in the U.S. Market

IVD market in the U.S.

Post pandemic, the U.S. market looks different than before. The rising cost of healthcare, labor shortages, and sheer number of tests and solutions in different settings makes it **challenging for labs to find the right test at the right time**

Molecular Diagnostics commercial strategy in the U.S

Simply put; We are positioned to offer patients and labs **the right solution for the right test, at the right time.**

Leveraging Diasorin Immunodiagnosics through Molecular Diagnostics portfolio

We are positioned well, geographically, with **all of our teams to drive synergistic cross selling and support opportunities** to help our customers with their diagnostic algorithms



Diasorin molecular strategy in the U.S. Market



POINT-OF-CARE

Expansion in Point-of-Care

DECENTRALIZED SETTING



TARGETED SOLUTIONS

Menu Expansion & Instrument Enhancement



MULTIPLEX SOLUTIONS

Expansion in Syndromic

DECENTRALIZED/CENTRALIZED LABORATORY SETTING

LIAISON PLEX[®]: Feedback from the first 2 months into the market



Go-to-market strategy

We have mapped the entire syndromic market when it comes to Respiratory, GI, BC, and Meningitis panels in order to target those customers to have relevant conversations



Competitive expansion

Customers have been very receptive to our solution with varying layers of feedback on why they are interested to switch or adapt to a new technology



VERIGENE conversion

Existing customers are excited about better workflow, room temperature storage, smaller footprint



Leveraging on Flex/pricing

Flex pricing represents the majority of our opportunities, which really touches on Diagnostic Stewardship and the need to have the right test at the right time to minimize cost and maximize reimbursement.



**The right test
at the right time**

