

**DiaSorin**

The Diagnostic Specialist

# Test the future

**Investor Day**  
June 11<sup>th</sup> Turin

# Disclaimer

These statements are related, among others, to the intent, belief or current expectations of the customers base, estimates regarding the future growth in the different business lines and the global business, market share, financial results and other aspects of the activities and situation relating to the Company.

Such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and actual results may differ materially from those expressed in or implied by these forward-looking statements as a result of various factors, many of which are beyond the ability of DiaSorin S.p.A. to control or estimate precisely.

The Company does not undertake to update or otherwise revise any forecasts or objectives presented herein, except in compliance with the disclosure obligations applicable to companies whose shares are listed on a stock exchange.

Piergiorgio Pedron, the Officer Responsible for the presentation of corporate financial reports of DiaSorin S.p.A., in accordance with the second subsection of art. 154-bis, part IV, title III, second paragraph, section V-bis, of Legislative Decree February 24, 1998, no. 58, declares that, to the best of his knowledge, the financial information included in the present document corresponds to book accounts and book-keeping entries of the Company.



# Agenda

1

**DIASORIN AT A GLANCE**

5

**MAIN BUSINESS ACHIEVEMENTS**

7

**HEALTHCARE SECTOR TRENDS**

17

**DIAGNOSTIC SECTOR TRENDS**

27

**DIASORIN POSITIONING AS A CONTENT SPECIALIST**

44

**GROUP STRATEGIES FOR MAIN GEOGRAPHIES**

59

**GUIDANCE 2019-2022**

61

**BUSINESS DEVELOPMENT OPPORTUNITIES**

63

**MAIN TAKEAWAYS**



**DiaSorin**

The Diagnostic Specialist

# **DiaSorin at a glance**

# Who are we?



DiaSorin is a Company committed to develop products that require complex technologies and high risk research spending.

In other words

**SPECIALTY PRODUCTS**



# DiaSorin WorldWide

WITH OVER 50 YEARS OF EXPERIENCE





# Growth through acquisitions & partnerships

2008-2009

2010-2012

2013-2014

2015-2016

2017-2018



STOOL

CONNECTIVITY FOR LAB AUTOMATION

HEPATITIS & RETROVIRUS

QFT



ENZYGNOST



PARVOVIRUS

ELISA HEPATITIS & RETROVIRUS

MOLECULAR DIAGNOSTICS

ELISA BUSINESS

CASH FLOW SERVING OUR GROWTH, EXPANSION AND INNOVATION TO PROVIDE RIGHT SOLUTIONS TO OUR CLIENTS





**DiaSorin**

The Diagnostic Specialist

# **Main business achievements**



# Main business achievements from 2017 long term guidance

## TARGETS

## STATUS

PRODUCT DEVELOPMENT


 5-6 new Immunodiagnostic tests/year 


 2 new molecular kits + 4 new ASRs/year 

VITAMIN B12	HDV	ANDROSTENEDIONE	C. DIFFICILE	BABESIA	ANAPLASMA PHAGOC.	GROUP B STREP.
FOLATE	SHBG	QFT LTBI	FGF 23	CBFB-MYH11	MYCOPLASMA PNEUM.	GROUP C STREP.
ELASTASE-1		PROCALCITONIN	BORDETELLA DIRECT	BCR-ABL 1.5	EHRlichia	GROUP G STREP.
	CALPROTECTIN	ZIKA IGM	VZV DIRECT	HSV 1	LEGIONELLA SPECIES	PNEUMOCYSTIS JIROV.
				HSV 2		

BUSINESS DEVELOPMENT

Partnerships



ELISA business acquisition

- ★ QFT franchise: launch of Latent Tuberculosis test  September 2018  Summer 2019  by 2020
- ★ Expansion of T-cells response to other new applications
- ★ Gastro-intestinal franchise: sale of H. Pylori SA on CLIA   October 2018
- ★ Hepatitis & HIV franchise: launch on CLIA in the US
- ★ Conversion of Siemens' ELISA clients to DiaSorin's CLIA solutions

TECHNOLOGY DEVELOPMENT

Development/launch of LIAISON XS



-  May 2019  by 2020  by 2021

INDUSTRIAL EFFICIENCY

EBITDA Margin safeguarding initiatives

- ★ Supply chain efficiencies
- ★ Operational excellence
- ★ Rationalization of manufacturing footprint



DiaSorin

The Diagnostic Specialist

# Healthcare sector trends



# Main challenges for companies working in the healthcare industry

Society overall expects us to deliver services and products that will help people live longer



Increase cost as the result of more expensive technologies, broader access to the welfare system and the demographic trend

Increase efficiency in the way we conduct our business

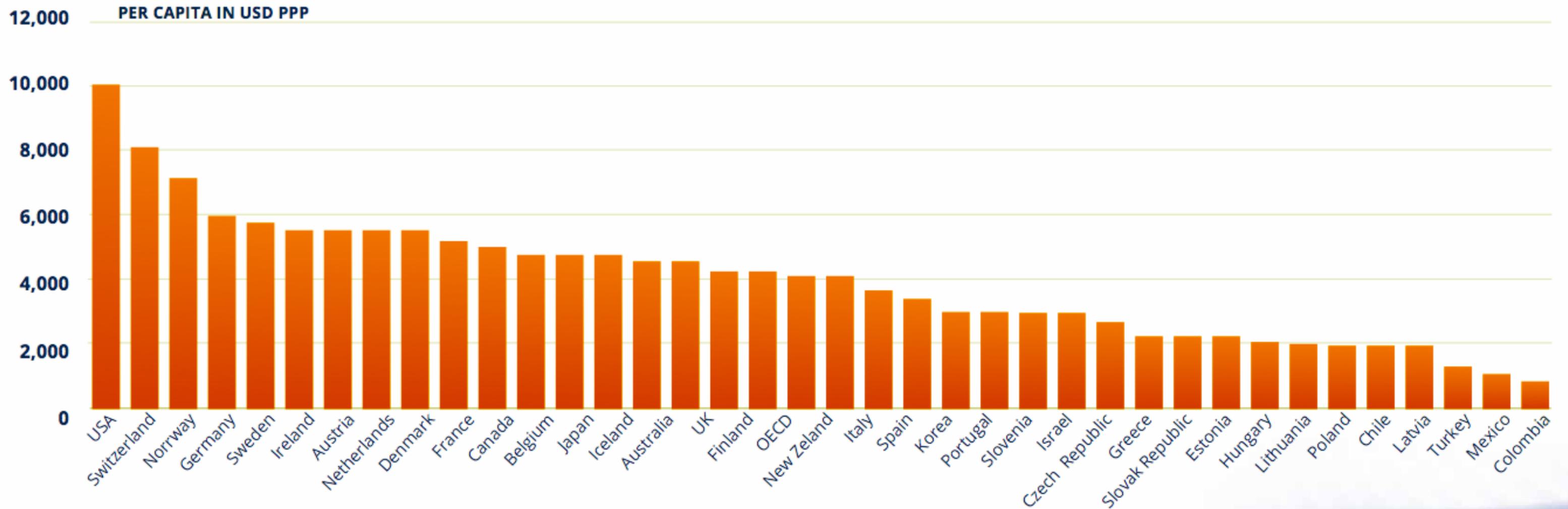


Tough competition cannot miss any business decision or we are taken out of the market



# Challenges in Healthcare

HEALTH SPENDING PER CAPITA (IN USD PPP)



2017 data estimated by the Secretariat for those countries that were not able to provide this information. PPP stands for Purchase Power Parity and adjusts health expenditure for differences in price levels between countries. Source: OECD Health Statistics 2018



# Challenges in Healthcare

MACROECONOMIC FORCES ON THE US ECONOMY



**19.7%**

Current health spending share in GDP is expected to reach 19.7% by 2026

The average US family pays ~30% of annual household income in health insurance premium and costs (2019). The cost is expected to be 50% of household income by 2021

**~30%**

**\$6.0 TRILLION**

Under current law, national health spending is projected to grow at an average rate of 5.5% per year for 2018-27 and to reach nearly \$6.0 trillion by 2027

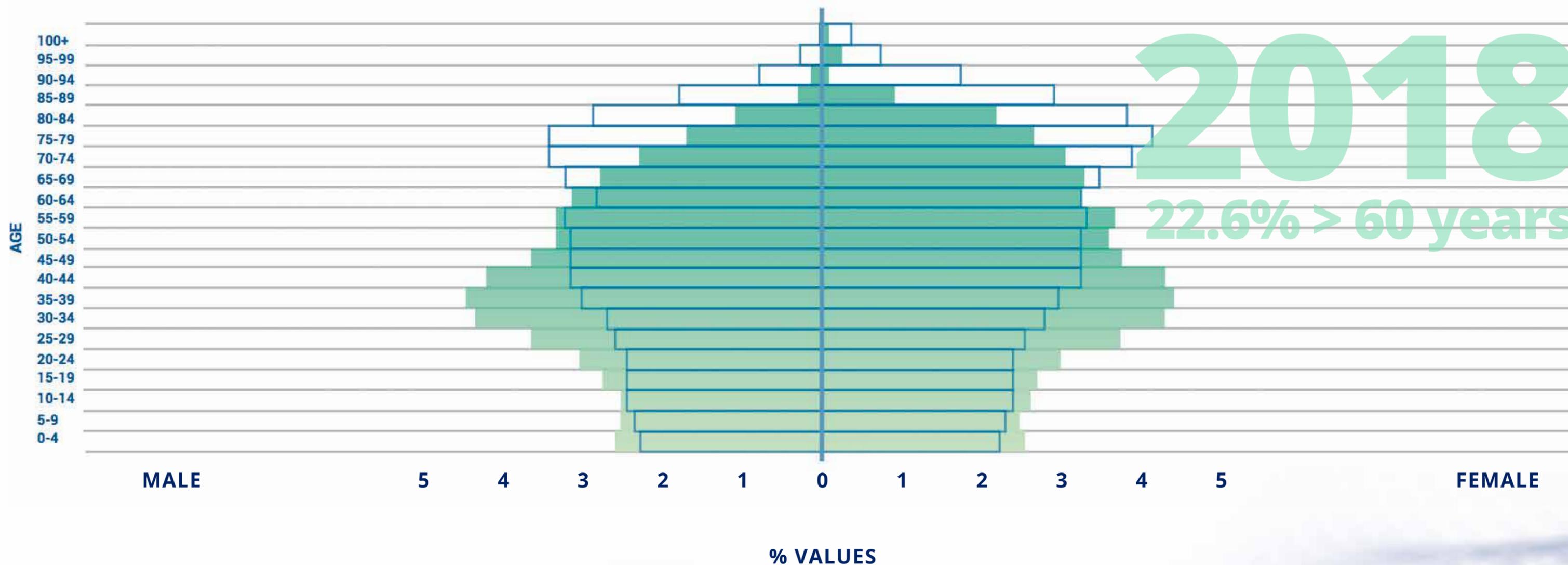
The healthcare system in America is costly and not sustainable

**COSTLY**



# Challenges in Healthcare

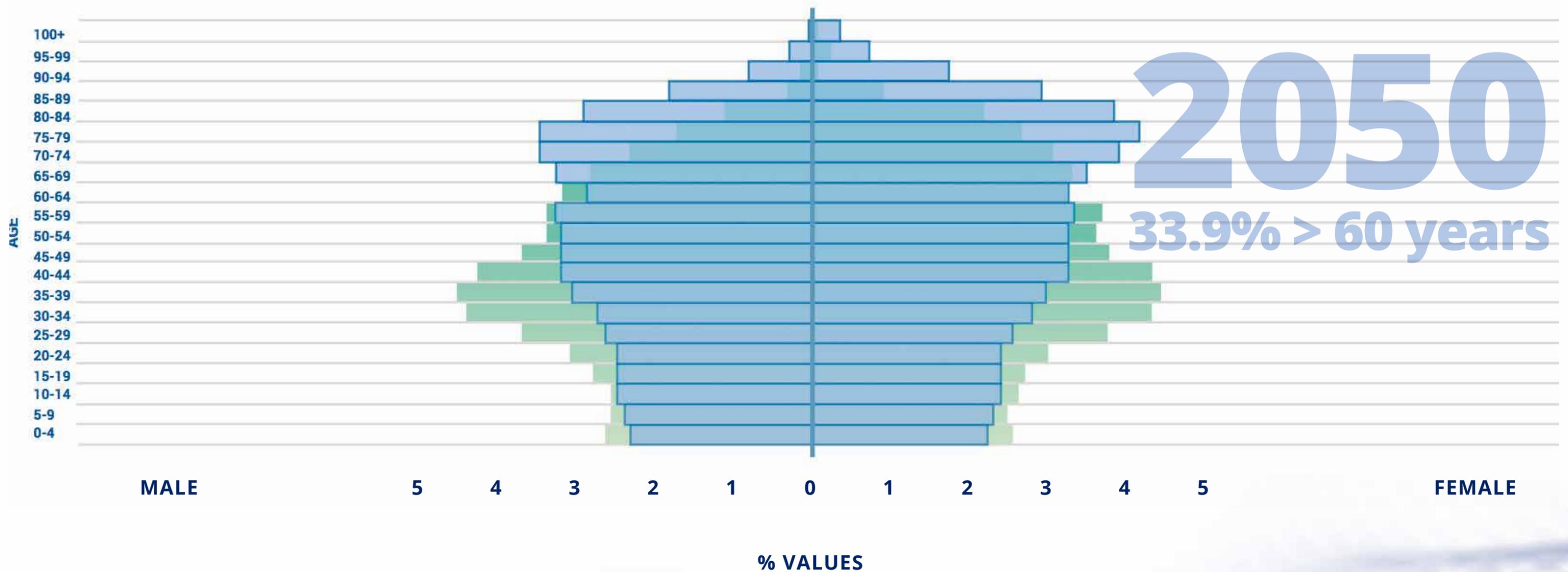
THE ROLE OF DEMOGRAPHY: ITALY IN 2018





# Challenges in Healthcare

THE ROLE OF DEMOGRAPHY: ITALY IN 2050



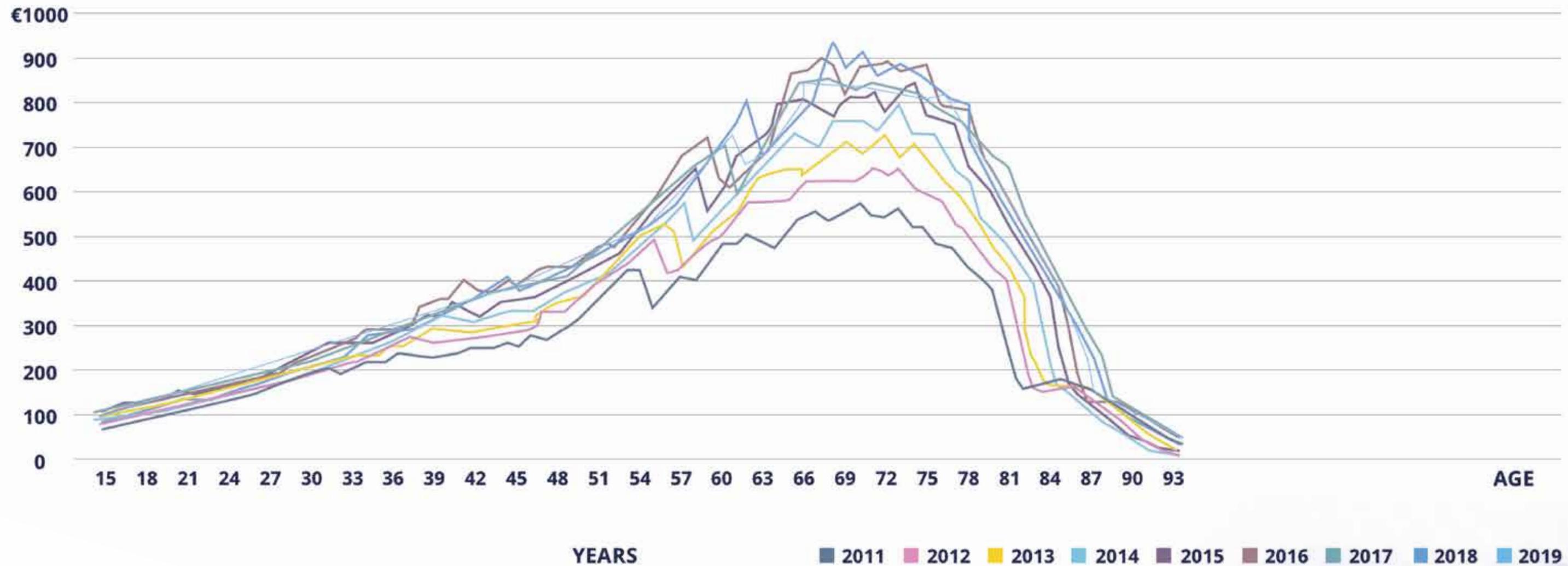


# Challenges in Healthcare

THE ROLE OF DEMOGRAPHY IN HEALTHCARE SPENDING - ITALY



Individual expense  
for healthcare



**What is the conclusion?**

WE NEED TO BE

**Innovative  
Adaptive to changes**



WE ARE ALL MOVING TO VALUE BASED CARE

# VBC (Value Based Care)

A model in which providers, including hospitals & physicians, are paid based on patient health outcome



Diagnostic companies are not just providing a test result, but a viable information associated to an algorithm that will support the medical decision



**DiaSorin**

The Diagnostic Specialist

# **Diagnostic sector trends**

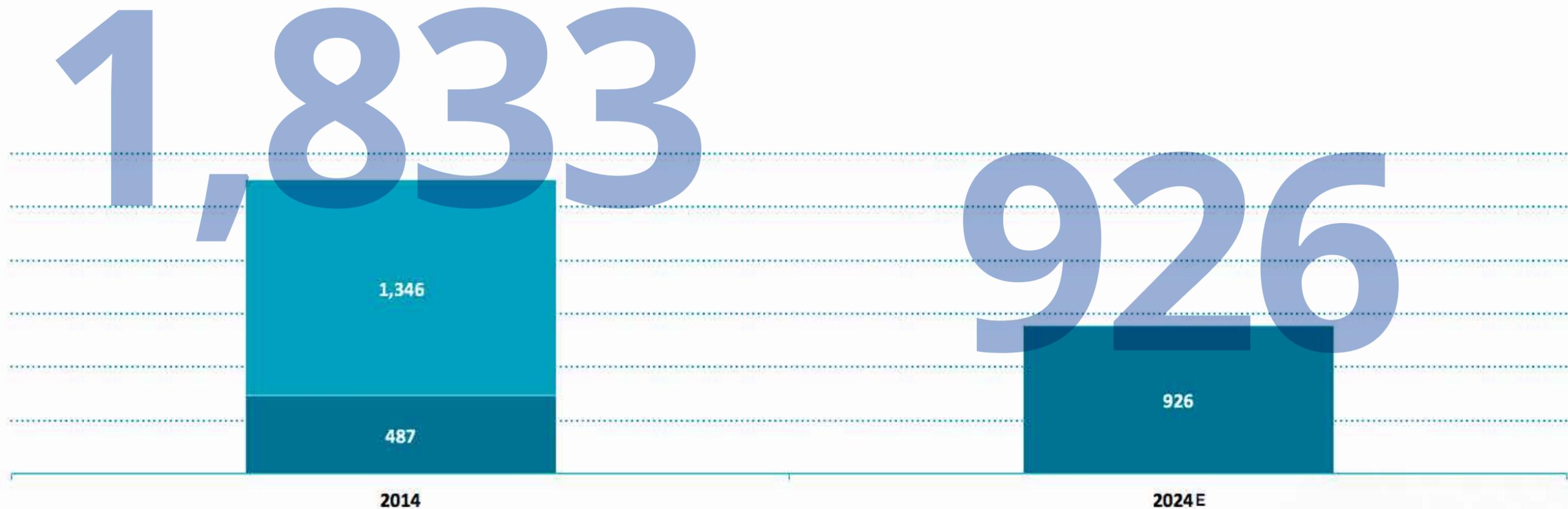
# **2** opposite forces are reshaping the laboratory space and the IVD Industry

**1**  
**CONSOLIDATION**  
to drive efficiency of routine  
laboratory services

**2**  
**DECENTRALIZATION**  
to drive efficiency of patient  
management as part of value  
based care (VBC) initiatives



# Consolidation: Key Factors



Multi-hospital health systems



Independent hospitals



# Consolidation: New Models

FRANCE (BALLERAU LAW)



**4,000**  
Private Labs



**139**  
Regional platforms  
(562 Labs)

**891**  
UH and GH  
Labs



**135**  
GHT + 12 APHP GH  
(295 Labs)

**14**  
Blood Banks  
Labs



**4**  
Blood Banks  
Labs



# Decentralization: decentralized testing

## MEDICAL

- Increasing worldwide prevalence of infectious diseases
- Reduce time from Diagnosis to Treatment
- Provide more precise treatment



## EFFICIENCY

- Alleviate seasonal spike in testing volumes
- Bring Testing closer to Patients
- Reduce labor costs

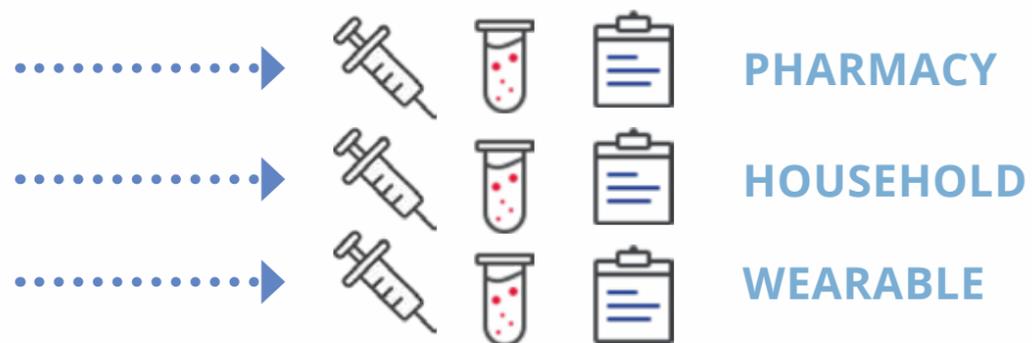
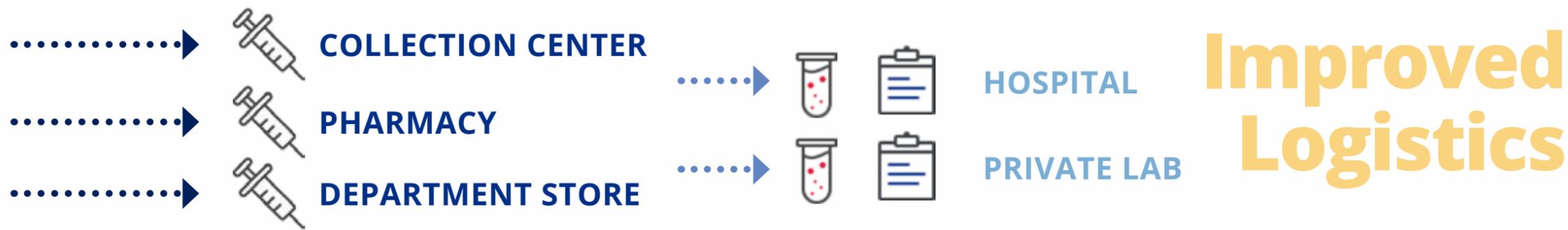


## ACCESSIBILITY TO NEW SOLUTIONS

Increasing number of tests and instruments proposed by Molecular Manufacturers



# How technology affects decentralization



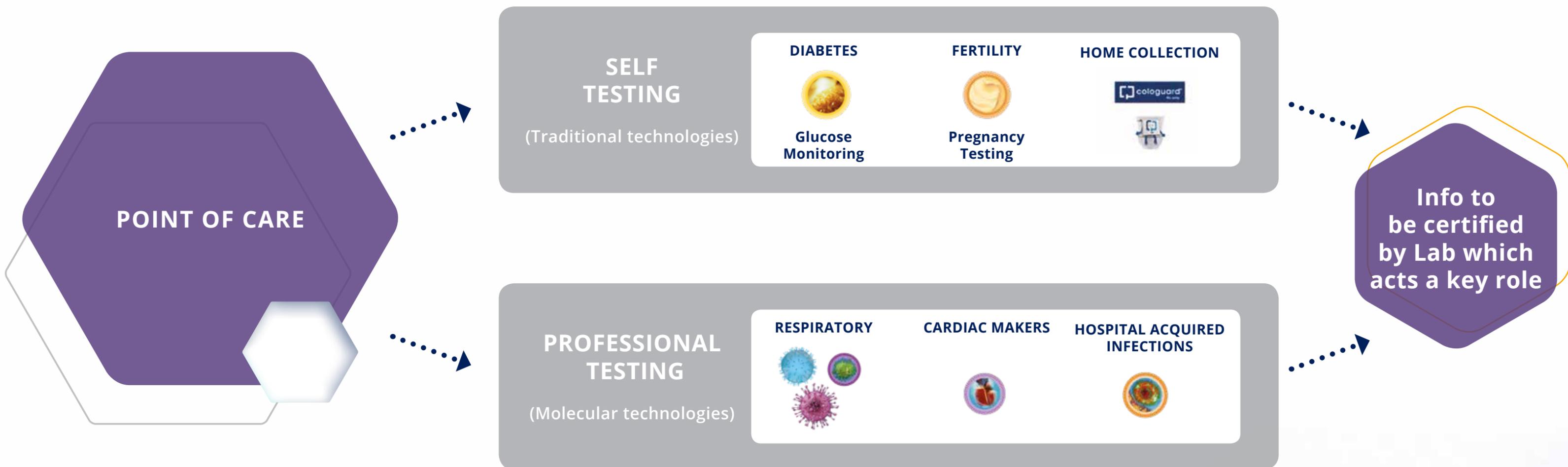
## Improved testing technology



## The Future



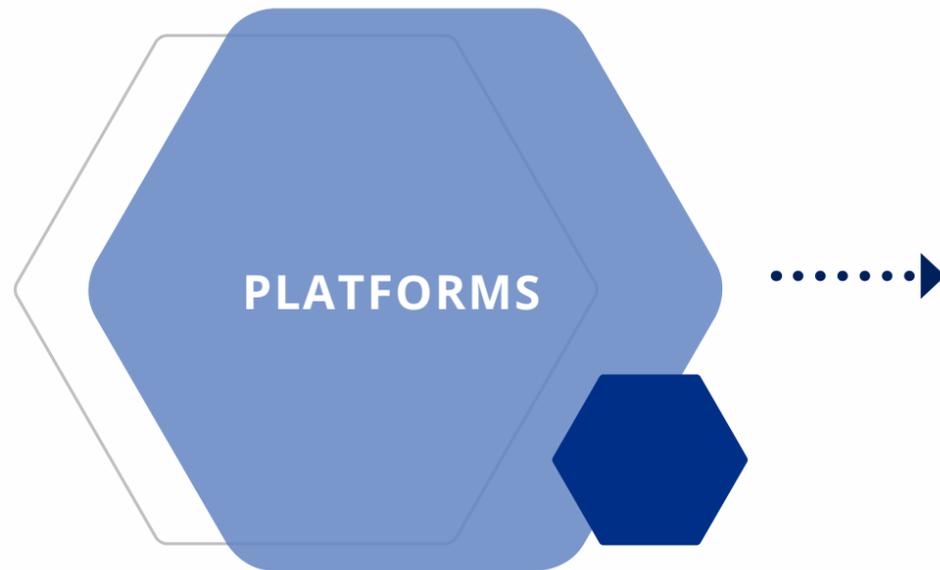
# Decentralization: what technology can deliver today



**What does it  
mean for DiaSorin?**



# How do we support consolidation?



HIGH VOLUME AUTOMATION



CONNECTIVITY TO EXISTING PLATFORMS

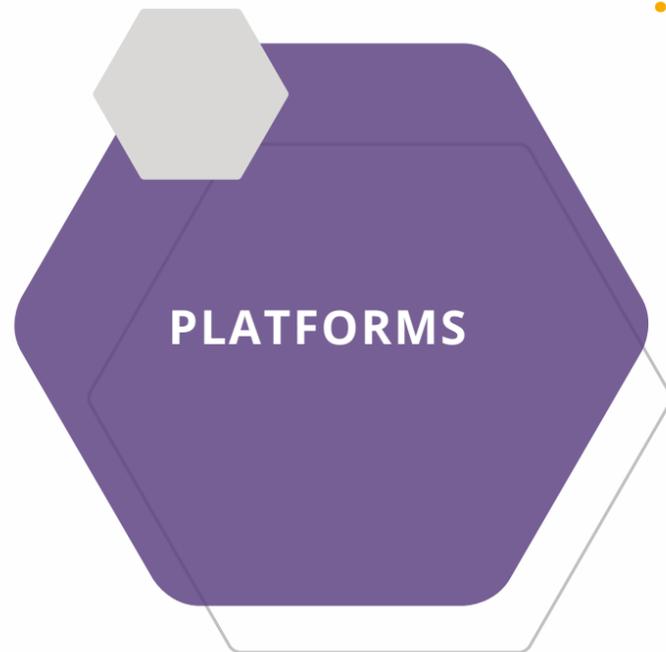


DEDICATED SPECIALTY PLATFORM





# How do we support decentralization?



1

HUB AND SPOKE MODEL



2

EASE OF USE  
NO EXTRACTION



3

MOLECULAR POC

Results  
< 15'

STRATEGIC FOCUS



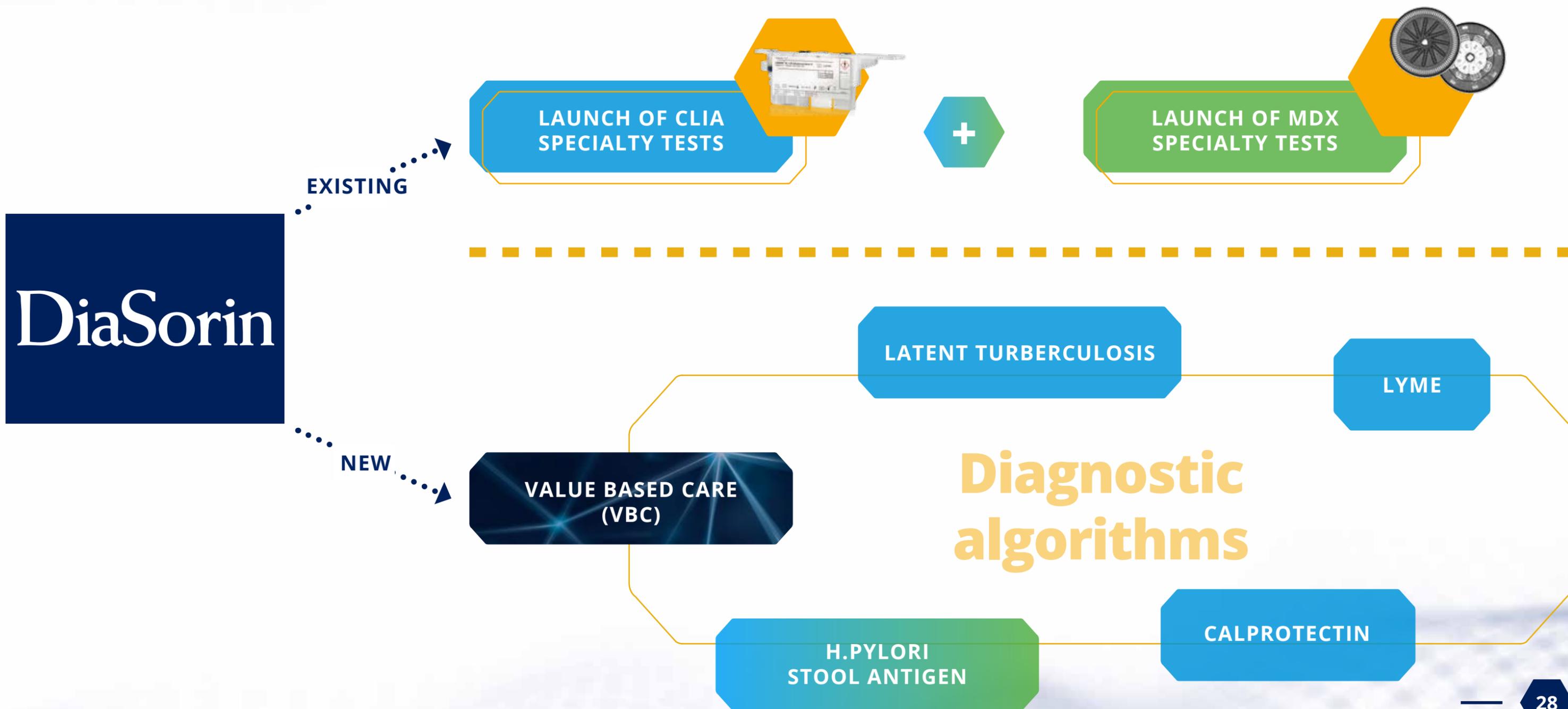
**DiaSorin**

The Diagnostic Specialist

# **DiaSorin positioning as a content specialist**



# A new path forward as a content specialist



**DiaSorin**



# A new path forward as a content specialist



EXISTING



LAUNCH OF CLIA  
SPECIALTY TESTS



# Our Specialist Menu



## ME-TOO

Common tests, known use

Mainly prescribed by GPs

Available from most providers

44

## HIGH VOLUME SPECIALTIES

Specialized tests, broadly known

Usually prescribed by specialists

Offered by a limited number of providers

42

## DIFFERENTIATING SPECIALTIES

Specialized tests, growing clinical acceptance

Usually prescribed by specialists

Offered by a very limited number of providers

32

## INNOVATIVE SPECIALTIES

New tests of unique clinical value

Education needed

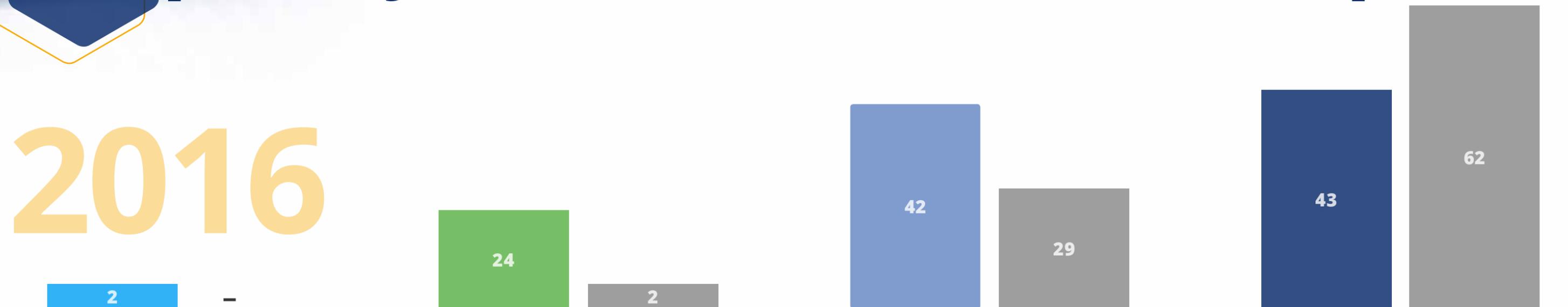
Single market provider

2

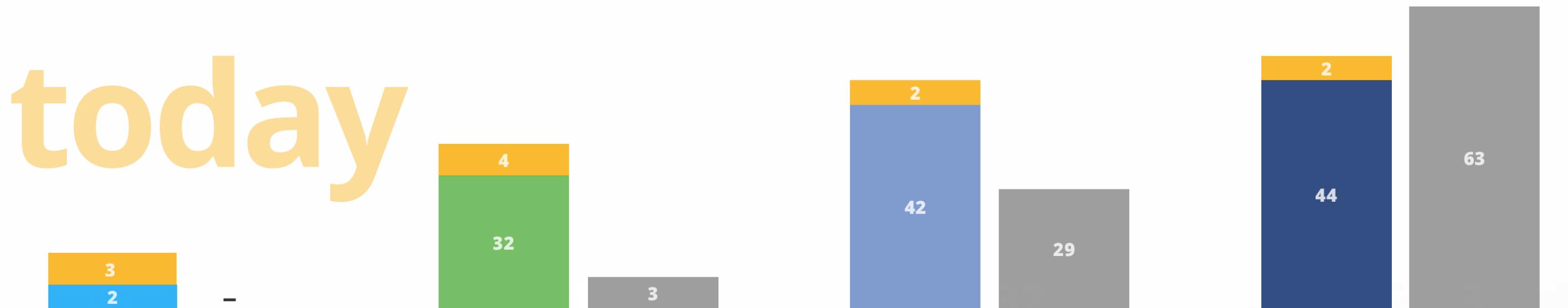


# Specialty tests differentiation vs. competition

2016



today



**INNOVATIVE SPECIALTIES**

**DIFFERENTIATING SPECIALTIES**

**HIGH VOLUME SPECIALTIES**

**ME-TOO**



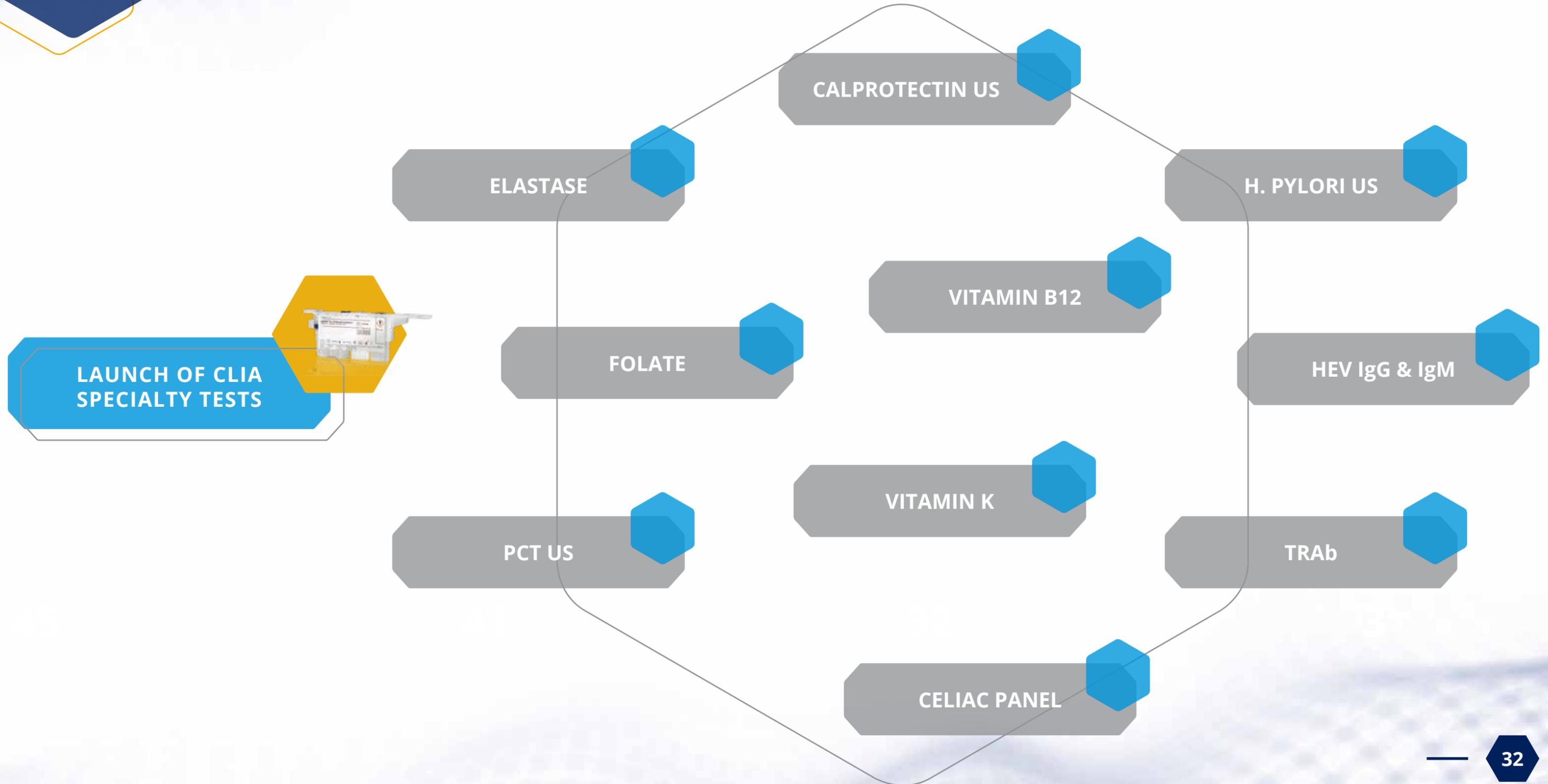
Tests of the main competitor within the area



New DiaSorin tests in 2019-2022



# Sustaining innovation: DiaSorin specialties R&D pipeline





# A new path forward as a content specialist



EXISTING



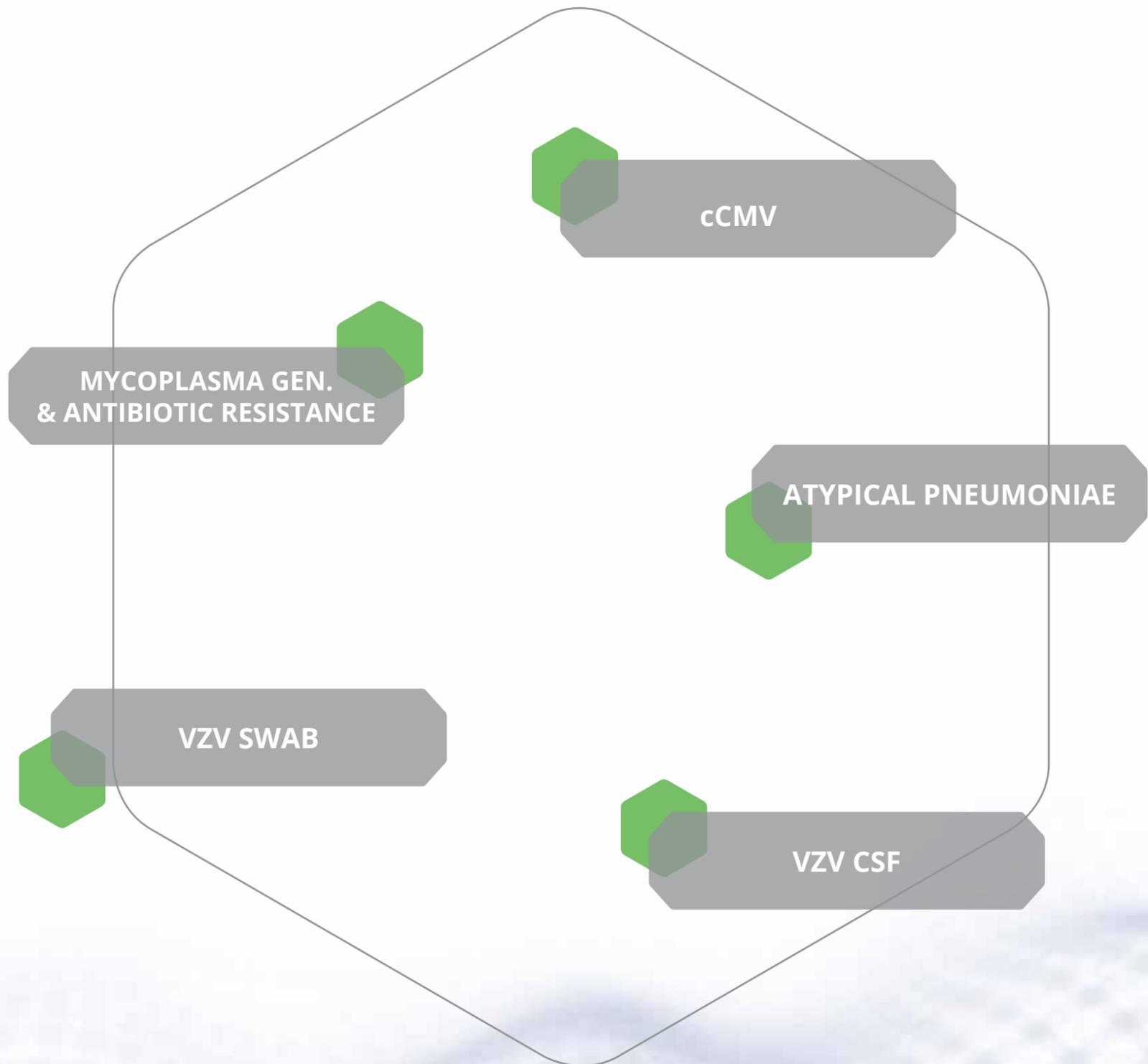


# Molecular Strategy - Overview

EXPANSION  
CONTENT MENU



DEVELOP TARGETED  
ASSAY PANELS





# A new path forward as a content specialist



NEW

VALUE BASED CARE (VBC)

LATENT TUBERCULOSIS

LYME

Diagnostic algorithms

H.PYLORI STOOL ANTIGEN

CALPROTECTIN



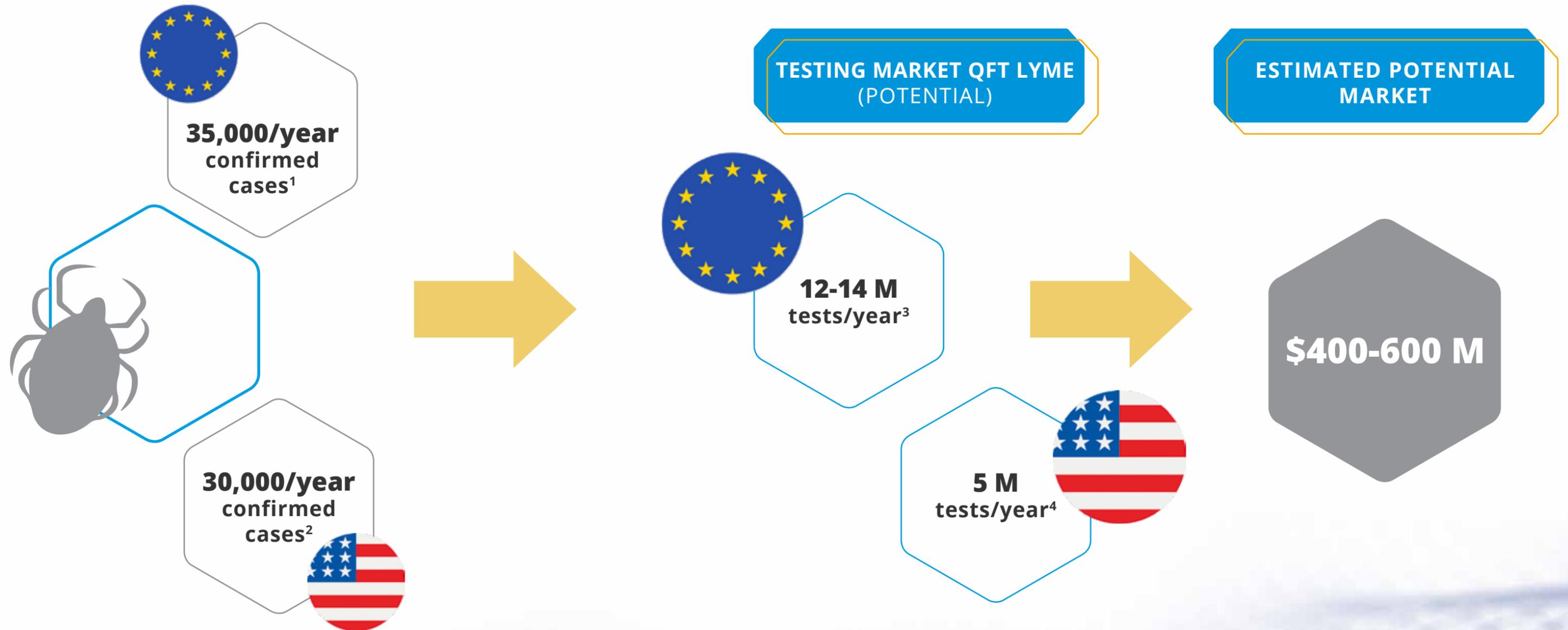
# Value Based Care: new initiatives through diagnostic algorithms





# QuantiFERON Lyme: addressing unmet and unanswered needs

LYME DISEASE: CAUSED BY BORRELIA BACTERIA SPREAD BY TICKS

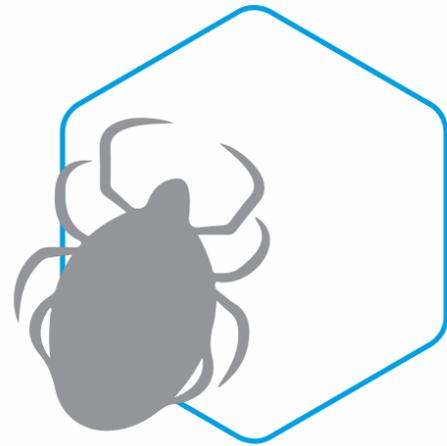


<sup>1</sup> <https://ecdc.europa.eu/sites/portal/files/media/en/healthtopics/vectors/world-health-day-2014/Documents/factsheet-lyme-borreliosis.pdf>

<sup>2</sup> <https://www.cdc.gov/lyme/datasurveillance/index.html> <sup>3</sup> EDMA Market Data & proprietary market intelligence <sup>4</sup> US healthcare insurance reimbursement data



# QuantIFERON Lyme: addressing unmet and unanswered needs



## DIAGNOSIS

**Current algorithm based on IgG, IgM & WB confirmation**  
 low sensitivity in acute infection, risk of delayed or missed diagnosis and long term medical complication cases.

## TREATMENT

**Treatment with antibiotics**  
**If untreated** loss of facial mobility, joint pains, severe headaches with neck stiffness, and heart palpitations **can develop**.  
 In absence of early antibiotic treatment, **10 to 20% of people** develop joint pains, memory problems, and tiredness for at least six months.

### QIAGEN QUANTIFERON TECHNOLOGY AND DIASORIN SEROLOGY TESTING COMBINED TO PROVIDE:

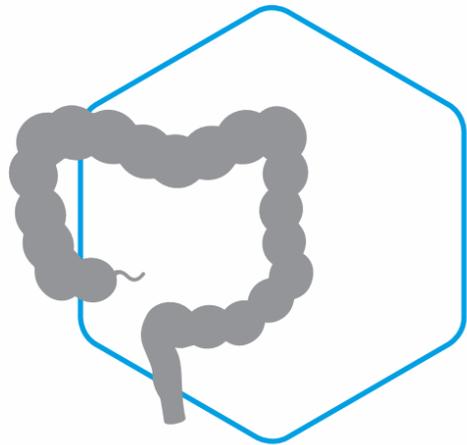




# Inflammatory bowel disease (IBD): patient treatment



IBD PATIENTS REQUIRE TESTING AND MONITORING THROUGH DIFFERENT CLINICAL MOMENTS



**DIAGNOSIS**

Colonoscopy  
Inflammatory markers (Calprotectin)

**TREATMENT**

Steroids or Biologics

**MONITOR REMISSION**

Symptoms, Diet, Lifestyle

## CALPROTECTIN TESTING IS AN UNDERUTILIZED TOOL

**10%**

**DIFFERENTIAL DIAGNOSIS**

Correctly identify IBD (vs IBS & other GI afflictions)

Reduce Colonoscopy where possible

**2%**

**TREATMENT**

Monitoring of Therapy to improve success & optimize therapy costs

LTBI test required: QuantiFERON

**2%**

**MONITOR REMISSION**

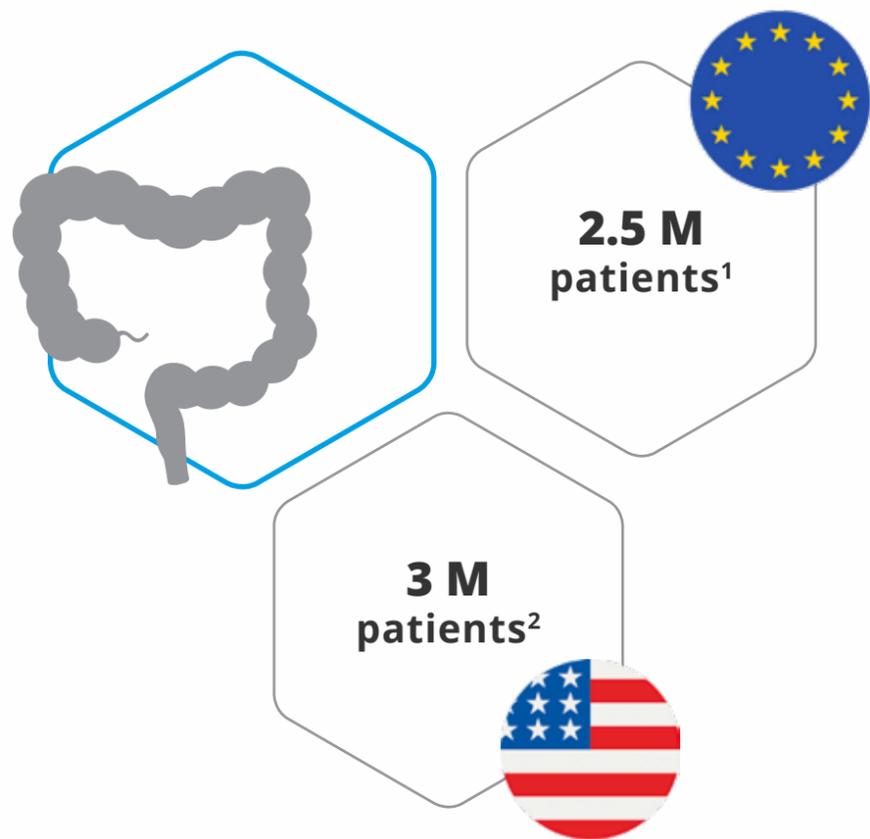
Prediction of Relapse can improve patient life quality

EURECA Study  
DiaSorin

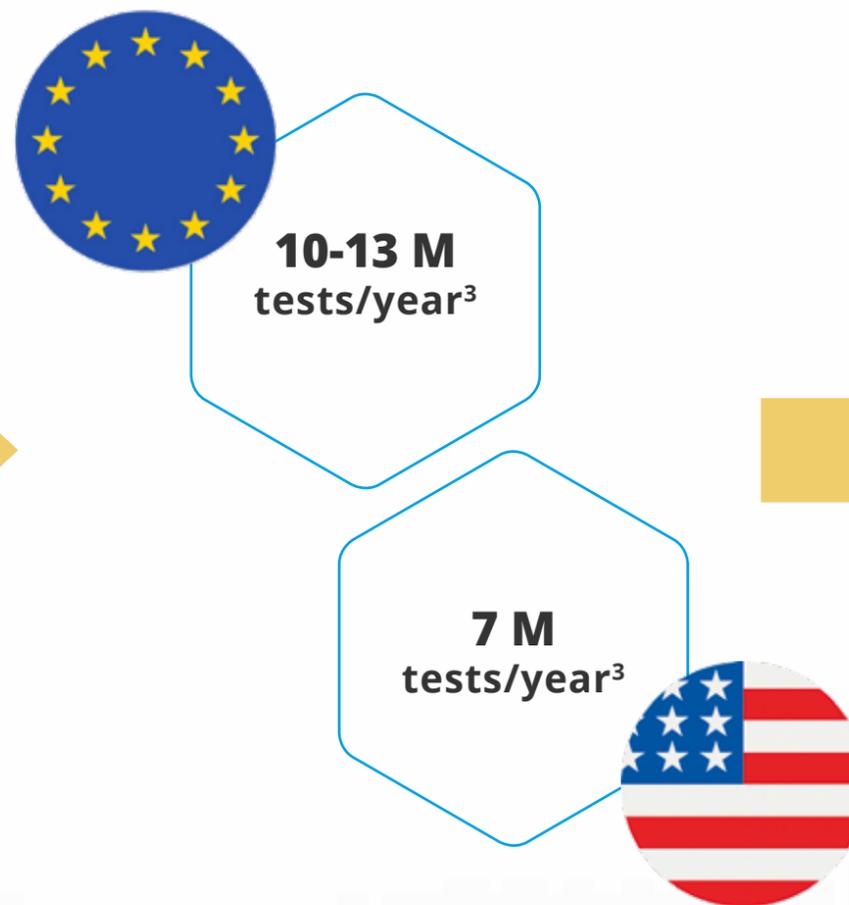


# Irritable bowel syndrome (IBS) vs. Inflammatory bowel disease (IBD)

**CROHN'S DISEASE  
& ULCERATIVE COLITIS**



**TESTING MARKET CALPROTECTIN  
(POTENTIAL)**



**ESTIMATED POTENTIAL  
MARKET**

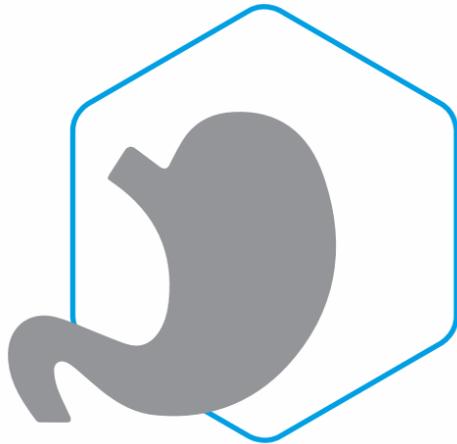


<sup>1</sup> Burisch, Johan, et al. "The burden of inflammatory bowel disease in Europe." Journal of Crohn's and Colitis 7.4 (2013): 322-337

<sup>2</sup> <https://www.cdc.gov/ibd/data-statistics.htm> <sup>3</sup> Proprietary market intelligence



# Helicobacter pylori: diagnosis & treatment



## DIAGNOSIS



### INVASIVE (ENDOSCOPY)

Needs specialized personnel, high patient impact, high cost, can miss low level infection

### NON INVASIVE (UREA BREATH TEST)

Needs specialized personnel, affected by diet, false negatives after treatment

### NON INVASIVE (STOOL ANTIGEN TEST)

Automated, does not require specialized personnel, reduced false negatives and diet effect

15%  
SHARE

## TREATMENT



PROTON PUMP INHIBITORS (PPI)  
+ ANTIBIOTICS  
(Clarithromycin & Amoxicillin)



**RAISE OF ANTIBIOTIC RESISTANCE  
DRIVES NEED FOR TESTING BEFORE  
TREATMENT START**

Testing suggested on all patients if  
local population resistance >15-20%



# Helicobacter pylori clinical need

OPTIMIZED DETECTION & ANTIBIOTIC RESISTANCE TESTING



## UREA BREATH TEST

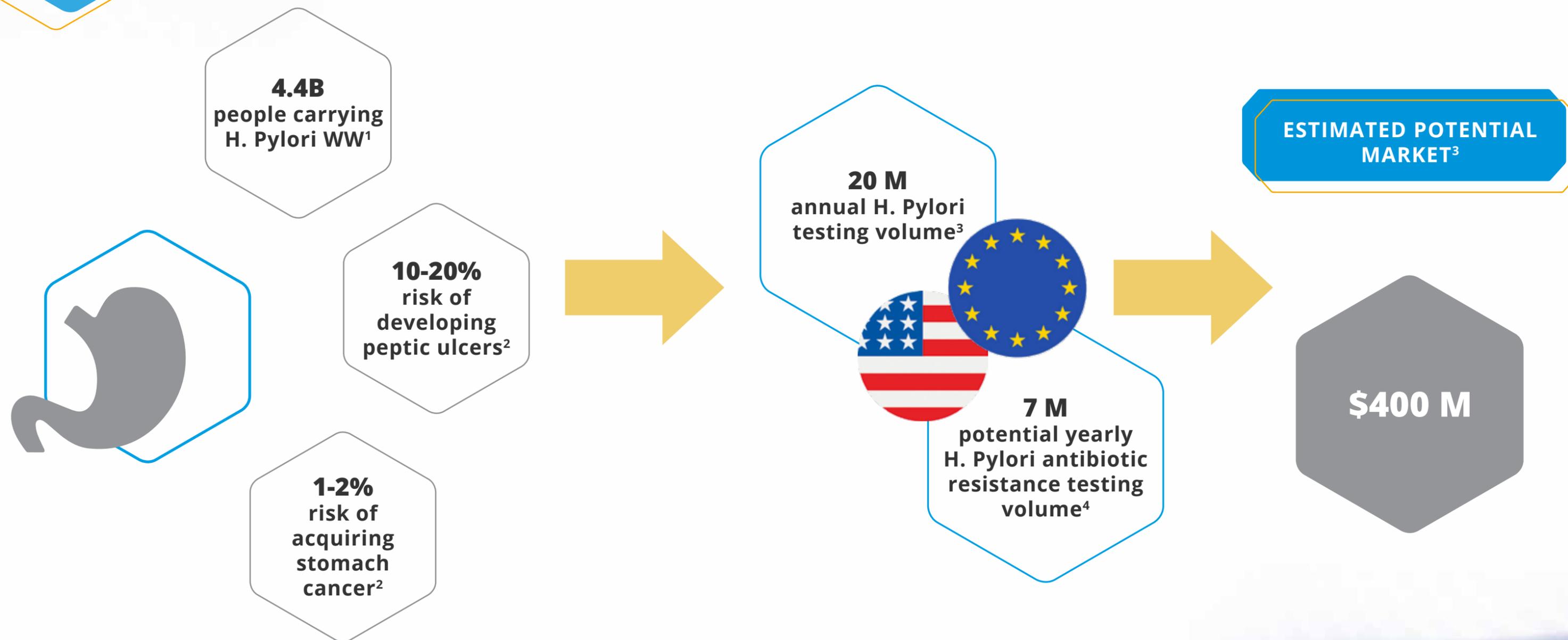


## DIASORIN COMBINED IMMUNODIAGNOSTIC + MOLECULAR DIAGNOSTIC SOLUTION





# Helicobacter pylori



<sup>1</sup> Hooi JKY et al. Global prevalence of Helicobacter pylori infection: Systematic review and meta-analysis. Gastroenterology 2017 Apr 26

<sup>2</sup> Pathogenesis of Helicobacter pylori Infection, Johannes G. Kusters, Arnoud H. M. van Vliet, Ernst J. Kuipers, Clin Microbiol Rev. 2006 Jul; 19(3)

<sup>3</sup> Proprietary confidential market data <sup>4</sup>Based on US and Europe H.pylori incidence rates



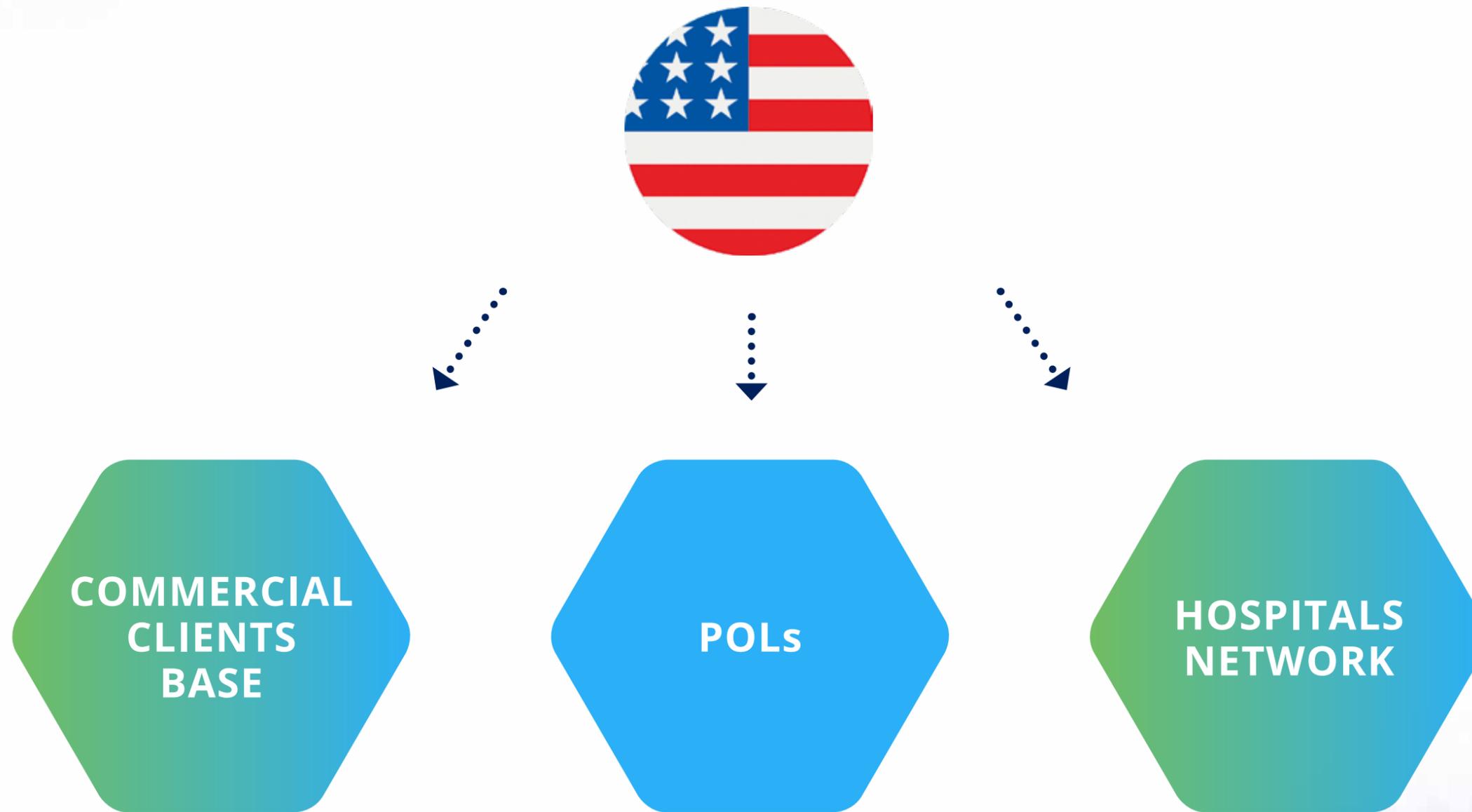
DiaSorin

The Diagnostic Specialist

# Group strategies by main geographies

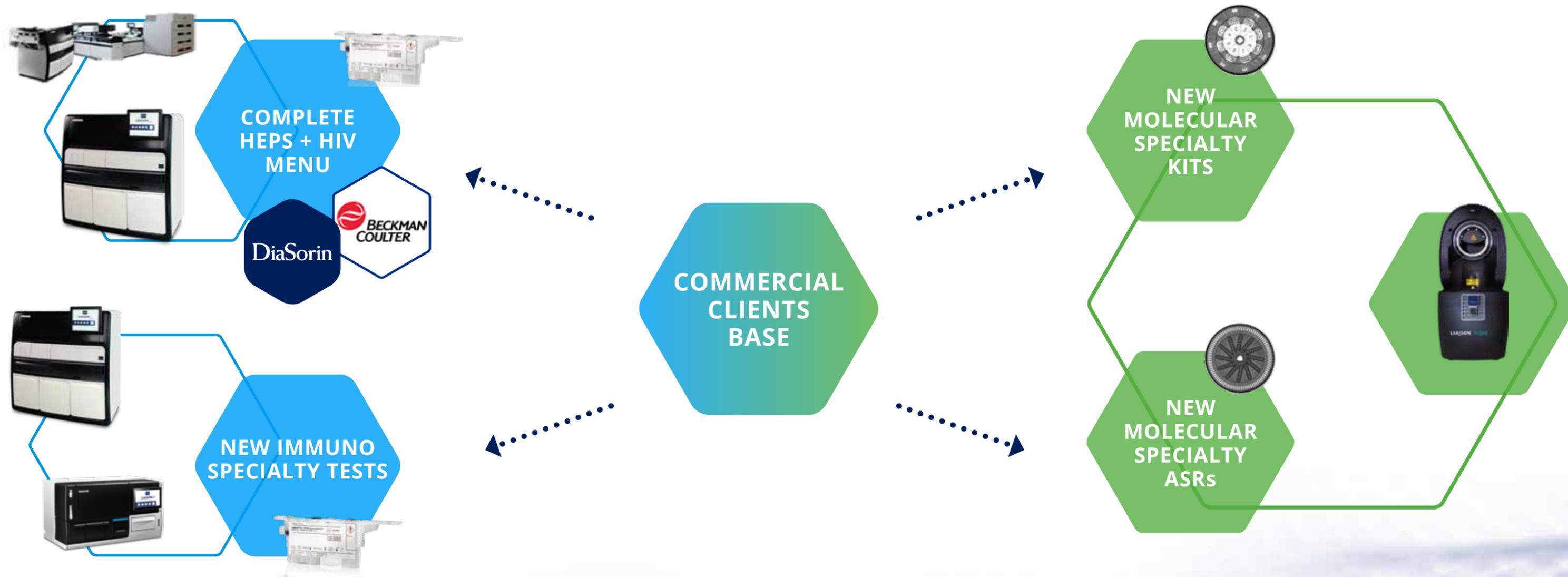


# US strategy





# commercial clients base strategy

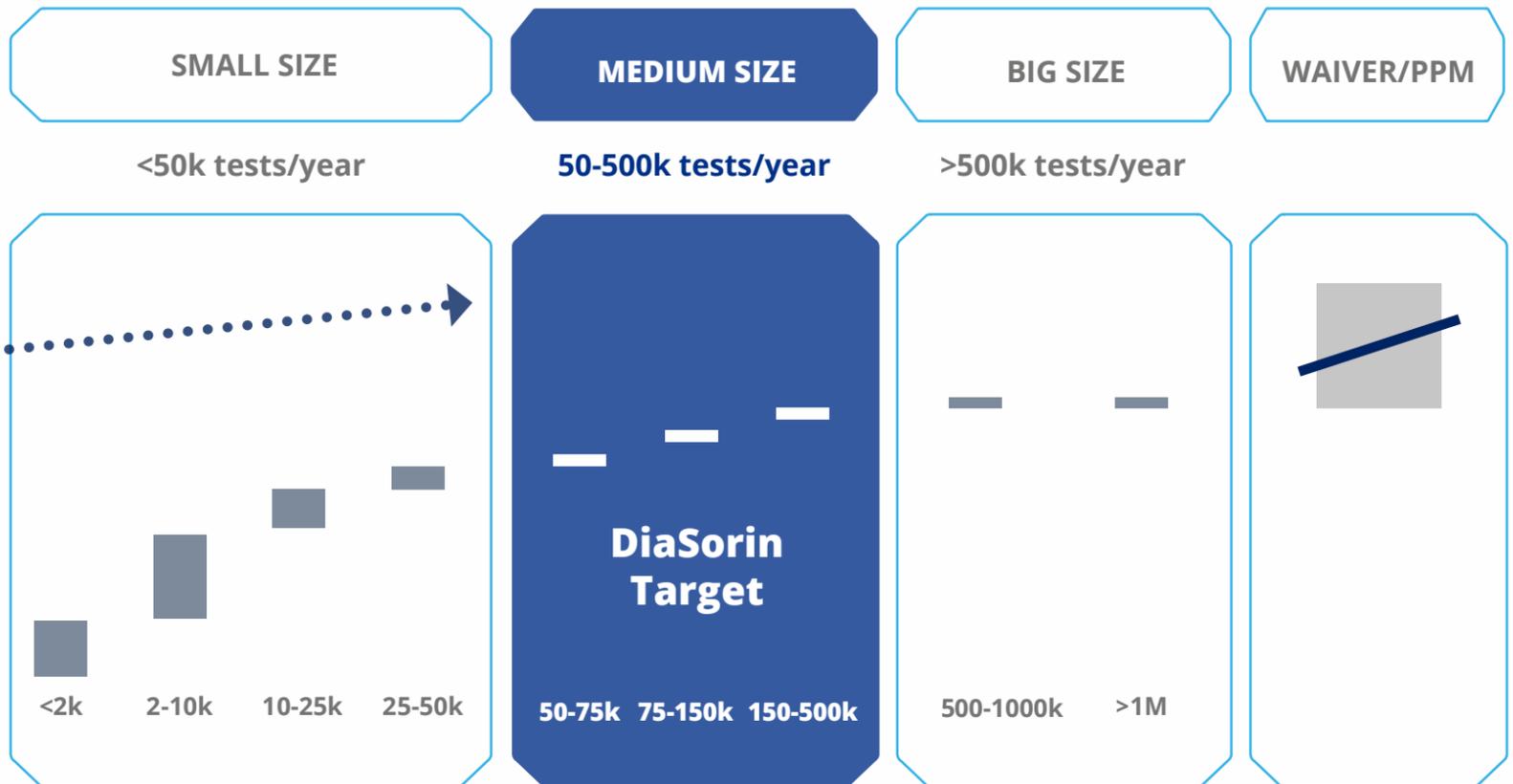




# LIAISON XS and POLs strategy



### # POLs IN THE US PER TEST VOLUMES (2017 DATA)



Tot POLs	~ 15,000	<b>~ 2,200</b>	~ 200	
Tot tests	~ 140M	<b>~ 300M</b>	~ 220M	~ 220M
% tests volumes	~ 16%	<b>~ 34%</b>	~ 25%	~ 25%



Market segment stable over next 5 years (slowdown of 1-2%). Lower exposure to PAMA effects vs. rest of the market.

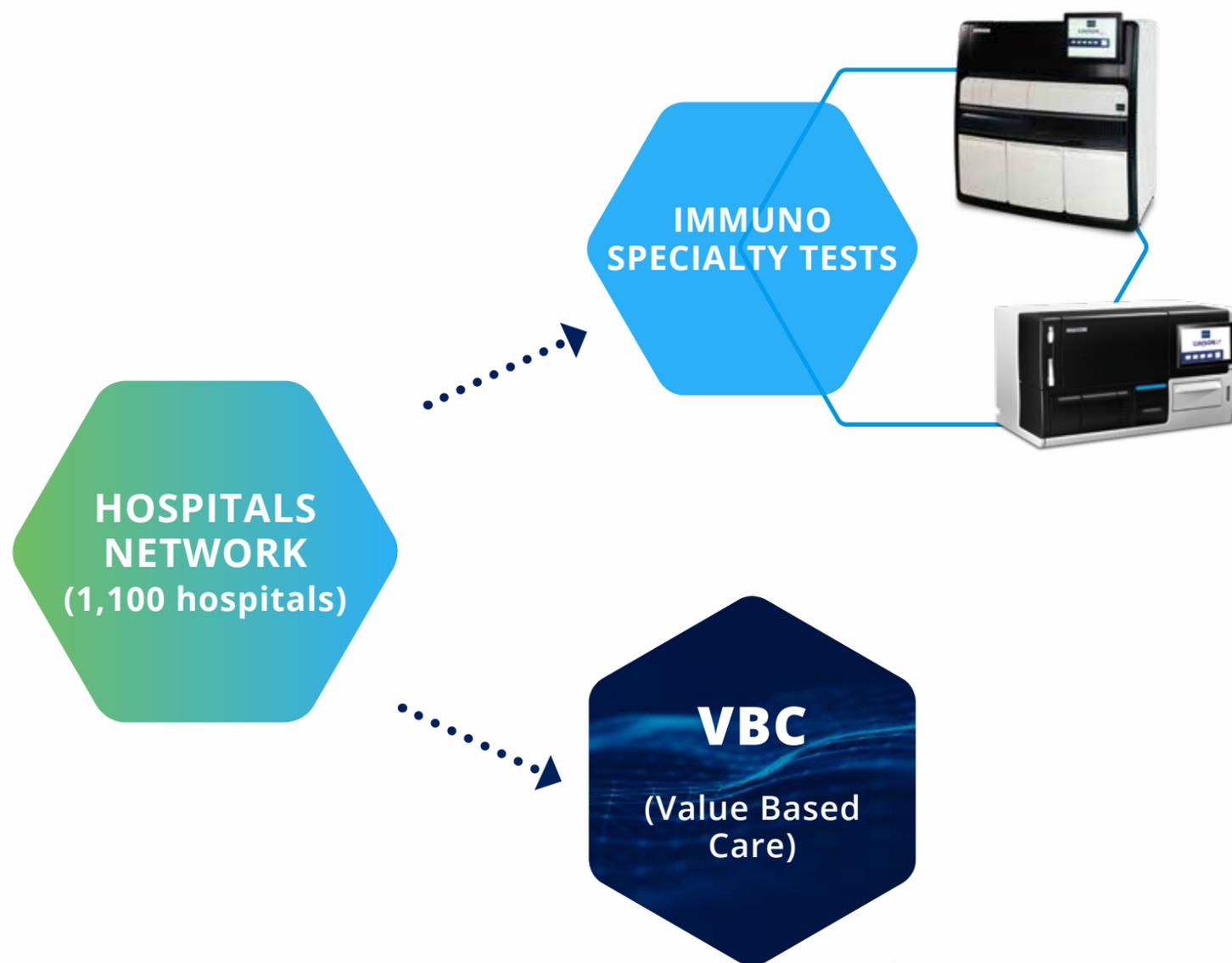
**"ME-TOO" IMMUNO TESTS**





# hospitals network strategy

EXPANSION IN THE HOSPITAL MARKET: STRATEGIC FOCUS ON INTEGRATED HEALTH NETWORKS AND MAJOR MEDICAL CENTERS



Leverage innovative product launches/ strategic partnerships to drive sales cycles in the strategic Hospital account segment

New dedicated resources to call on the top Health Networks and Group Purchasing Organizations to remove barriers to entry

Sales organization efforts focused in the strategic segment with new value based messaging

Additional sales resources to accelerate the uptake in the segment



# **European strategy**

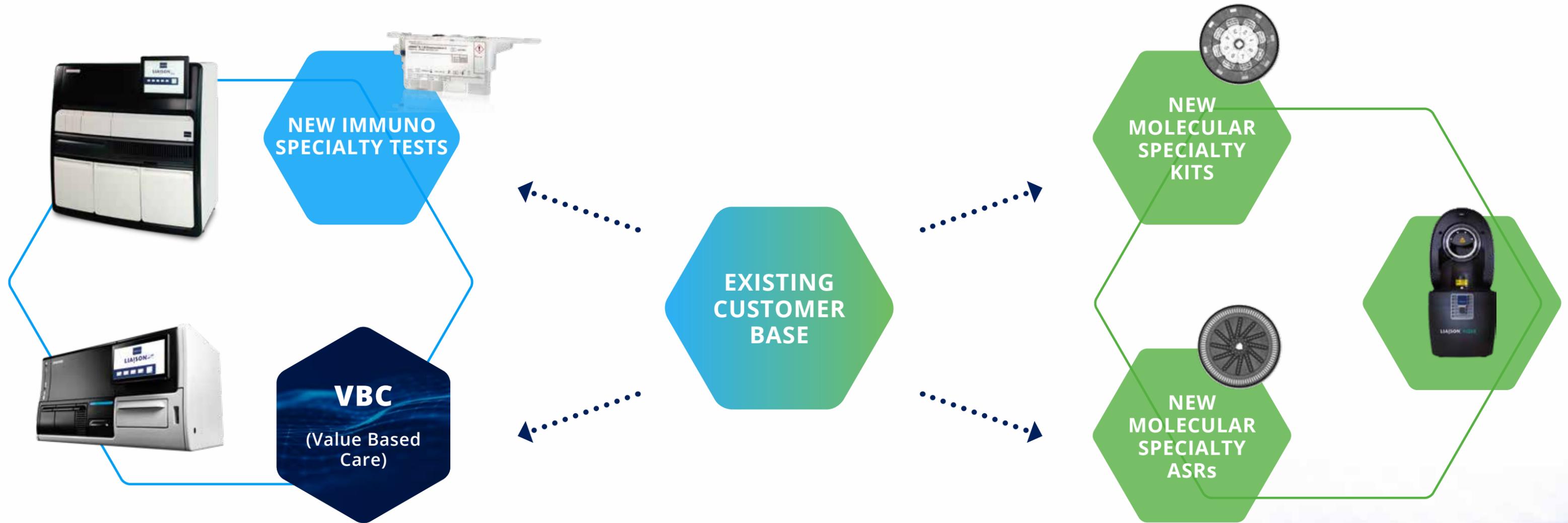


**EXISTING  
CUSTOMER  
BASE**

**ELISA  
CONVERSION  
TO CLIA**

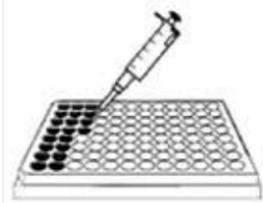


# European strategy





# Europe: LIAISON XS enabling QFT and Siemens ELISA conversion to CLIA



ELISA testing



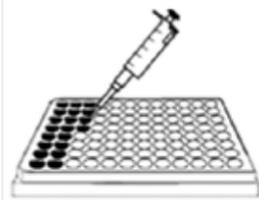
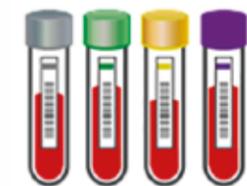
**LIAISON<sup>®</sup> X**

for mid-to-big volumes conversion



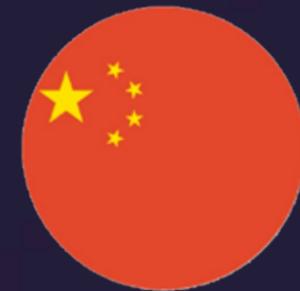
**LIAISON<sup>®</sup> X**

for mid-to-small volumes conversion

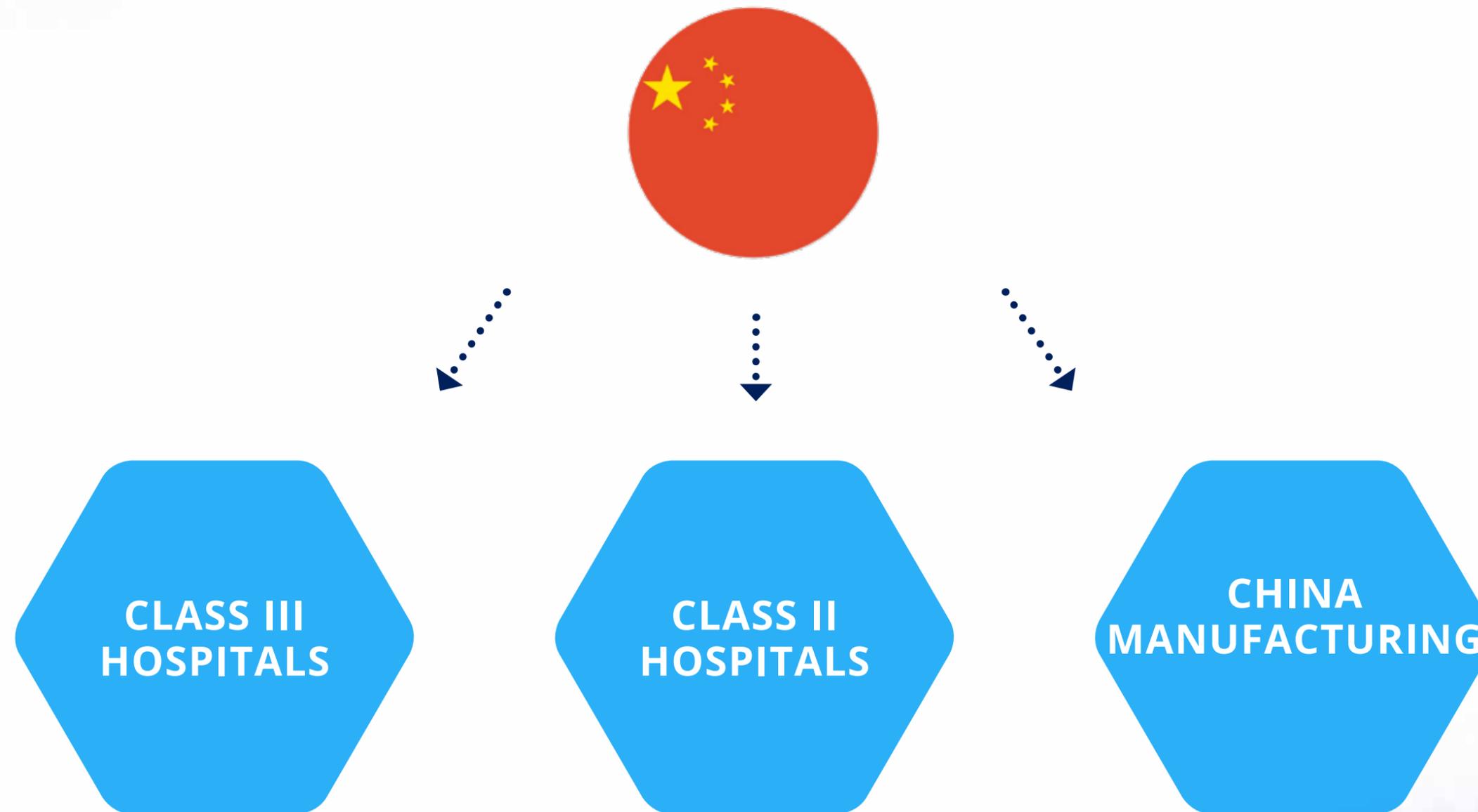


ELISA Detection





# hinese strategy

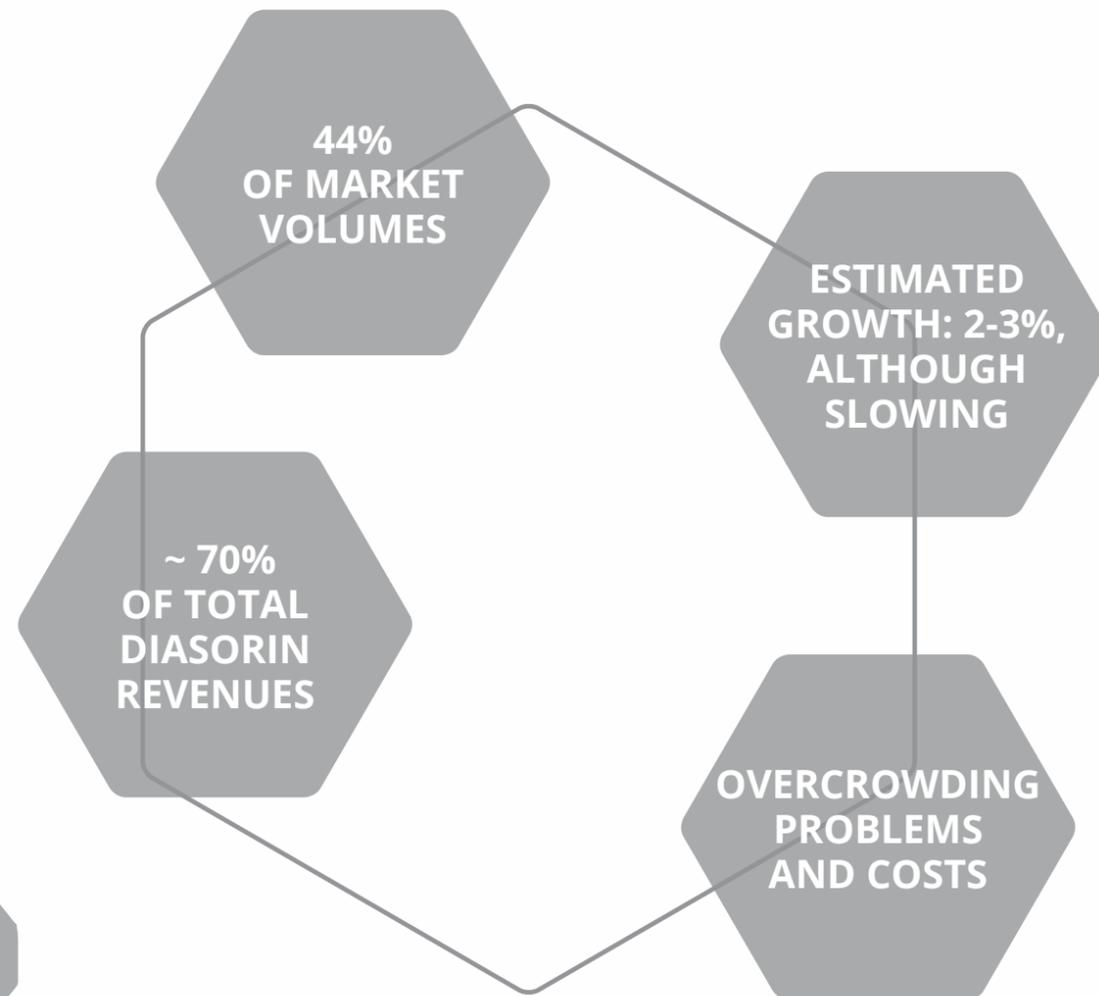
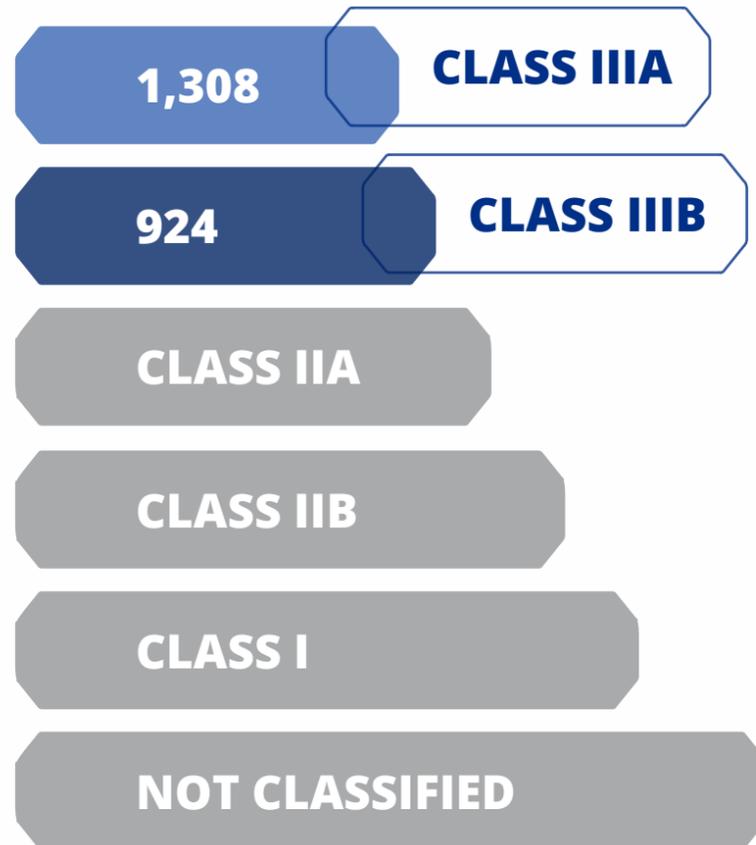




# China: Class III hospital strategy



## #HOSPITALS

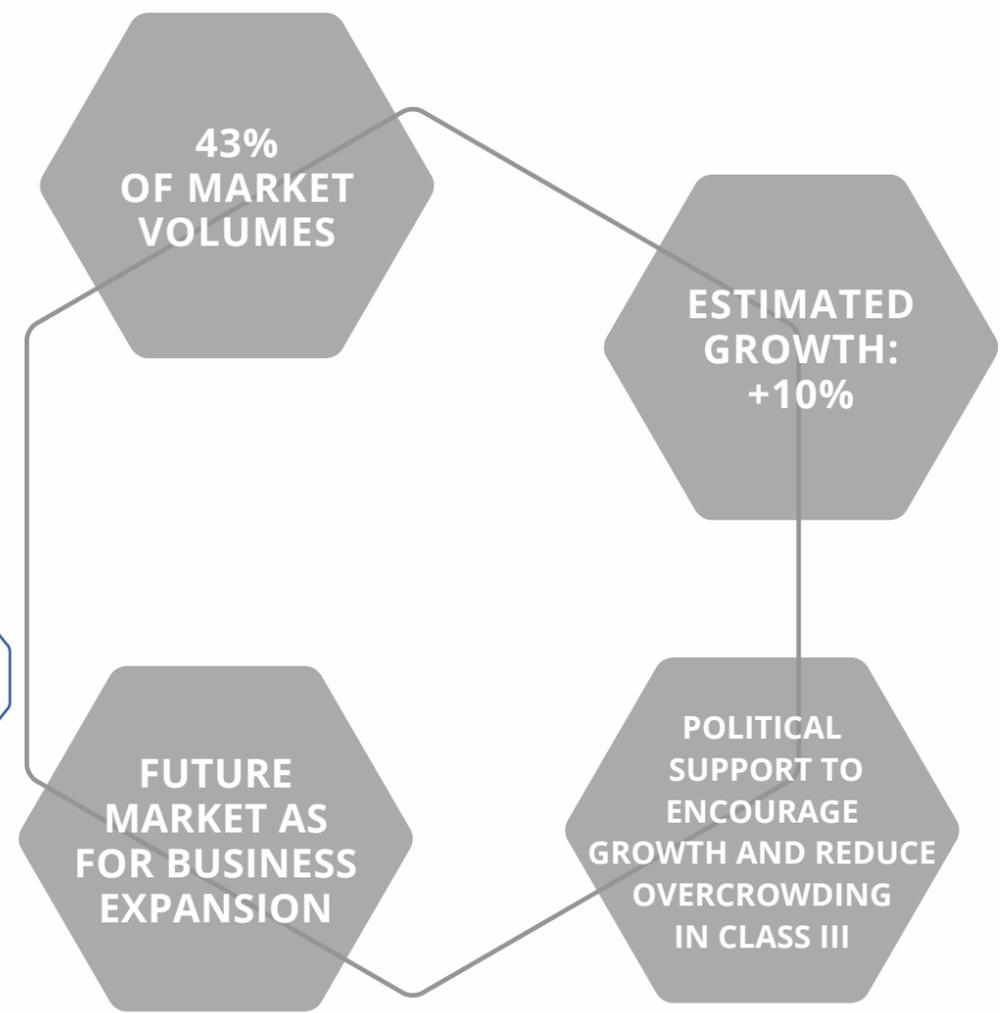
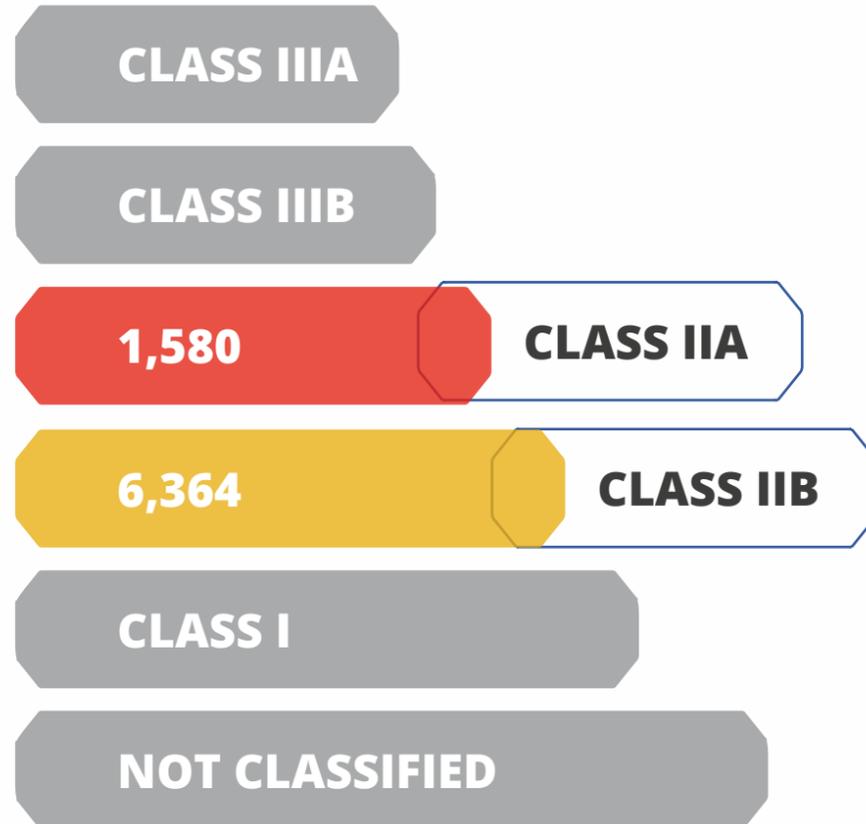




# China: Class II hospital strategy



## #HOSPITALS

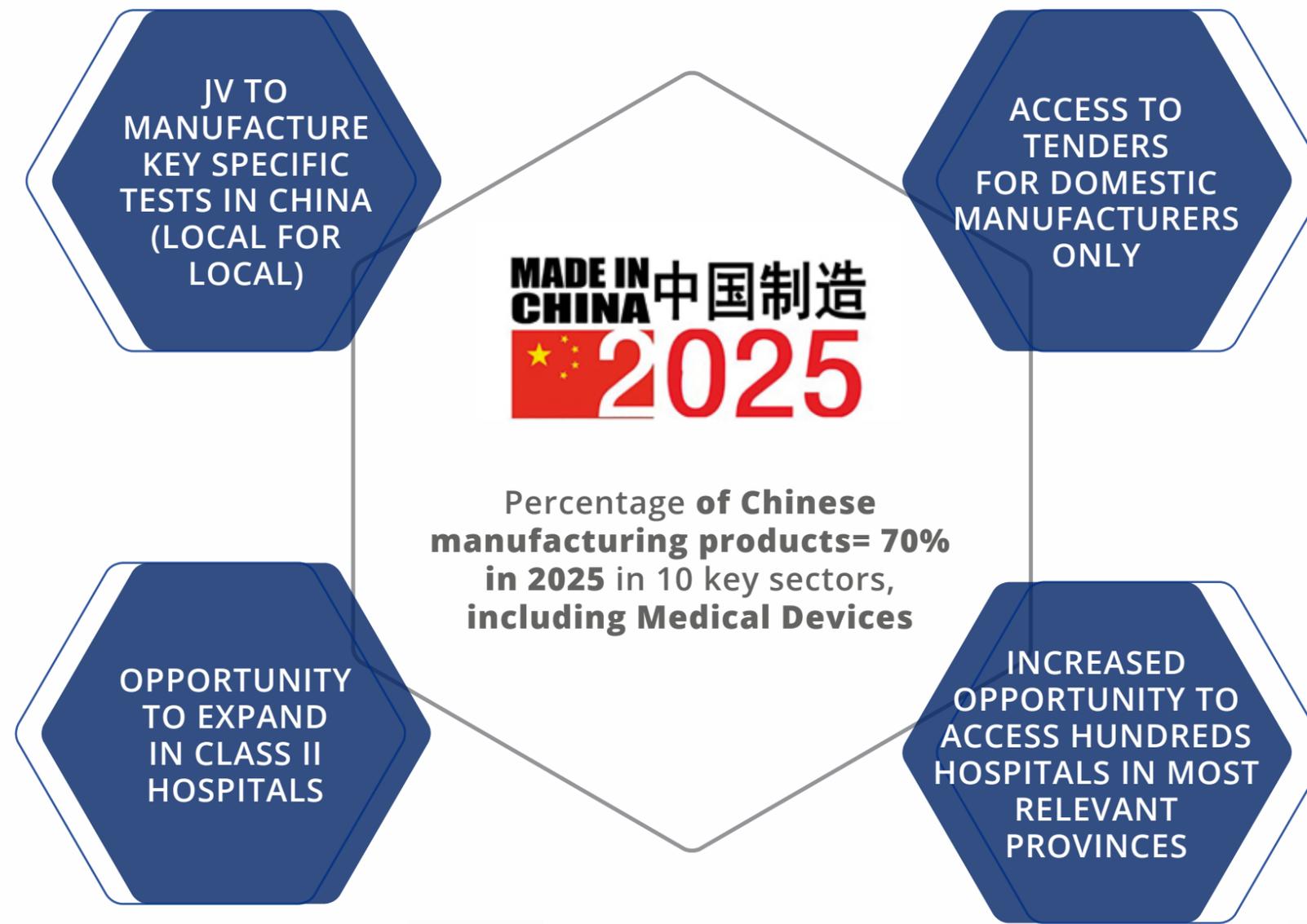


New distribution network to address the segment with LIAISON XL

LIAISON XS to penetrate this new segment



# China manufacturing: from export to high quality local CLIA developer



DiaSorin positioning as a high quality "made in China" CLIA diagnostic manufacturer through a new Joint Venture with a recognized Chinese academic institution

**DiaSorin**

The Diagnostic Specialist

# **Guidance 2019 - 2022**



# Guidance 2019 - 2022

**REVENUES  
GROWTH  
CAGR  
@ 2018 CER**

**MID-TO-HIGH  
SINGLE DIGITS**

**EBITDA  
MARGIN  
@ 2018 CER**

**COMPARABLE  
TO 2018 EBITDA  
MARGIN RESULT**

**2019 - 2022  
CUMULATIVE  
FCF @  
2018 CER**

**€700 - 750 M**



**DiaSorin**

The Diagnostic Specialist

# **Business development opportunities**



# Business development opportunities

2019-2022: continuous focus  
on Business Development opportunities

**NEW ALLIANCES  
AND/OR  
PARTNERSHIPS**

**VBC**  
(Value Based Care)

**M&A**



DiaSorin

The Diagnostic Specialist

# Main takeaways



# Main takeaways

