

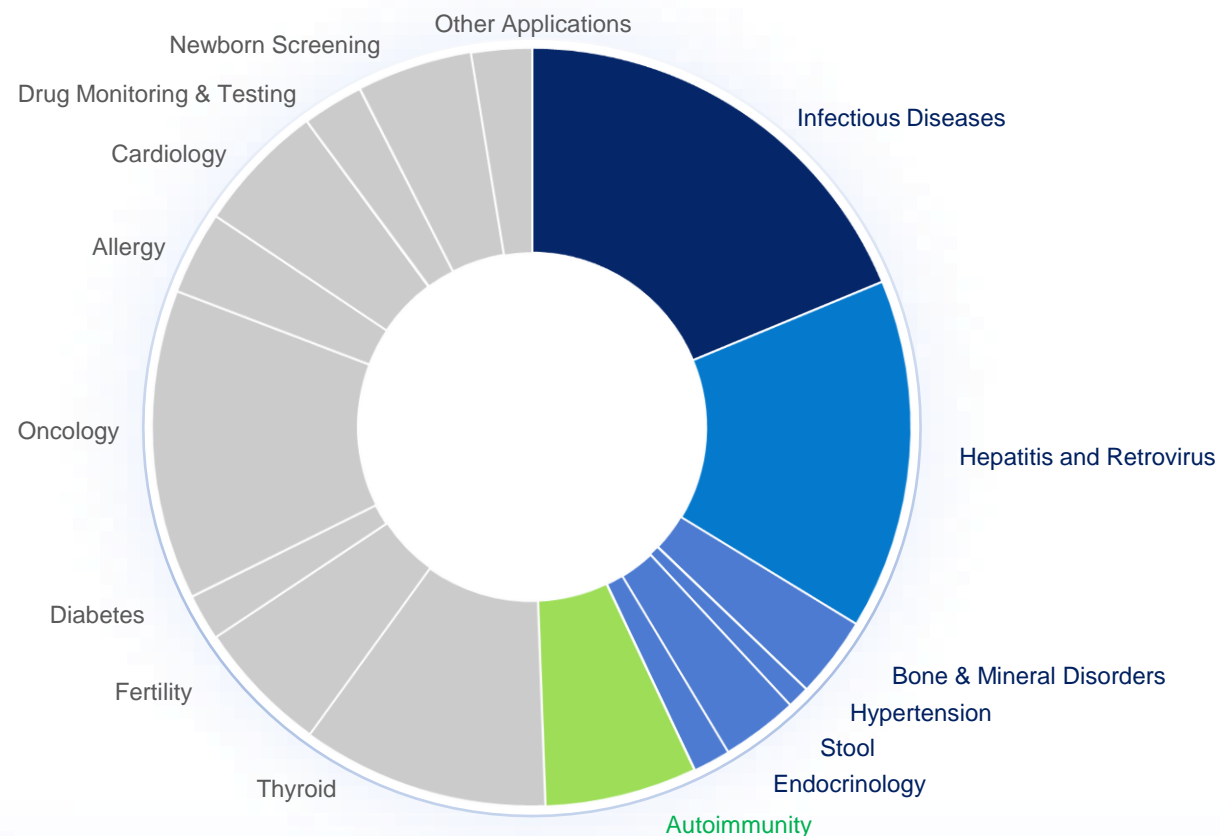
03

IMMUNODIAGNOSTICS

Chen Even

CCO

Immunology Market Size and Clinical Areas



GLOBAL MARKET - IMMUNOASSAYS

~18 €/bn

- Focus Clinical areas for Diasorin
- Future areas of development
- Clinical areas not served by Diasorin

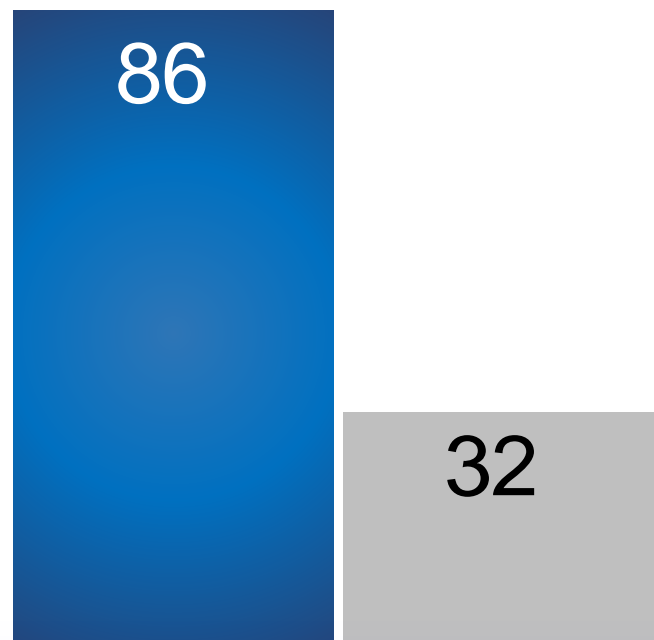
Sources: Diasorin sales data, Diasorin internal market research, GDMS data, Markets & Markets Immunodiagnosics forecast to 2030 report, DHC

**Diasorin serves with strategic focus roughly 40% of the market
Future opportunities in one specific segment (autoimmunity)**

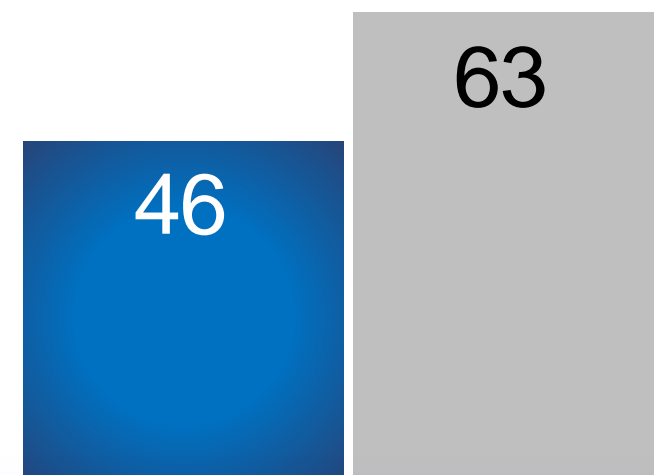
Broadening the distance to competition





Differentiating & High-Volume Specialties



High-routine tests



-  Diasorin Immunoassay tests
-  Tests of the main competitor within the area

“ We have the broadest immunoassay menu available on the market ”

PRODUCTS

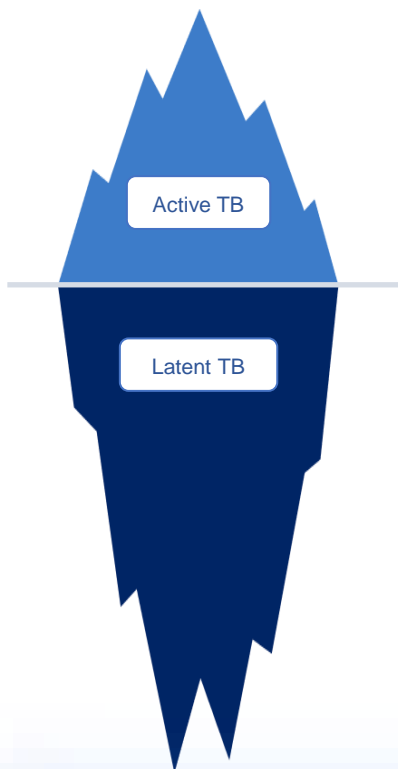
Latent Tuberculosis



Latent Tuberculosis - Market



Tuberculosis



Active TB

- > 10 million active cases globally
- Symptomatic and contagious
- Often deadly if not treated

Characteristics

- TB is actively spreading
- Testing through NAAT, chest X-Ray, sputum culture

Latent TB

- ~2 billion latent infections globally
- Asymptomatic and not contagious
- 10% of infected will develop active TB

Characteristics

- Hard to identify
- Testing through skin or IGRA tests (QuantiFERON – market leading test)

~2 bn

People infected with latent TB

>75 mln

latent TB tests annually

>45 mln

skin tests to be converted to QFT

1.6 \$/bn

latent TB testing TAM in 2026

TUBERCULOSIS IS THE WORLD'S DEADLIEST INFECTIOUS DISEASE

Source: QIAGEN and Diasorin

Latent Tuberculosis – Full automation and improved efficiency



Advancing workflow automation

Inpeco partnership
move QuantiFERON
and LIAISON
towards a full
ecosystem solution



- Addressing the need to **improve pre-analytical steps in labs**
- QIAGEN **fully automates** the process with Inpeco and Diasorin partnerships
- Process automation can be adapted to **specific customer needs**
- Ambition to be the first FDA-approved, CE-marked **fully automated TB test**
- LIAISON QuantiFERON-TB Gold Plus II assay delivering **25% faster turnaround time** and enabling testing of **~75% more patients/hour**

Source: QIAGEN and Diasorin



Our competitive advantage



Tubes for **CD4** and **CD8** antigen testing



Market leader in TB segment



QFT-TB brand recognized as **WHO Gold-Standard**



Broadest claims for patient population

COMPETITIVE ADVANTAGES TO FACE POTENTIAL COMPETITION ON TB

Gastrointestinal



GI Health: Serving Dx Needs for Gastroenterologists



BACTERIAL

- Simplexa® *C. difficile* Direct Kit
- LIAISON® *C. difficile* GDH
- LIAISON® *C. difficile* Toxins A&B
- LIAISON® Campylobacter Ag
- LIAISON® Meridian *H. pylori*
- LIAISON® *H. pylori* IgG
- LIAISON® Legionella Urinary Ag
- LIAISON® PLEX GI Flex

VIRAL

- NxTAG® Gastrointestinal Pathogen Panel*
- LIAISON® PLEX GI Flex
- LIAISON® Adenovirus
- LIAISON® Rotavirus



MELABSORPTION

- LIAISON® Elastase-1
- LIAISON® tTG IgA

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- LIAISON® Elastase-1
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PRE-TREATMENT INFECTIOUS SCREENING

- LIAISON® QuantiFERON-TB Gold Plus II
- LIAISON® Cytomegalovirus (CMV) Diagnostic Solution
- LIAISON® EBV Diagnostic Solution
- LIAISON® Hepatitis Diagnostic Solution

■ SERUM/PLASMA SAMPLE
 ■ STOOL SAMPLE
 ■ URINE SAMPLE

■ MOLECULAR ASSAYS
 ■ IMMUNOASSAYS

Diasorin GI Immunodiagnosics Panel

BROAD, INTEGRATED GI MENU (8 LIAISON TESTS)

- Covers **inflammation, infectious diseases, pancreatic markers, and celiac**
- Drives both clinical value and sustainable growth, from GI diagnostics to an **integrated, patient-centric GI management ecosystem**
- **Strengthens clinical depth** and competitive differentiation
- **Unique system-level** advantage
- **Enables management of related conditions** through broad adjacent menu



NEAR-TERM INNOVATION AND NEXT-WAVE PIPELINE (2026-2027)

- **LIAISON Q.S.E.T. Quick Pick – home stool collection kit:**
 - reduces lab workload
 - improves sample quality
 - enhances patient convenience

- **LIAISON Calprotectin HD**
- **LIAISON Lactoferrin**
- **LIAISON FOB**
- **LIAISON expanded Celiac panel**



One-platform solution for diagnosis + monitoring across GI diseases

Calprotectin – Market overview

5-10% of the world population has **IBS**

~1% of the **western world population** has **IBD**

10% of all **primary care visits** are due to **GI symptoms**

Calprotectin is the key test to distinguish IBS vs. IBD and to monitor inflammation

Rising prevalence of chronic GI diseases (IBD, IBS), with increasing burden of gastrointestinal infections

→ **Sustained demand growth for non-invasive diagnostics**

Gastrointestinal – Calprotectin HD for enhancing diagnostic power

IBD* DIAGNOSIS – AS IS

- **Diagnosis complexity:** differentiation from diseases with similar presentation but with higher prevalence (IBD vs. IBS**)
- **Global prevalence:** ~230 per 100,000 people
- **Global incidence:** ~10 per 100,000 people-years
- ~ 7 mln people worldwide live with **IBD**, of which 3.2 mln in the U.S. (source CDC)



THE CHALLENGE

- **Limited specificity** (“grey zone”): Moderate calprotectin elevations are not disease-specific
- **Limited decision value:** Low specificity prevents calprotectin from reliably guiding decisions
- **Residual need for colonoscopy:** In grey-zone cases, colonoscopy remains the only available diagnostic option for clinicians



THE SOLUTION



Calprotectin HD

- **Combining Calprotectin with a novel biomarker** (MMP-8 metalloproteinase)
- Enhance assay **specificity** without compromising **sensitivity**
- **Accelerate diagnosis time** supporting for endoscopies prioritization

Calprotectin HD turns calprotectin from a screening marker into a decision-making tool, reducing unnecessary procedures and lowering healthcare burden

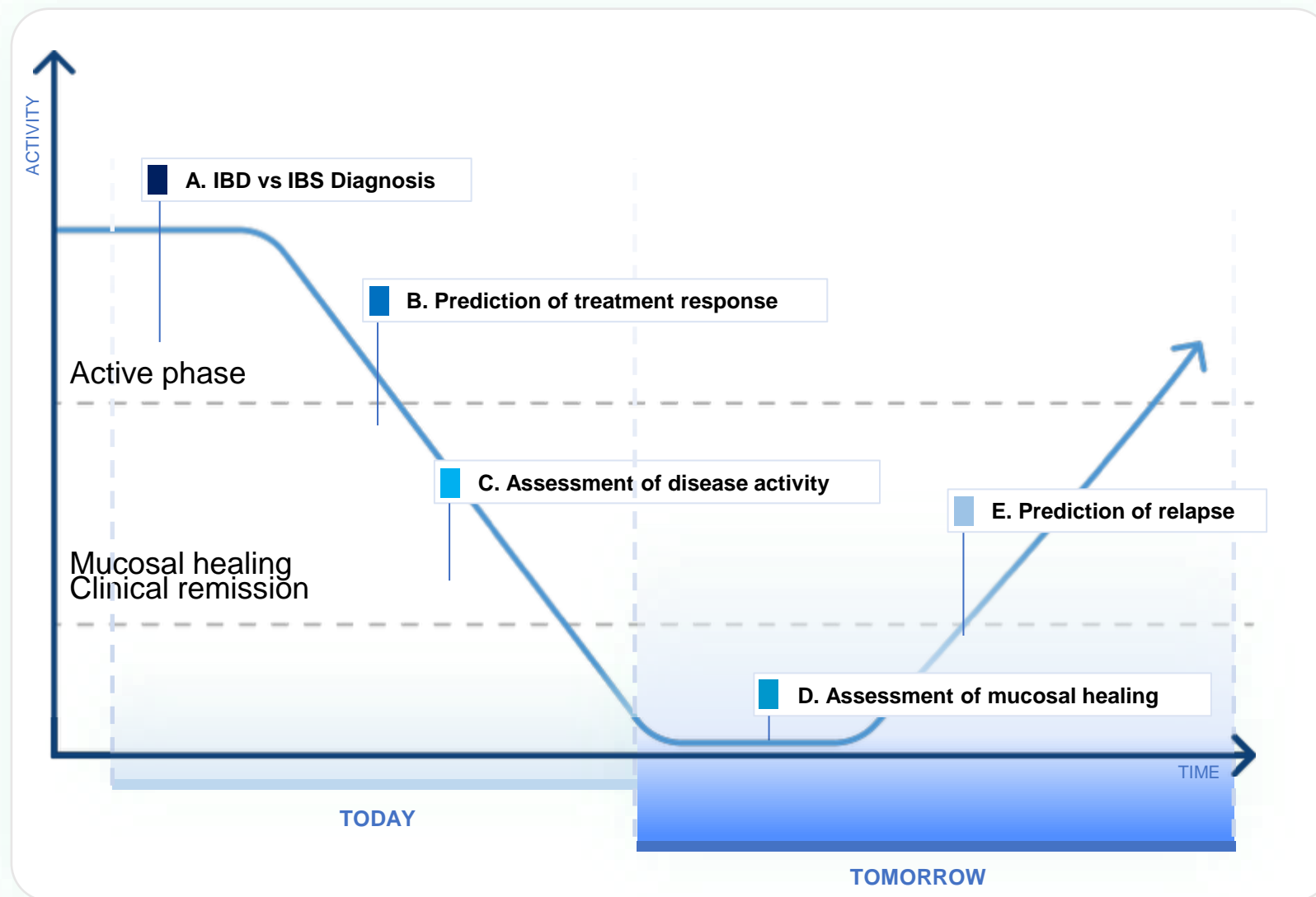
Uniquely available to Diasorin through patent protection

* Inflammatory Bowel Disease

** Irritable Bowel Syndrome



Gastrointestinal - Stool and Blood biomarkers inform IBD management across patient journey



5 key phases of the patient journey with IBD:

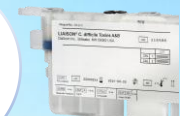
- Diagnosis
- Prediction of treatment response
- Assessment of disease activity
- Assessment of mucosal healing
- Prediction of relapse



Hypertension



Hypertension – a new guideline for primary Aldosteronism Including Diasorin established cutoffs



Primary Aldosteronism (PA): current market scenario

Severely underdiagnosed form of Hypertension: only 0.5-2% of total diagnosed population are tested for Aldosteronism

PA affects

- ~6% of **total hypertensive patients** in primary care
- ~30% of patients with **resistant hypertension**
- ~1-2% of **adult population worldwide**
- ~5-14% of **all hypertensive patients globally**

PA remains substantially underdiagnosed



The opportunity: a changing clinical environment



- **New 2025 guidelines** recommend universal screening for **Primary Aldosteronism** in all individuals diagnosed with hypertension
- **Screening recommended** through measurement of plasma aldosterone concentration, plasma renin concentration or activity, and the aldosterone-to-renin ratio (ARR)
- **2025 guidelines represent a major shift** towards universal screening and systematic management of primary aldosteronism



Hypertension – a new guideline for primary Aldosteronism Including Diasorin established cutoffs

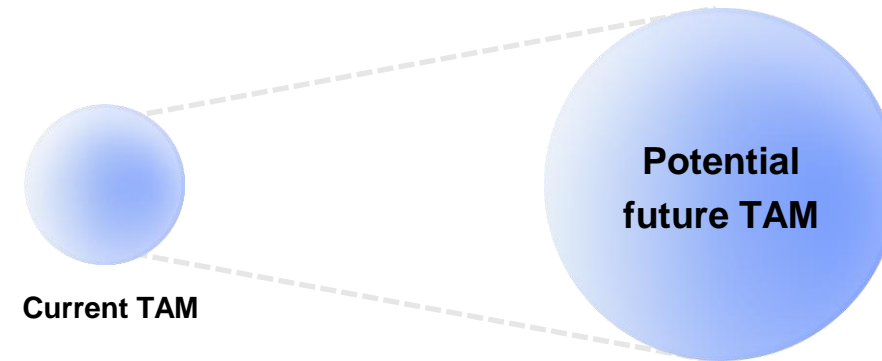


DIASORIN LEADING THE WAY



- Recommended cut-off for ARR reflects **Diasorin's Aldosterone and Direct Renin ones**
- **LIAISON Aldosterone and LIAISON Direct Renin tests** are a reliable, accurate and simple to use method **for determining ARR**
- Seek FDA and IVDR specific approval for **ARR screening intended use and purpose**

TOTAL ACCESSIBLE MARKET (TAM)



- **Full adoption on new Guidelines could increase TAM to ~50M screening tests/year in Europe, US and Australia (25x growth vs today)**
- Historical data from similar guideline drive market changes shows **6-8x market size growth**

New guidelines creating a significant opportunity for LIAISON Aldosterone and LIAISON Direct Renin assays testing

MeMed



Memed – Target and initiatives 2026-2030 (US focus)



2026-2030

NEW CUSTOMERS	~50 per year
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by 2030

TOTAL CUSTOMERS TARGET	>250	= 1/3 of Diasorin's U.S. Hospital Targets
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What enables MeMed opportunity to grow initiatives

Jupiter study

- MeMed BV guidance **reduced unnecessary antibiotic prescriptions** in viral patients **by 52% (25% vs 12%)**
- **Improved identification of bacterial infections with increased appropriate** antibiotic treatment (**41% → 78%**)
- **No increase in return ED visits** or hospitalization
- **Supports antibiotic stewardship** and optimized clinical decision-making

Unbundling from DRG

- **CMS unbundling request submitted** to enable separate reimbursement vs bundled payments
- If approved, unlocks **fee-for-service model** and improves hospital adoption economics

Private reimbursement

- **Dossiers submitted to multiple US payers**; ongoing advisory boards and appeal support
- Expected **progressive coverage expansion** across national/regional plans and IDNs

SYSTEMS

LIAISON XL Evolution

TODAY



LIAISON® X



H1'27



LIAISON® XL

Compact size. Expanded power. Fully Integrated.

- Maximum flexibility in every configuration
- Expanded capacity without increasing footprint
- Immediate access to a complete reagent menu
- Full compatibility with existing Total Lab Automation ecosystem
- Fewer steps, more walk-away time

Increased Sample Capacity and Accelerated workflow



Automated ID & De-capping



Smart tube handling



Optimized workflow & connectivity



Flexible installation



No Buffer Preparation Need

Improved Walk-away time, safety and workflow efficiency



diluteX



Automated

Throughput improvement up to 50%

Walkaway time minimum of 10 hours

U.S. HOSPITALS STRATEGY

U.S. Hospitals Strategy

TOTAL HOSPITALS

~150

NEW HOSPITALS

Identification of 2,200 hospitals (Addressable market)



START 2019



PHASE 1 2020-2022

~300

+150



PHASE 2 2023-2026

~600

+300



PHASE 3 2027-2030

~900

+300

Continue penetration and focus on add-on specialties

Diasorin continues to gain market share in the hospital segment with target of serving ~40% of US hospitals by 2030

FUTURE OPPORTUNITIES

Autoimmunity



Autoimmunity market

Specialty Autoimmune testing

Presenting the best opportunity for expansion in an untapped area of Immunodiagnostic testing



Size and competition

Global market¹:
~ 1.3 €/bn

~45% high-volume;
~55% specialty

Global specialty market¹:
~ 750 €/mln

~63% in Europe and NA, with **4 established specialty players**



Growth Driver

Reimbursement

Consistent global high single digit growth,
reaching **10%+** for some specialty areas

¹ 2025 data

Autoimmunity – Diasorin positioning

Autoimmunity testing is evolving from a niche specialty area into a **core component of centralized laboratory workflows**



Existing major **Total Lab Automation (TLA) suppliers** to Core Labs **do not offer** autoimmunity solutions



Diasorin recognized by leading TLA players as a complementary solution

~25% of LIAISON installed base already connected to laboratory automation tracks



Building a comprehensive autoimmunity panel creates a natural fit with major TLA platforms. By connecting LIAISON systems to automation tracks, autoimmunity becomes a high-value complementary segment within Core labs

Complementary Diagnostics



Diagnostics are no longer support – they are the decision

PRECISION MEDICINE | STRATEGIC CONTEXT

Precision medicine (companion and complementary diagnostics) is redefining how drugs reach patients—and how every clinical dollar is justified

COMPANION DIAGNOSTIC (CDx)

- Central to personalising drug treatment
- Provides information essential for safe & effective use of the therapy
- The test is required by the drug's Indications for Use

COMPLEMENTARY DIAGNOSTIC (ComDx)

- FDA-defined (mid-2015): identifies patients who respond particularly well to a drug
- Aids risk/benefit assessment—but is not a prerequisite for receiving the drug
- Not required by Indications for Use — but may be mentioned in drug labelling

Source: FDA Drug Approvals 2025; ClinicalTrials.gov pipeline analysis; IQVIA Institute 2025

40%

of all FDA drug approvals in 2025 are precision medicine / biomarker-driven

2 in 3

late-stage pipeline drugs are biomarker-driven in clinical development

70%

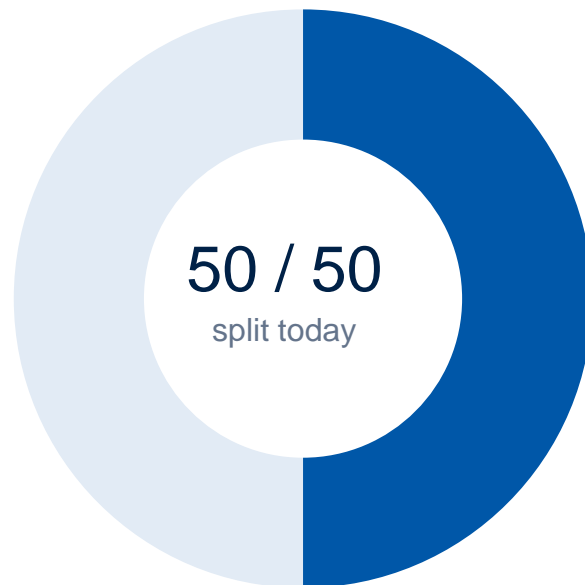
of the most advanced clinical decisions rely on diagnostic results to guide treatment

Diagnostic testing is no longer optional - it is the gateway to treatment

Half the precision medicine wave lies outside oncology – and we have the first proof points to act on it

STRATEGIC OPPORTUNITY | NON-ONCOLOGY EXPANSION

Precision medicine is mainstream in oncology—but 50% of biomarker-driven drugs already target other therapeutic areas, signaling the next frontier.



■ Oncology ■ Non-Oncology



HYPERTENSION – Primary aldosteronism and Aldo. Synthase Inhibitors (ASIs)
Biomarker and drug's response
Volume potential 6-10M tests/year



Anti-TNF- α - biologic drugs that block tumor necrosis factor-alpha (TNF- α)

+ Additional areas: GLP-1 agonists, Diabetes, Obesity, Chronic Inflammatory Diseases, Thyroid, bone-mineral, adrenal, etc.

Testing is a critical spend gateway—winning in non-oncology diagnostics means influencing the next generation of treatment pathways

Key Takeaways on Immunodiagnosics

Immunodiagnosics as a high-quality, innovation-driven growth platform, combining

- exposure to structural healthcare trends,
- sustainable competitive advantages with 20+ new products launching by 2030,
- significant long-term optionality in high-value adjacencies — anchored by a clear U.S. hospital penetration roadmap and the emerging role of diagnostics as the operating system of personalized medicine.

Strong positioning in large/attractive market

Strategic exposure
Focused portfolio targeting high-value segments

Differentiated competitive positioning/menu leadership

Broadest immunoassay menus in the market
Clear edge in high-value specialty testing

Clear execution

Across different key products:

- **Latent TB** global leadership,
- **Gastrointestinal** transition toward an integrated, patient-centric ecosystem,
- **Hypertension** guideline-driven upside,
- **MeMed** clinical evidence and reimbursement progress supporting adoption

Innovation-led growth

Tangible pipeline delivery
Continued pipeline execution reinforcing differentiation

Technology/systems as structural enabler

New LIAISON XL improving throughput, automation & TLA integration

Visible long-term growth optionality

2 key main projects: i) Autoimmunity and ii) Complementary diagnostics & precision medicine

Acceleration of U.S. hospital strategy

Clear penetration roadmap through a model focused on high-value specialties



Diasorin