

The Diagnostic Specialist

### **Investor Day**

# **Specialty** is in our DNA

June 26<sup>th</sup>, 2017

### DiaSorin

### Disclaimer

These statements are related, among others, to the intent, belief or current expectations of the customer base, estimates regarding 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 preparation 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 of accounts and book-keeping entries of the Company.

### DiaSorin

### Agenda

#### Introduction

Immunodiagnostics Strategic Setting Strategic Projects

• Molecular Diagnostics Strategic Setting

Immunodiagnostic execution
 USA
 Europe
 China

Molecular Diagnostic execution
 USA
 Europe

#### • Financials

#### Main takeaways

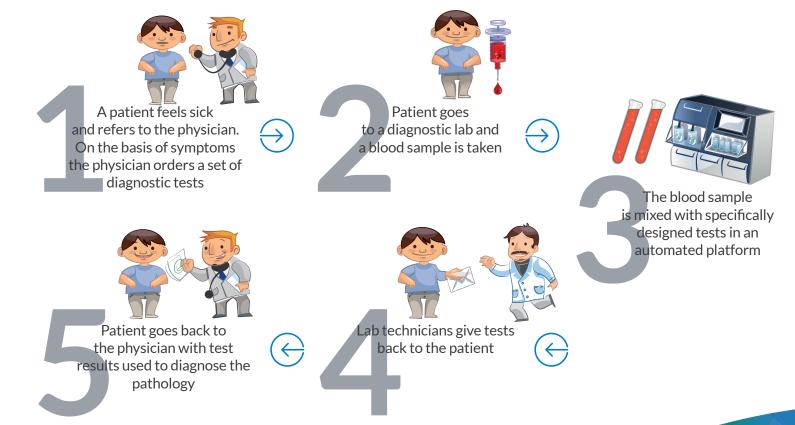


## Introduction





#### What we do



### **Three different cycles**

#### 2000-2008

• ELISA/RIA to CLIA conversion



• Menu expansion with Infectious Disease Specialties



• Vitamin D leadership

#### 2008-2016

• Conversion from LIAISON to LIAISON XL



• Menu expansion with unique specialties



#### • Strategic alliances



- KMAN TER
- Acquisitions

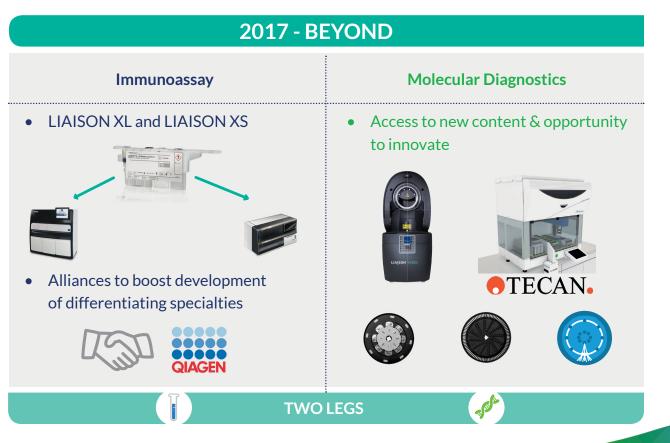
BIOTRIN MULEX KORDIAG



#### **ONE SEGMENT, ONE TECHNOLOGY**

2017-BEYOND

### **Three different cycles**





# Main targets & achievements from 2015 long-term guidance



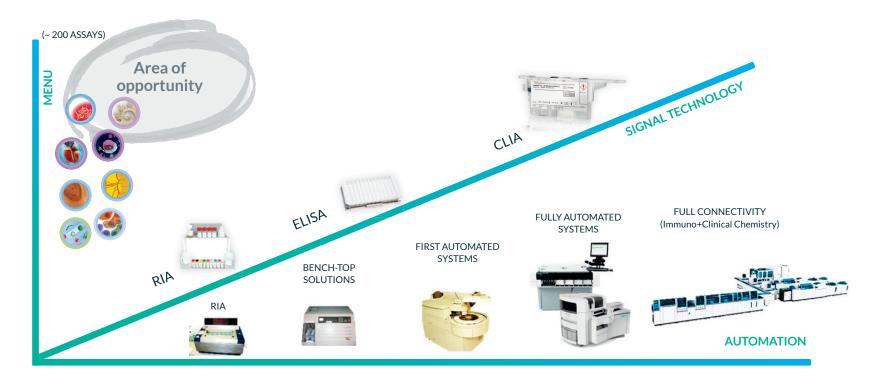
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# **Strategic Setting:** Immunodiagnostics

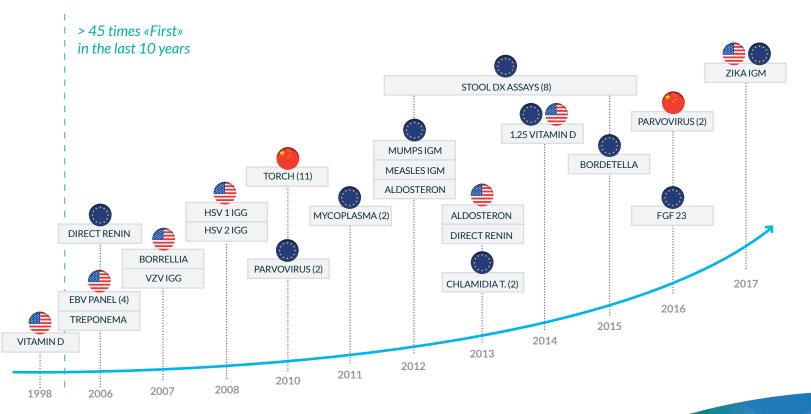


### **Immunoassay innovation:** 1970-2016





### DiaSorin «First» : Fully Automated CLIA assays



### **DiaSorin menu positioning**





Investigational markers

#### **Differentiating specialties**

#### DiaSorin

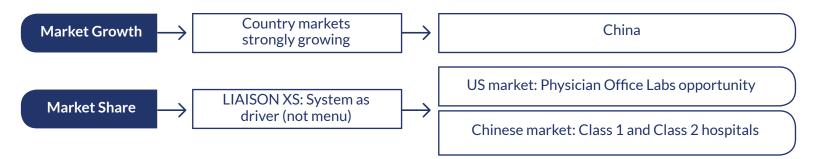
#### **Me-too tests**

#### Main characteristics

- No Research & Development required
- No menu differentiation
- No marketing costs required

	OONCOLOGY TUMOUR MARKERS CEA Free PSA	ß2-Microglobulin TK Calcitonin	GROWTH hGH IGF-I	REPRODUCTIVE ENDO- CRINOLOGY LH
Menu	Total PSA		ADRENAL FUNCTION	FSH Prolactin Progesterone
	CA 15-3	THYROID	ACTH	Testosterone
	CA 125 II	TSH (3rd Gen.)	Cortisol	Estradiol
	CA 19-9	Free T3	DHEA-S	hCG/ß-hCG
Ĩ	TPA-M	Free T4		Androstenedione
2	NSE	Т3	ANAEMIA	SHBG
	S100	T4	Ferritin	
	AFP	Tg		OBONE & MINERAL
	Tg	Tg Gen II	DIABETES	25-OH Vitamin D TOTAL
	Tg Gen II	Anti-Tg	C-Peptide	N-TACT PTH II
	hCG/ß-hCG	Anti-TPO	i Insulin	1

#### Growth opportunities linked to:





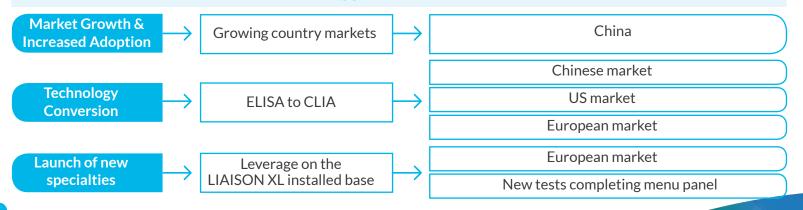
### **High volume specialties**

#### **Main characteristics**

- Limited Research & Development required (menu already developed)
- Menu differentiation
- Limited marketing costs required

	<b>OINFECTIOUS DISEASE</b>	Toxo IgG Avidity	Measles IgM	HBc IgM
	EBV	Rubella IgG	Mumps IgG	HBeAg
	EBV IgM	Rubella IgM	Mumps IgM	Anti-HBe
	VCA IgG	CMV IgG	VZV	Anti-HAV
	EBNA IgG	CMV IgM	VZV IgG	HAV IgM
	EA IgG	CMV IgG Avidity	VZV IgM	HCV Ab
Ē	H.PYLORI	HSV-1/2 IgG		HIV Ab/Ag
a)	H. Pylori IgG	HSV-1 lgG	VIRAL HEPATITIS	HT HTLV I/II
Me	TREPONEMA	HSV-2 lgG	& RETROVIRUSES	CHAGAS
2	Treponema Screen	HSV-1/2 lgM	HBsAg	Chagas IgG
	SEPSIS	BORRELIA	HBsAg Quant	
	BRAHMS PCT II Gen	Borrelia burgdorferi IgG	HBsAg Confirmatory test	
	TORCH	Borrelia burgdorferi IgM	Anti- HBs II	
	Toxo IgG	MEASLES & MUMPS	Anti- HBs II plus	
	Toxo IgM	Measles IgG	Anti- HBc	

#### **Growth opportunities linked to:**





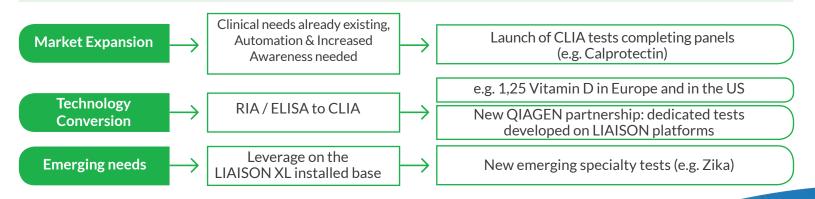
### **Differentiating specialties**

#### Main characteristics

- Relevant Research & Development required
- Strong menu differentiation First to the market
- Relevant marketing costs required

OCHRONIC KIDNEY	
DISEASE	
1-84 PTH	
Osteocalcin	
BAP OSTASE	
1,25 dihydroxy Vitamin D	
Mycoplasma pneumoniae	
OENDOCRINOLOGY	
HYPERTENSION	
Direct Renin	
Aldosterone	
<b>OVIRAL HEPATITIS</b>	
& RETROVIRUSES	
Anti-HDV	

#### Growth opportunities linked to:

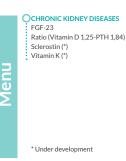




### **Investigational markers**

#### **Main characteristics**

- High Research & Development capabilities required
- Very strong menu differentiation & Patent Protection
- $\diamondsuit$  Very high marketing and clinical costs required



#### Growth opportunities linked to:

**Market Creation** 

Clinical utility not yet defined Europe first (shorter regulatory approval)

US second (more complex regulatory approval)

### Investigational markers: hormones dysregulated in CKD





 eGFR is a calculation based on creatinine blood levels currently used to assess kidney function.

2. eGFR cannot anticipate the worsening of renal function; low eGFR values just certificate an established kidney damage.

3. Early detection of worsening of renal functional would be important in the clinical management of CKD and other renal conditions

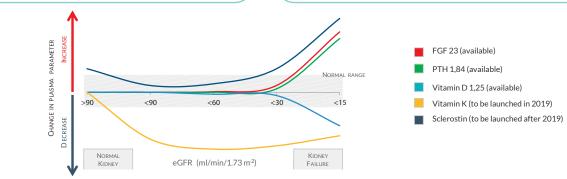
#### Future market opportunity in the US and Europe

Market value tomorrow

~ 200 €/mln

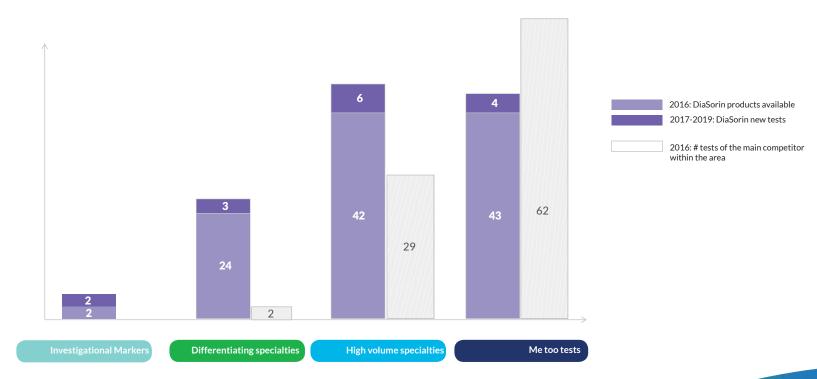
DiaSorin is investigating the Ratio VitD 1,25 / PTH 1-84 as an early marker to predict the worsening of renal function in different clinical conditions:

- 1. Chronic heart failure —> the ratio is a strong and independent predictor of mortality
- 2. Acute heart failure  $\longrightarrow$  enrollment completed, data analysis ongoing
- 3. CKD progression (prospective study)  $\rightarrow$  recruitment started
- 4. CaNPREDDICT cohort study (2,500 CKD patients): data analysis ongoing
- 5. PROGREDIR cohort study (454 CKD patients): data collection ongoing



### Where we plan to invest R&D money







# Immunodiagnostic Strategic Projects





### LIAISON XS: the opportunity

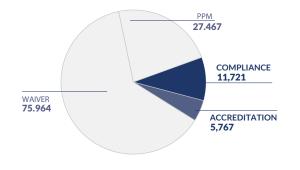


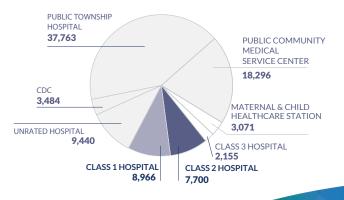
- Moderate to High complexity POLs
- These POLs use Instruments normally found in Hospitals and Private Labs



LIAISON

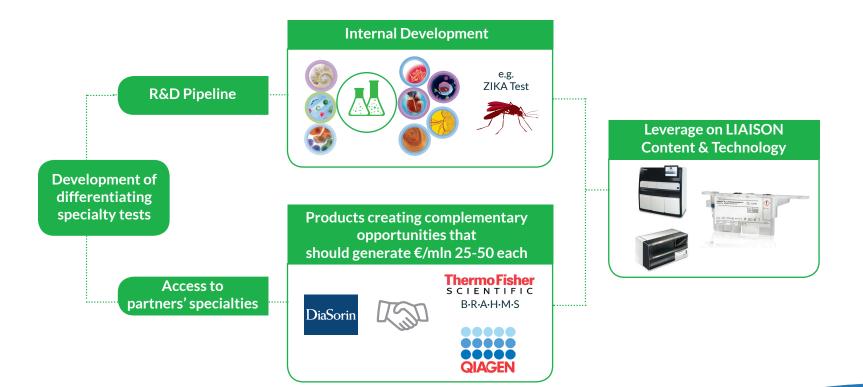
- Professional Medical Service Institution
- Basic Medical Service Institution







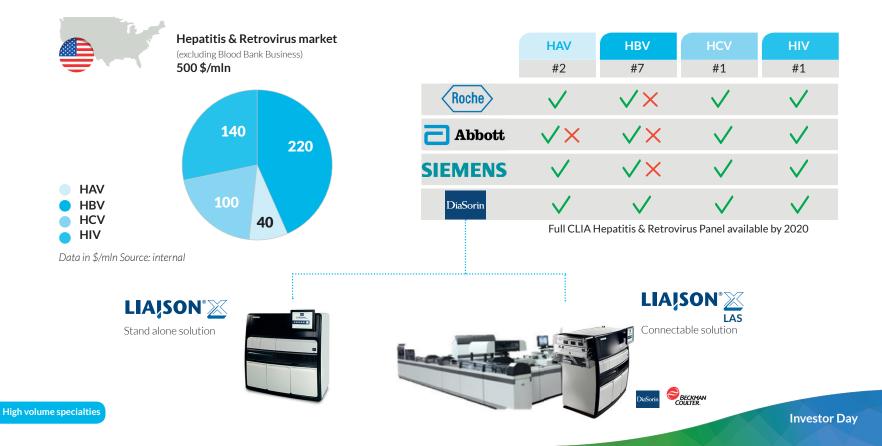
### **Development of Differentiating Specialty Tests**





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### US Opportunity: partnership with Beckman Coulter





# **Strategic Setting:** Molecular Diagnostics





### **Technologies in the Molecular Diagnostic Market**





## **2017-2019** Immunodiagnostic execution



#### Source: Company data on Q1 2017 Results



### Strategic markets

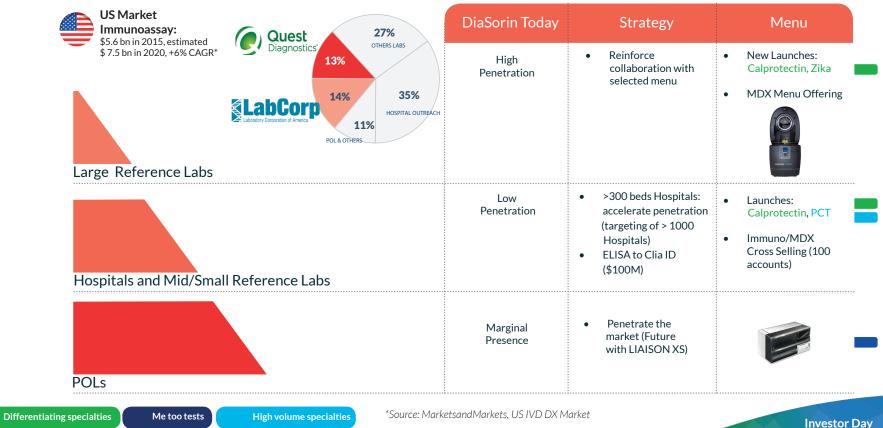






#### DiaSorin

### **US** market



### US: 2017-2019 Menu



### **US:** Calprotectin



#### Strategy

#### Large Reference Labs

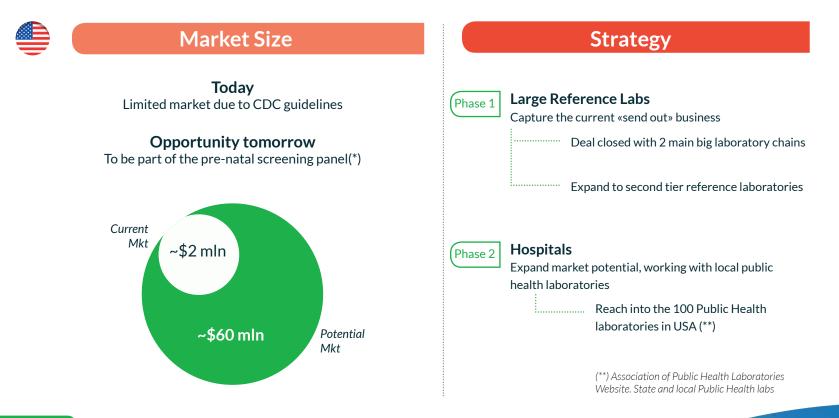
- Increasing volumes
- Need for Automation

#### Hospitals

- Opportunity to enter the GI labs in large hospital centers to address a growing clinical need
- Fully automated assays to:
  - Increase efficiency
  - Drive conversion of Send out  $\longrightarrow$  In House
- Competition: Only ELISA

US: Zika





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### **EU** markets



Europe is a flat market, undergoing lab consolidation since several years

- France: -69% labs in the last 5 years
- Italy: -31% labs in the last 5 years





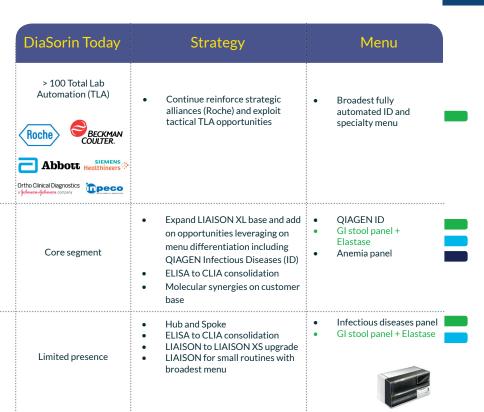
Mid size Labs



Differentiating specialties



Me too tests



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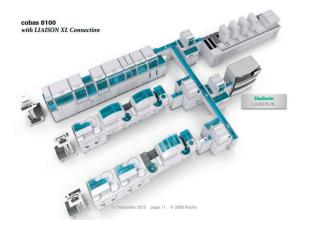


### **EUROPE:** Total Lab Automation (TLA) with Roche





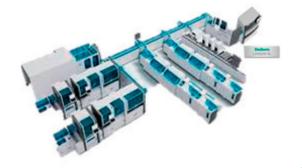
#### Cobas 8100 – Large Hospitals



#### **CCM - Large Private Labs**

Cooperation Agreement expanded to include Cobas Connection Module (CCM)

CCM allow more scalable and flexible Total Lab Automation including analytics





# **EUROPE:** GI stool testing, unique panel and fast growing customer base



- DiaSorin pioneered the automation of the stool matrix, a very complex and diversified matrix
- Growing acceptance of the fully automated DiaSorin solution
- Focus on data driven best in class Calprotectin: new European multi-center trial ongoing



#### **GI** Infections

- C. Difficile GDH (available)
- C. Difficile Toxins A&B (available)
- H. Pylori (available)
- Rotavirus (available)
- Adenovirus (available)
- E. Coli (available)
- Campylobacter (available)

#### **GI** inflammations

- Calprotectin (available)
- Elastase (under development)



### **CHINA:** Healthcare Development



### **Two Invoice Policy**

**Objective:** reduce healthcare costs consolidating current multi-layered distribution

### Proposed solutions test in 2 provinces:

#### 1)Shaanxi:

Limit number of distributors
2 invoices to be presented to the Hospital, Company to distributor and distributor to end user

### 2) Heilongjiang

No limit to distributors number
2 invoices as in Shaanxi

**Timelines:** Currently in testing Phase, deployment uncertain (2018?)

### **GPOs** (Package Deals)

**Consolidation of dealers** 

Uncertainty on implementation of policies

### **CHINESE** market

IVD China Market: €2.3 bn in 2016, estimated €4.0 bn in 2020, +12% CAGR*	DiaSorin Today	Strategy	Menu	
Class III Hospitals	64% of total revenues +25% YoY	<ul> <li>Leverage BECKMAN COUL- TER collaboration in TLA</li> <li>ELISA to CLIA conversion</li> </ul>	<ul> <li>Hepatitis &amp; Retroviruses</li> <li>HEV</li> <li>ToRCH, Parvovirus, EBV</li> </ul>	
Class II Hospitals	29% of total revenues +25% YoY	<ul> <li>Increase penetration in Mater- nity and Children Hospitals</li> <li>ELISA to CLIA conversion</li> </ul>	Hepatitis & Retroviruses     HEV     ToRCH, Parvovirus, EBV	
Class I Hospitals	1% of total revenues +9% YoY	Beyond 2019	Beyond 2019	

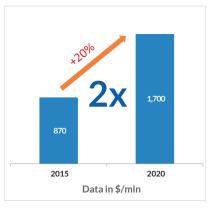
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### **CHINA:** Private labs



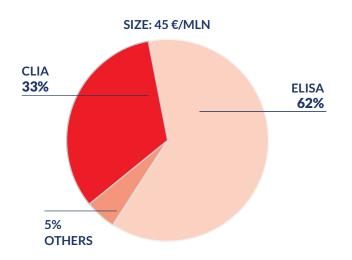
### Strategy

- Establish collaboration with selected main Private Labs groups
- Menu focus on High volume and Differentiating specialties



### **CHINA:** Infectious Diseases panel





### **Infectious Disease Market**

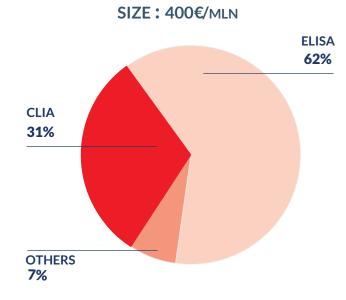
- DiaSorin Market Share: 28%
- Growth: +18%
- ELISA still 62% of the market (market reimbursement open for CLIA as well)

### Strategy

- ELISA to CLIA conversion
- Leverage installed base with add-on: EBV, Parvovirus (130 Instruments in Maternal & Children Hospitals)
- New Launches: Mycoplasma, PCT

### **CHINA:** Heps & Retrovirus (ex Blood Banks)





### Hepatitis & Retrovirus (ex Blood Banks) market

- DiaSorin Market Share: 2%
- Growth: +15%
- ELISA still 62% of the market

### Strategy

- ELISA to CLIA Conversion
  - with Beckman for TLA
  - DiaSorin stand alone
- Add new differentiating assays: HEV



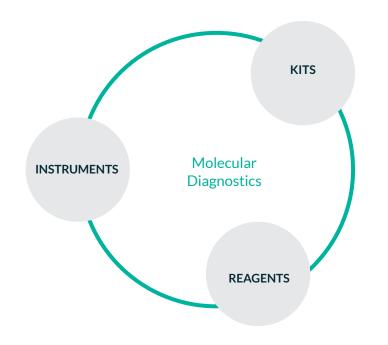
# Molecular Diagnostics: the market

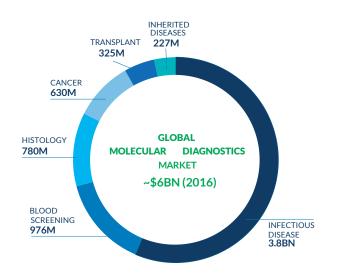




### **Molecular Market is Growing at a Rapid Pace**

Tests used to detect, quantify or characterize nucleic acid analytes in patient RNA or DNA





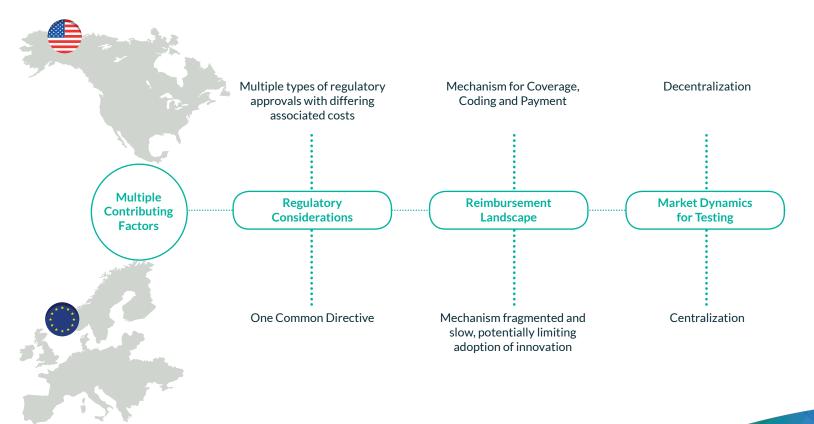
- Molecular Diagnostics is one of the fastest growing segment of a ~\$ 55 billion IVD Market\*
- Infectious disease is projected to account for 60% of the global molecular diagnostic market by 2021 or roughly \$ 5.9 billion in sales

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## **Technologies in the Molecular Diagnostic Market**

TECHNOLOGY Mini Panel & **Single Assay** Sequencing **Multiplex** Respiratory HPV MENU **Gastro-intestinal** Oncology **HCV Sepsis** ... .... Luminex. INSTRUMENT 🚺 QUIDEL Koche Roche muly Thermo Fisher SCIENTIFIC GenMark Dx illumina BIOSFIRE Cepheid.

## **Strategic Considerations for US and Europe**



### **Molecular Kits and Reagents**



Produced by manufacturer rigorously tested for safety and efficacy in clinical trials for "approval or clearance"

Level of complexity given to approved test Highly complex to Clia Waived

Reagents ASRs

Kits

**CE or FDA** 

cleared

Sold as separate components instead of a kit, building blocks or "active ingredients" of LDT

Manufactured in compliance with cGMPs to help ensure quality

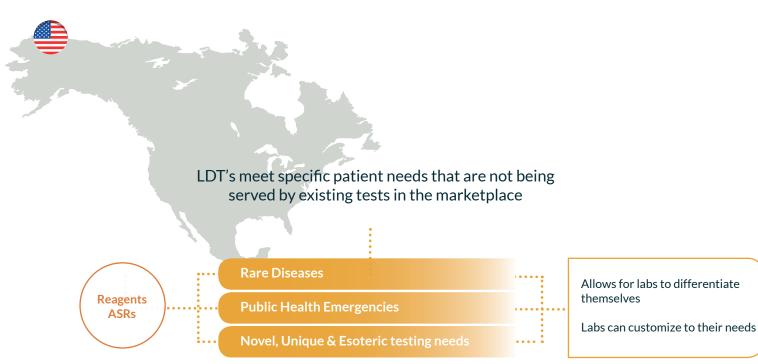
#### Investor Day



### **Strategic Considerations for US and Europe**



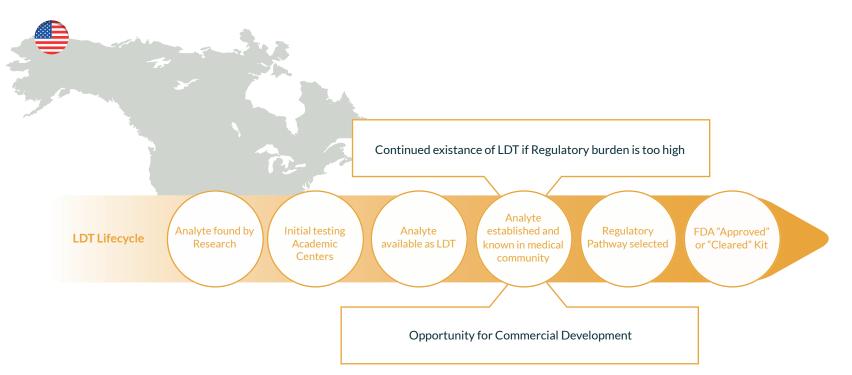
### **Laboratory Developed Test Market**





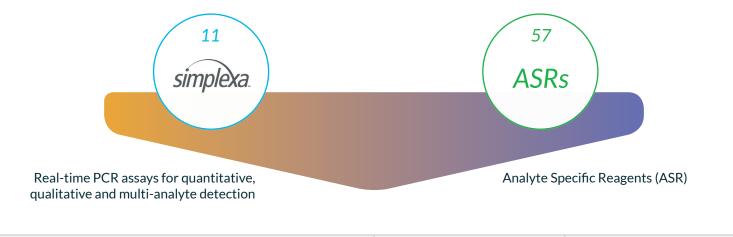
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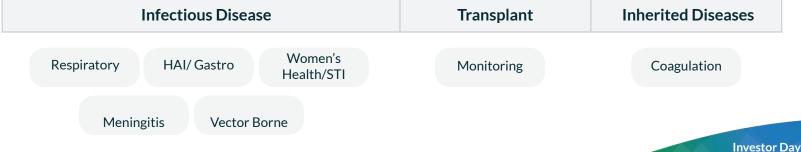
### Laboratory Developed Test Market





## Well Positioned for Growth in Molecular Diagnostics Tests and Reagents

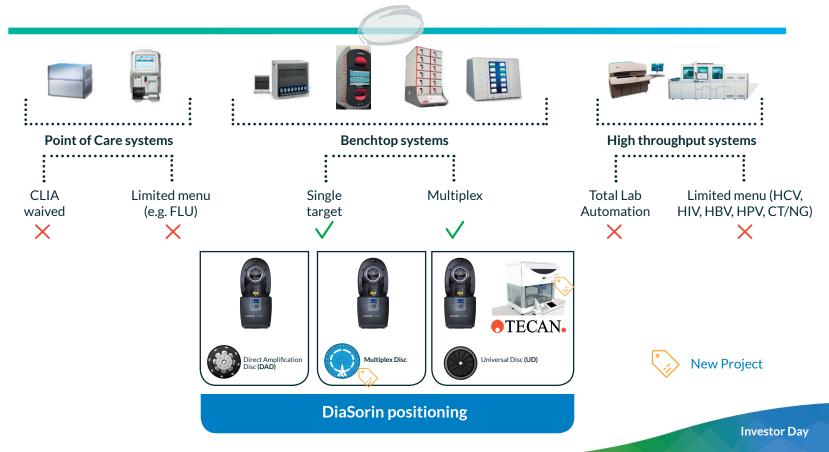






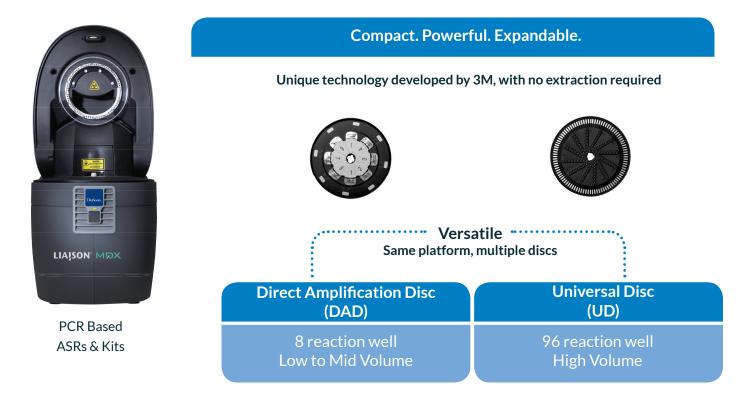
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## **Platforms in the Molecular Diagnostic Market**



### **Our technology**





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### In use across multiple lab segments





# **DiaSorin Molecular** Strategy for the US





### **Molecular Innovation- Drivers of Growth**



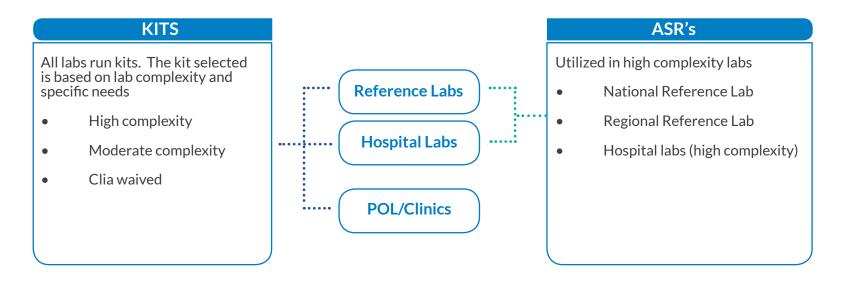
Specialty Testing Strategy

- ASRs
- Kits

### **US:** Market dynamics and trends



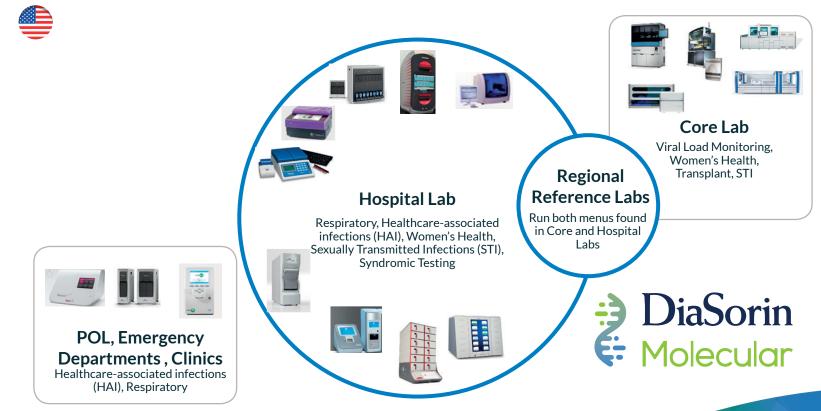
Molecular testing has decentralized across lab segments



Reference and Hospitals labs offer a mix of testing. Need system capability to do both.



### **Assay Menu Segmentation**



### **US Regulatory Landscape**

**ASR** 

No regulatory

review or study

required



Pathway differs for assays based on classification and risk with varying levels of **Cost and Time** to "clearance" or "approval"

TIME

510K

~1 year to Market

~2-3 years to Market, even longer depending on condition prevalence for clinical trial

~1.5 years to

Market

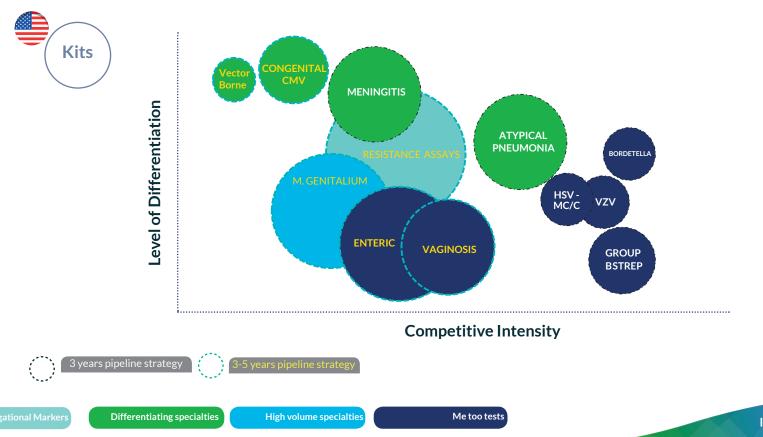
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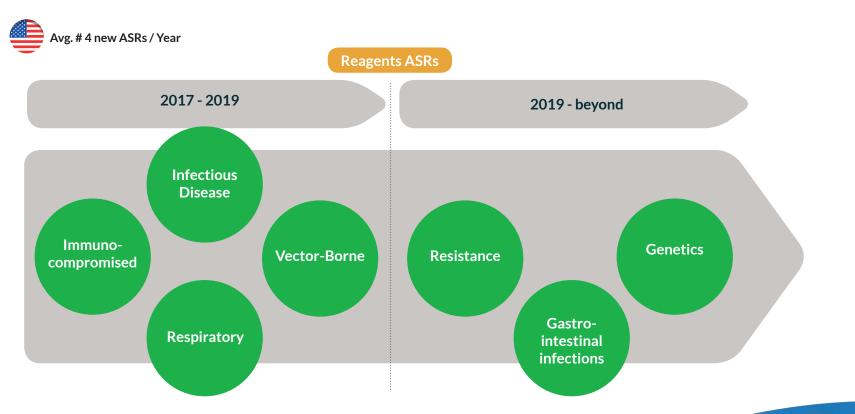
### **USA: Options for Infectious Disease Testing**

	Viral Load Monitoring		Transplant	ŀ	HAI's		
	HIV Hepatitis B Virus Hepatitis C Virus		4V/EBV/BKV/HSV/VZV HHV6/HHV8/ Adeno Parvo/JCV	MRSA CRE VRE			
	Large Systems High Regulatory Cost Burden		High Regulatory Cost Burden DSM Presence Already Rapidly		ed competitor roding Market /IRSA)		
Women's Health			Other Infectious Disease				
HPV CT/NG	GBS Vaginitis		Respiratory		Other: Meningitis, Vector Borne, Gastro, Genetics, Resistance		
ow Regulatory Burden Price Erosion	Low Regulatory Burden Acceptable Price point		Lower Regulatory Burden Differentiation, Acceptable Price point				

### **Molecular Kits Pipeline Strategy**



### **ASRs Pipeline Strategy**





# **DiaSorin Molecular** Strategy for Europe



## **Molecular Innovation- Drivers of Growth**



Post Transplant Strategy

**KITS ONLY** 



## DiaSorin

## **Europe: Centralization of Pathology Services**

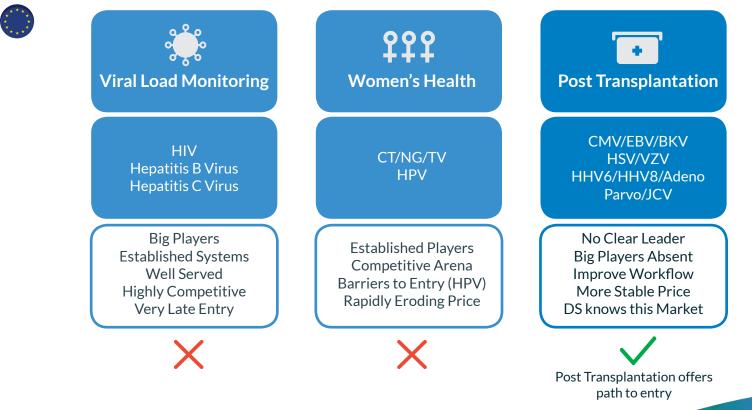
Molecular Diagnostics Driven to Centralized Services



The same labs run high volume and speciality testing. Need system capability to do both.



## **Europe: Options in High Throughput testing**





### **Current Post Transplant Landscape - EU**



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## **Europe Molecular Post Transplant**



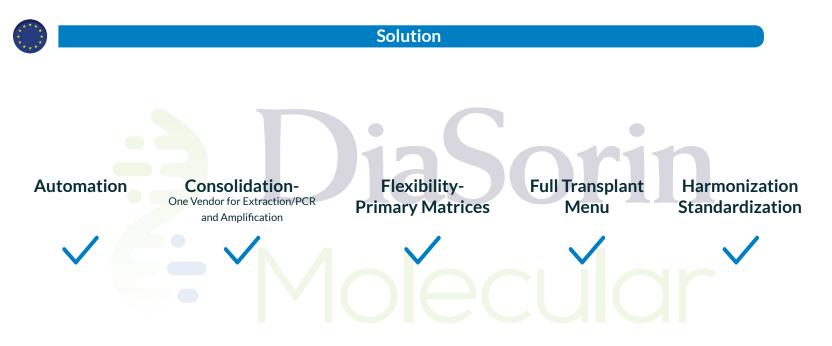
Strategy Instrument for 11 transplant assays extraction/PCR set up CMV HSV 1 HHV8 EBV HSV 2 ADENOVIRUS VZV PARVOVIRUS BKV LIAISON MDX for HHV6 JCV Amplification

Provide complete transplant menu

DiaSorin Molecular

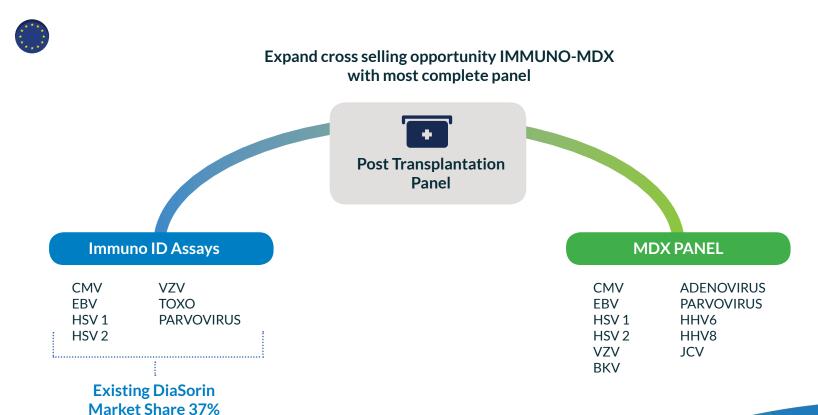
### **Europe Molecular Post Transplant**





## **Europe: IMMUNO - MDX Synergy**





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### WW Molecular Strategy



Expand our position by developing menu content on three discs in three segments (Reference Labs, Hospital Labs and Community Hospital Labs)



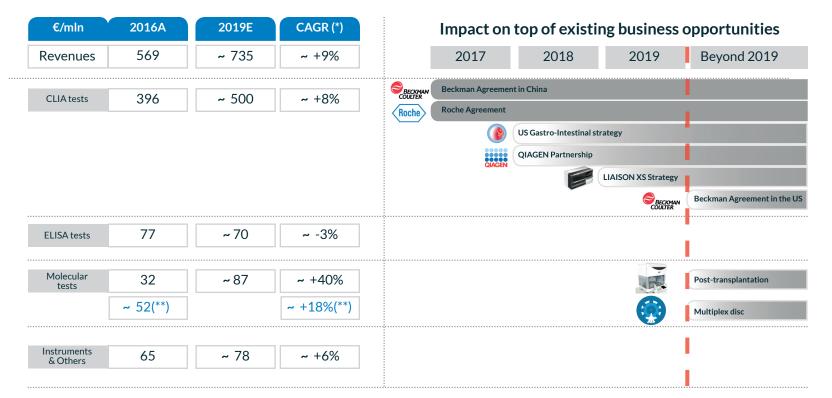
Targeted expansion into central core labs with automation and full transplant menu



## 2017-2019 financials



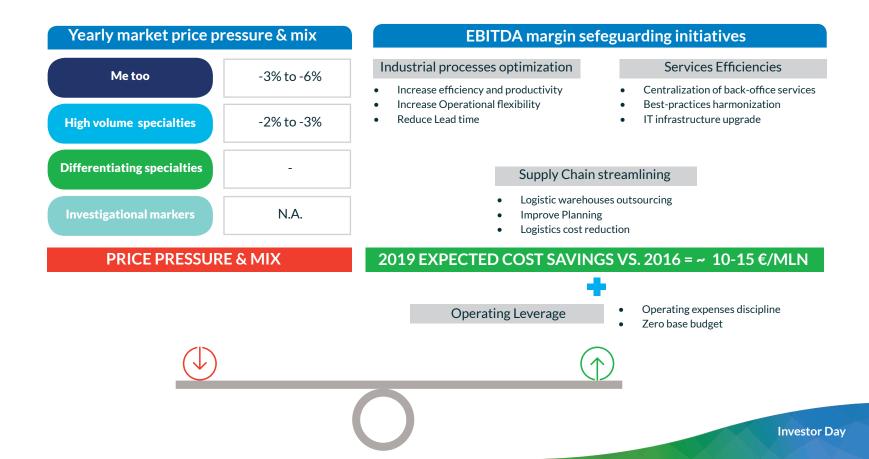
### 2019 Revenues guidance (@ 2016 Exchange rates)



(\*) Different scope of consolidation: Focus Business acquisition completed in May 2016 (\*\*) Managerial outlook: includes Focus Molecular Sales for Full Year 2016; Growth over FY2016

### **EBITDA** margin safeguarding initiatives

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### 2019 guidance (@ 2016 Exchange rates)



(\*) Different scope of consolidation: Focus Business acquisition completed in May 2016

(\*\*) Managerial outlook: includes Focus Molecular Sales for Full Year 2016; Growth over FY2016

Investor Day



## Main takeaways



### Main takeaways



1 Solid growth of the Immunoassay franchise with addition of innovative and differentiating new products



2 Launch of Liaison XS allows penetration of the small labs/POL segment

3 QIAGEN partnership demonstrates that DiaSorin is seen well positioned to serve the Specialty market also by other large IVD players

4 Molecular diagnostic is a second leg and will offer lots of opportunities to develop Specialty ID products

5 Strong financial performance driven by solid margins in both segments (IA and Molecular)

6 Committed to targeted bolt on acquisitions to strengthen our product portfolio or allow access to new customers in consolidated markets

