



The Diagnostic Specialist

# J.P. Morgan Global Healthcare Conference

# Disclaimer



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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.

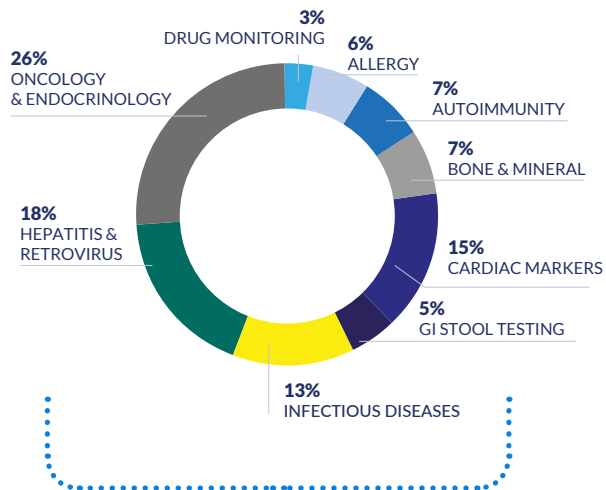
Piergiorgio Pedron, the Officer Responsible for the preparation of corporate financial reports of DiaSorin S.p.A., in accordance with the second subsection of art. 154-bis, part IV, title III, second paragraph, section V-bis, of Legislative Decree February 24, 1998, no. 58, declares that, to the best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

# We operate in two IVD segments

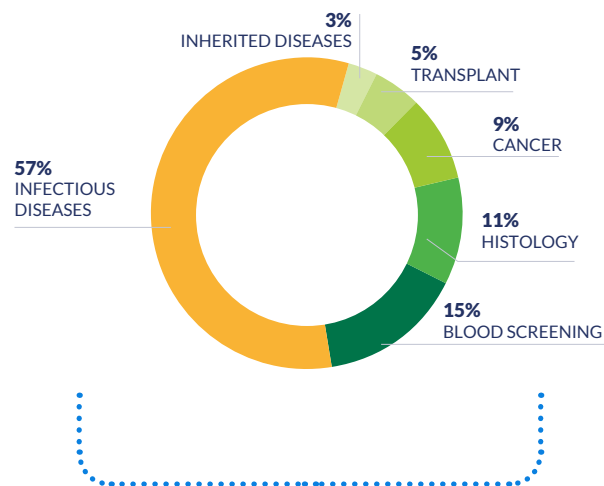


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## Immunodiagnosics: ~ 18% of IVD market



## Molecular Diagnostics: ~ 12% of IVD market



# Where we are

**SUBSIDIARIES**  
**DISTRIBUTORS**

\*R&D facility **USA Stillwater**  

Bone & Mineral  
Stool Diagnostic  
Hypertension  
Fertility (Steroids)

**UK Dartford** 

Murex Elisa

\*R&D facility  
**ITALY**  
**Saluggia**    
**Gerenzano** 

Infectious Disease  
Autoimmunity  
Endocrinology

\*R&D facility  
**GERMANY**    
**Dietzenbach**

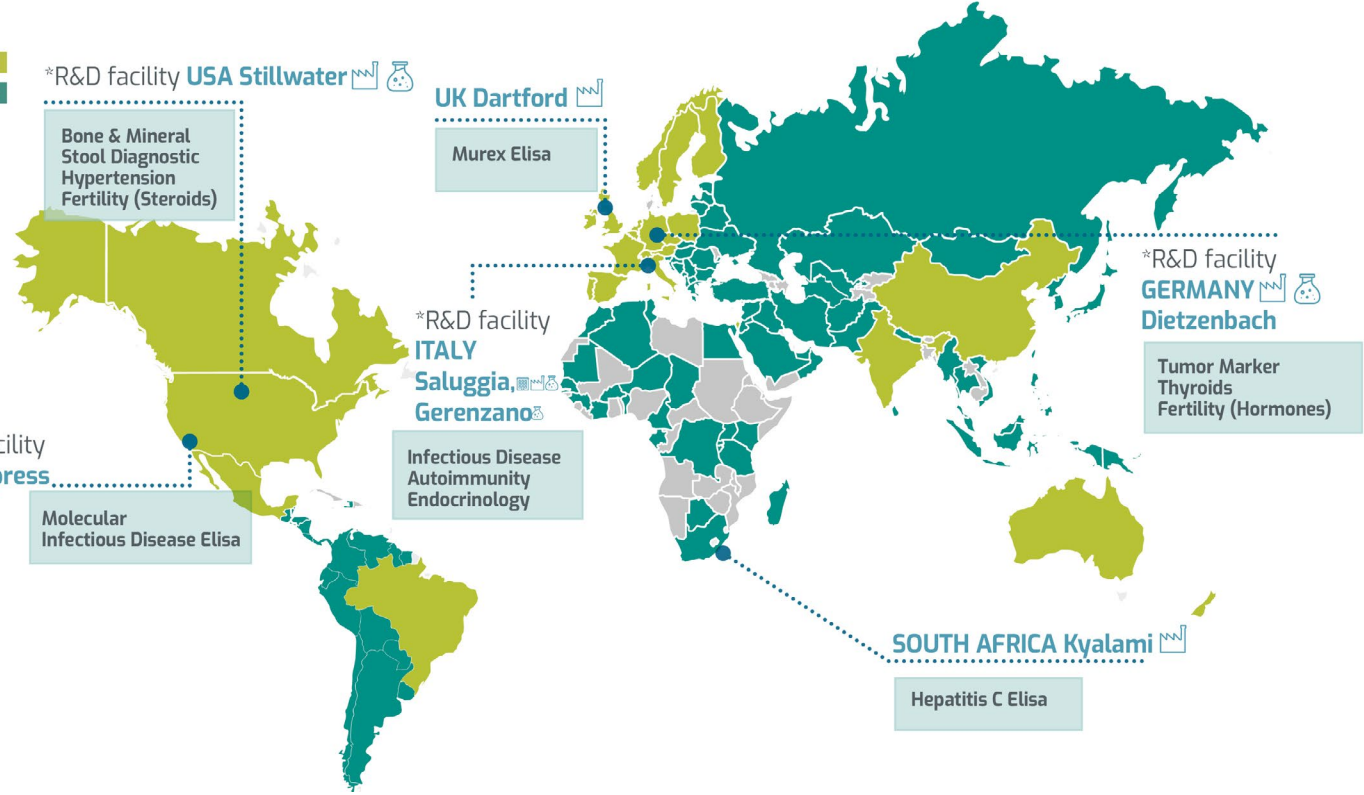
Tumor Marker  
Thyroids  
Fertility (Hormones)

\*R&D facility  
**USA Cypress**  

Molecular  
Infectious Disease Elisa

**SOUTH AFRICA Kyalami** 

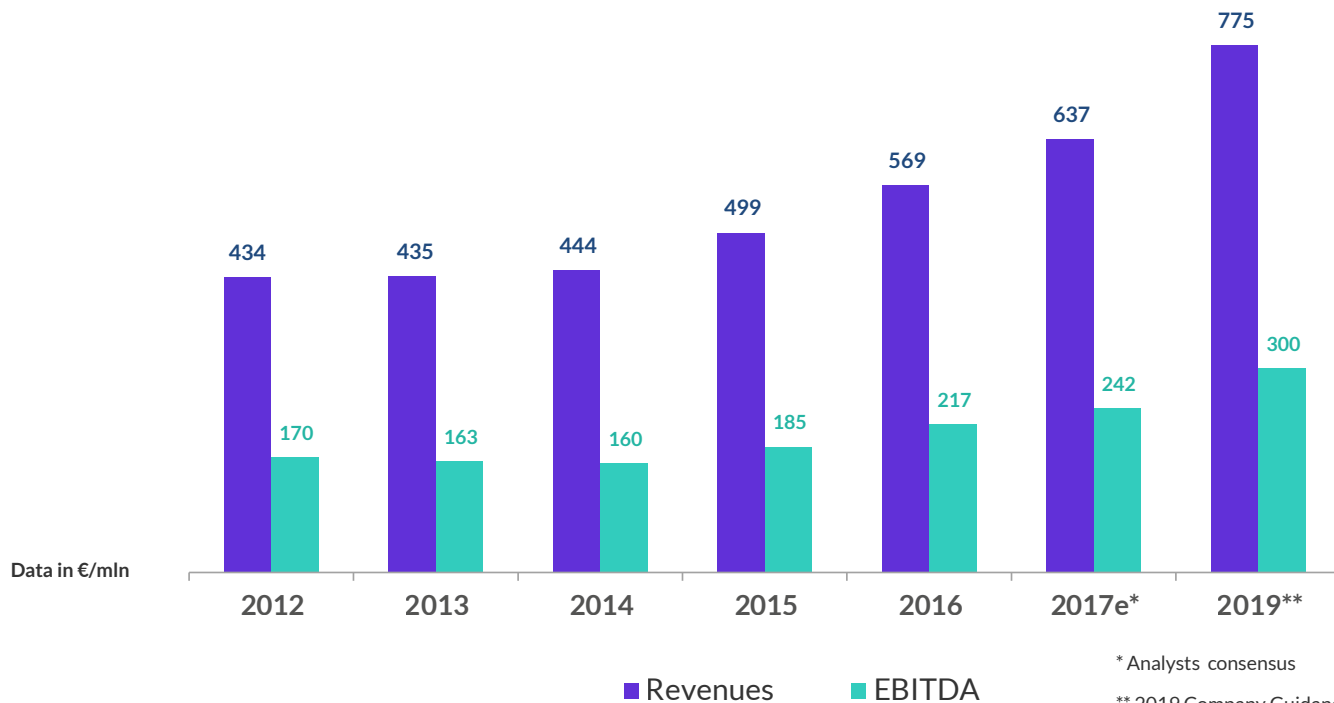
Hepatitis C Elisa



# Revenues and EBITDA



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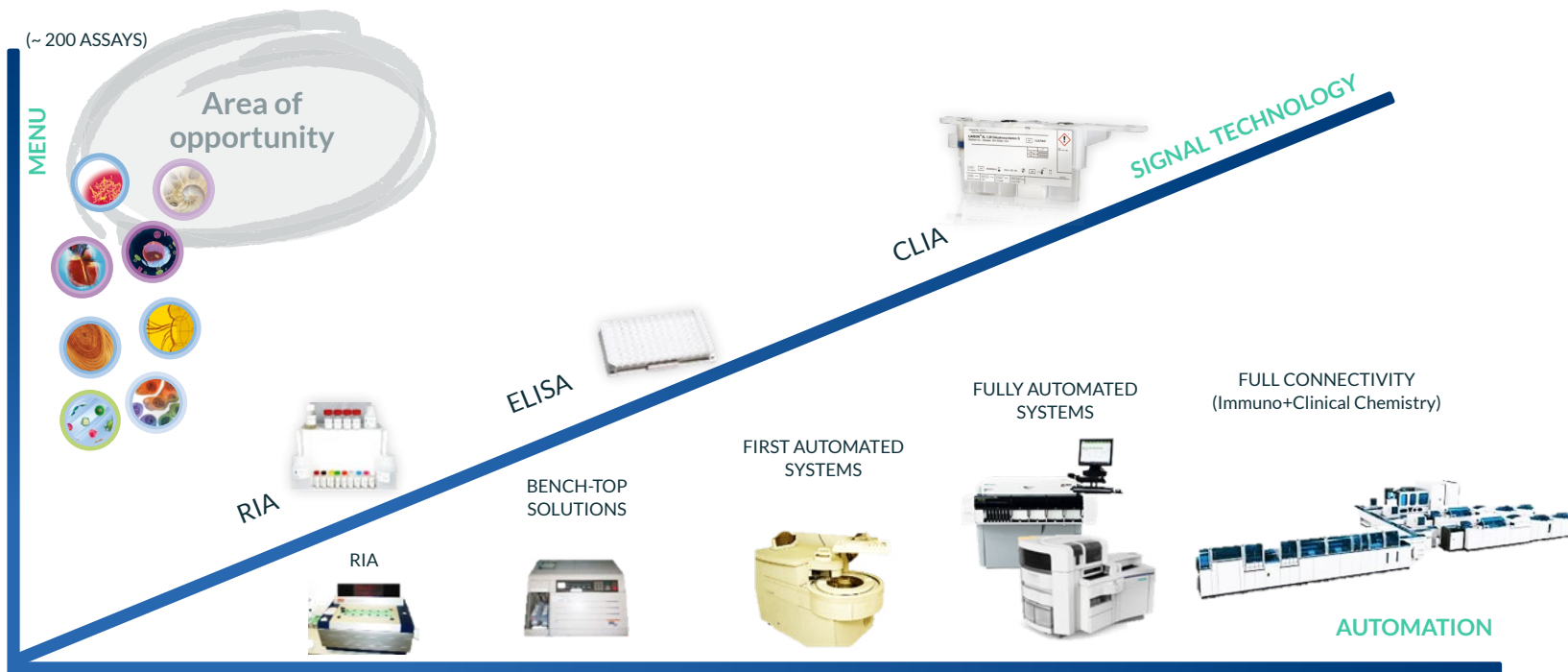




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# Immunodiagnosics

# Immunoassay innovation: 1970-2016



# LIAISON family platforms

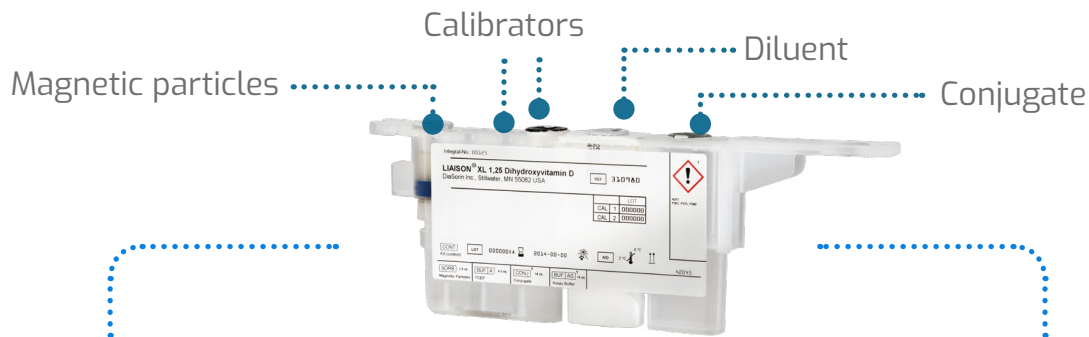


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Each test has its specific cartridge

100 samples for each cartridge

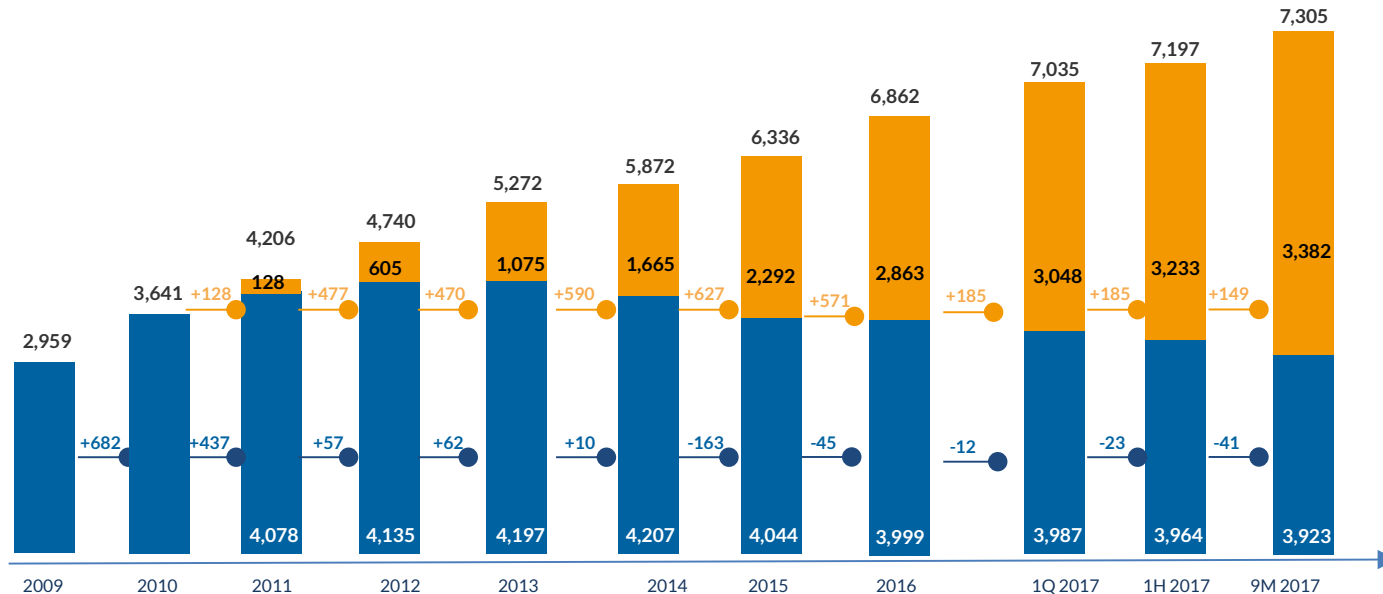
Same raw material for routine and specialty tests



New in 2019



# Installed base evolution



# Menu positioning: 115 tests - the broadest CLIA menu



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## Menu

- ONCOLOGY
- TUMOUR MARKERS
- CEA
- Free PSA
- Total PSA
- CA 15-3
- CA 125 II
- CA 19-9
- TPA-M
- NSE
- S100
- AFP
- Tg
- Tg Gen II
- hCG/β-hCG

- β2-Microglobulin
- TK
- Calcitonin
- ENDOCRINOLOGY
- THYROID
- TSH (3rd Gen.)
- Free T3
- Free T4
- T3
- T4
- Tg
- Tg Gen II
- Anti-Tg
- Anti-TPO

- GROWTH
- hGH
- IGF-I
- ADRENAL FUNCTION
- ACTH
- Cortisol
- DHEA-S
- ANAEMIA
- Ferritin
- DIABETES
- C-Peptide
- Insulin

- REPRODUCTIVE ENDOCRINOLOGY
- LH
- FSH
- Prolactin
- Progesterone
- Testosterone
- Estradiol
- hCG/β-hCG
- Androstenedione
- SHBG
- BONE & MINERAL
- 25-OH Vitamin D TOTAL
- N-TACT PTH II

## Menu

- INFECTIOUS DISEASE
- EBV
- EBV IgM
- VCA IgG
- EBNA IgG
- EA IgG
- H.PYLORI
- H. Pylori IgG
- TREPONEMA
- Treponema Screen
- SEPSIS
- BRAHMS PCT II Gen
- TORCH
- Toxo IgG
- Toxo IgM

- Toxo IgG Avidity
- Rubella IgG
- Rubella IgM
- CMV IgG
- CMV IgM
- CMV IgG Avidity
- HSV-1/2 IgG
- HSV-1 IgG
- HSV-2 IgG
- HSV-1/2 IgM
- BORRELIA
- Borrelia burgdorferi IgG
- Borrelia burgdorferi IgM
- MEASLES & MUMPS
- Measles IgG

- Measles IgM
- Mumps IgG
- Mumps IgM
- VZV
- VZV IgG
- VZV IgM
- VIRAL HEPATITIS & RETROVIRUSES
- HBsAg
- HBsAg Quant
- HBsAg Confirmatory test
- Anti- HBs II
- Anti- HBs II plus
- Anti- HBe

- HBc IgM
- HBcAg
- Anti-HBe
- Anti-HAV
- HAV IgM
- HCV Ab
- HIV Ab/Ag
- HT HTLV I/II
- CHAGAS
- Chagas IgG

## Menu

- STOOL DIAGNOSTICS
- C. difficile GDH
- C. difficile Toxin A and B
- H. pylori SA
- EHEC
- Rotavirus
- Adenovirus
- Calprotectin
- Campylobacter
- INFECTIOUS DISEASE
- Zika IgM
- PARVOVIRUS
- Parvovirus B19 IgG
- Parvovirus B19 IgM

- BORDETELLA
- Bordetella pertussis
- Toxin IgG
- Bordetella pertussis
- Toxin IgA
- MYCOPLASMA
- Mycoplasma pneumoniae
- IgG
- Mycoplasma pneumoniae
- IgM
- CHLAMYDIA
- Chlamydia T. IgG
- Chlamydia T. IgA

- CHRONIC KIDNEY DISEASE
- 1-84 PTH
- Osteocalcin
- BAP OSTASE
- 1,25 dihydroxy Vitamin D
- ENDOCRINOLOGY
- HYPERTENSION
- Direct Renin
- Aldosterone
- VIRAL HEPATITIS & RETROVIRUSES
- Anti-HDV

## Menu

- CHRONIC KIDNEY DISEASES
- FGF-23
- Ratio (Vitamin D 1,25-PTH 1,84)
- Sclerostin (\*)
- Vitamin K (\*)

\* Under development

# Menu positioning: 115 tests - the broadest CLIA menu



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Menu

**Me too tests  
#44**

...CTIVE ENDO-  
...Y  
...ogesterone  
...e  
...lione  
...NERAL  
...in D TOTAL  
...II

Menu

**High volume specialties  
#42**

Menu

**Differentiating specialties  
#27**

...STOOL DIAGNOSTICS  
...ROBUSTLY  
...CHRONIC KIDNEY

Menu

**Investigational markers  
#2**

# Where we plan to invest R&D money



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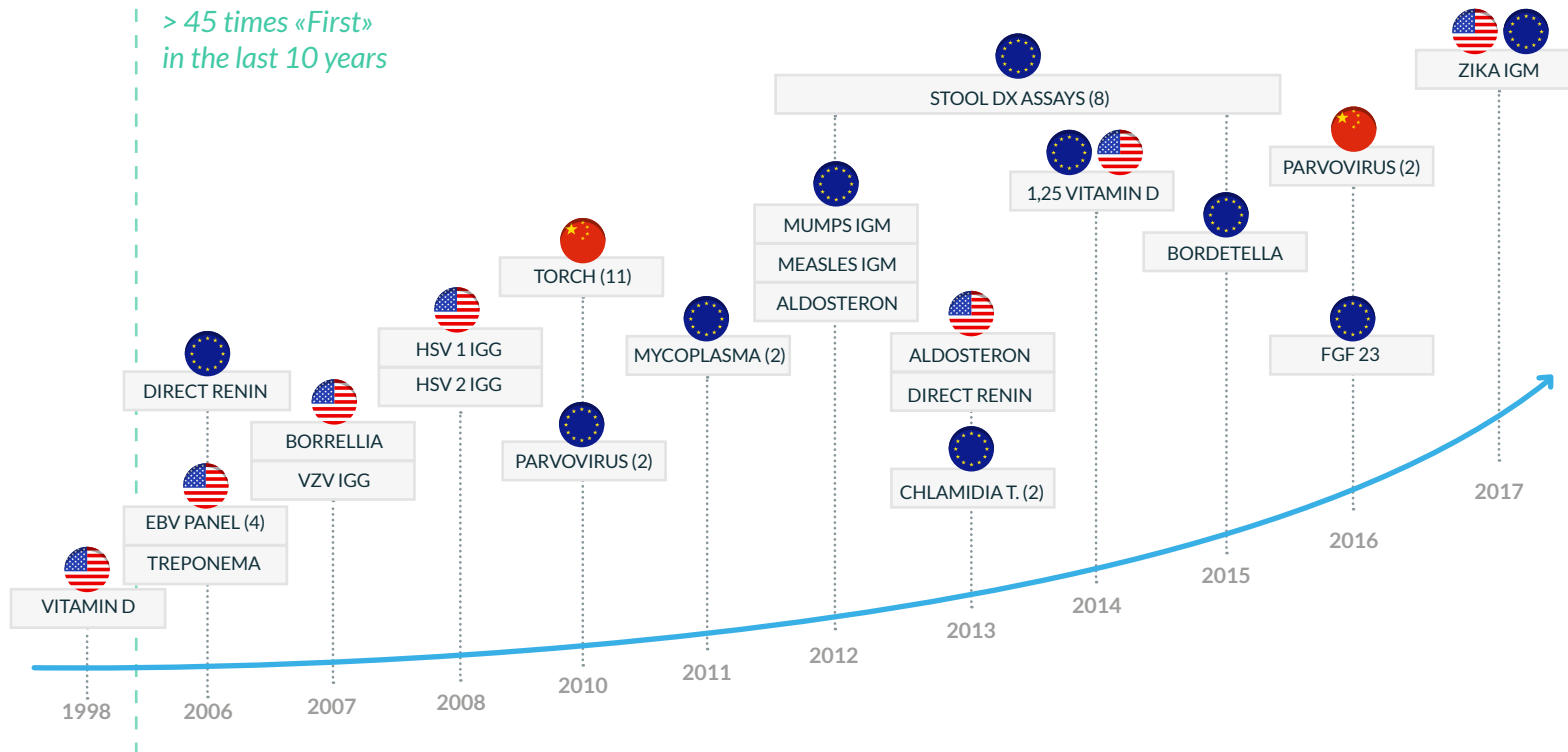


# DiaSorin «First» : Fully Automated CLIA assays

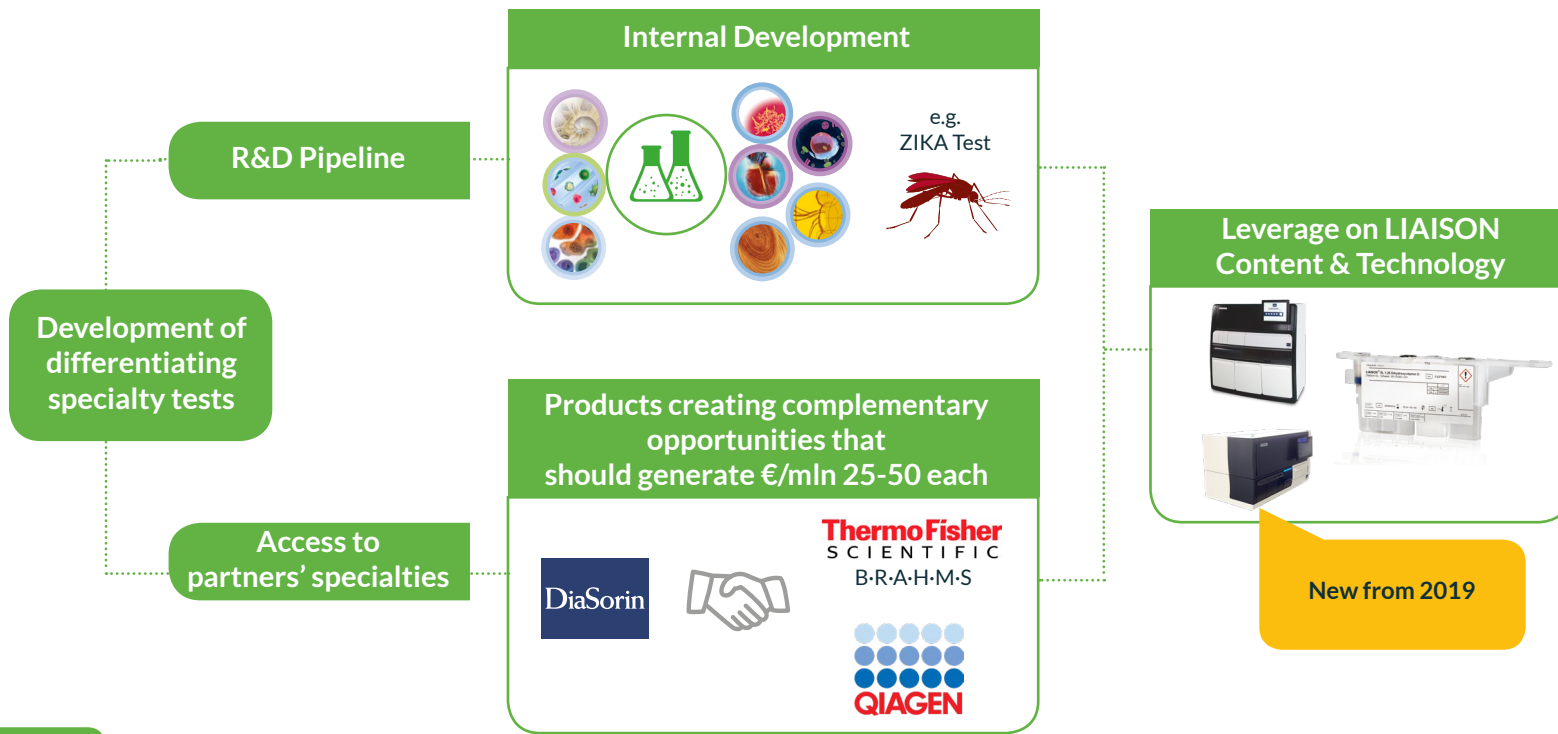


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> 45 times «First»  
in the last 10 years



# Development of Differentiating Specialty Tests



Differentiating specialties

# LIAISON XS: the opportunity

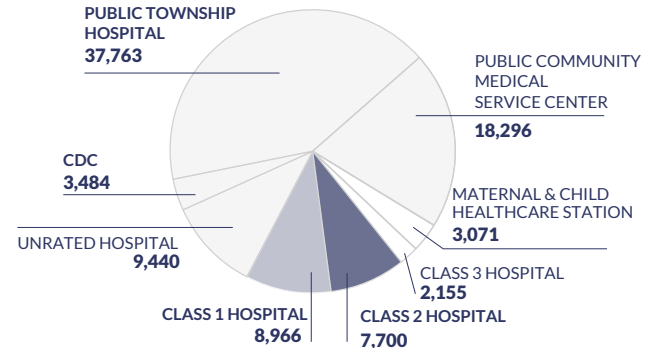
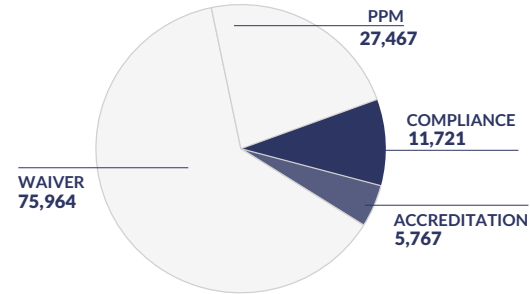


- Moderate to High complexity POLs
- These POLs use Instruments normally found in Hospitals and Private Labs



**LIAISON<sup>®</sup>** X

- Professional Medical Service Institution
- Basic Medical Service Institution



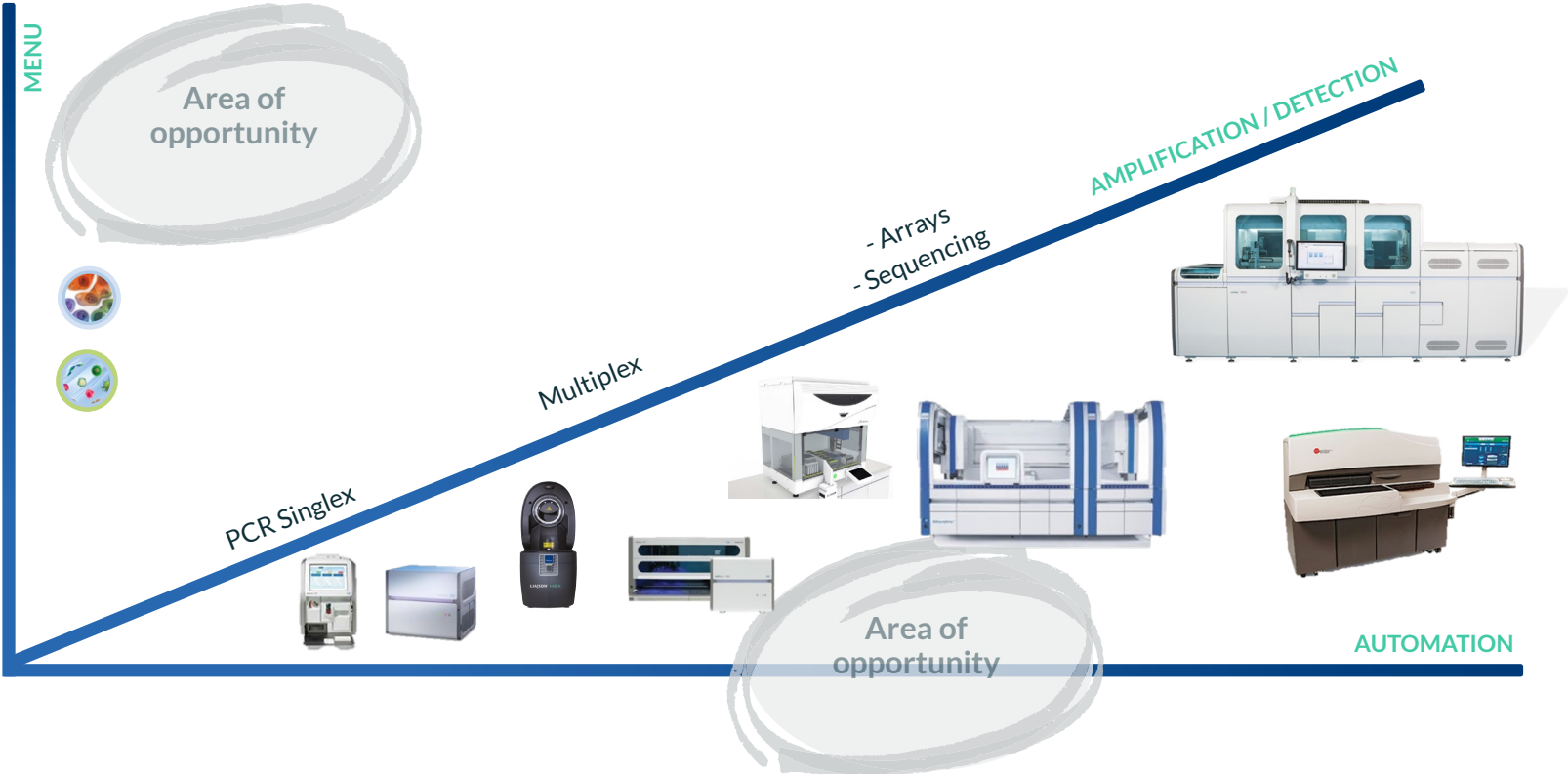


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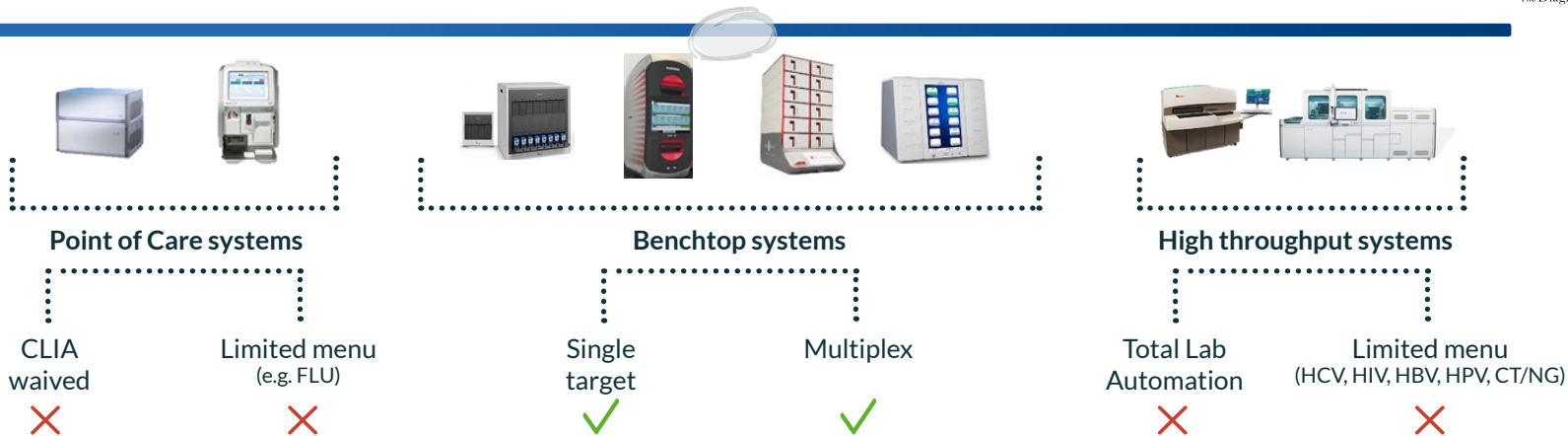
# Molecular Diagnostics



# Technologies in the Molecular Diagnostic Market



# Platforms in the Molecular Diagnostic Market



Direct Amplification Disc (DAD)	Multiplex Disc	Universal Disc (UD)

**DiaSorin positioning**

New Project

# Our technology: Liaison MDX



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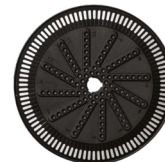
## Technology



PCR Based  
ASRs & Kits

Compact. Powerful. Expandable.

Unique technology developed by 3M, with no extraction required



Versatile  
Same platform, multiple discs

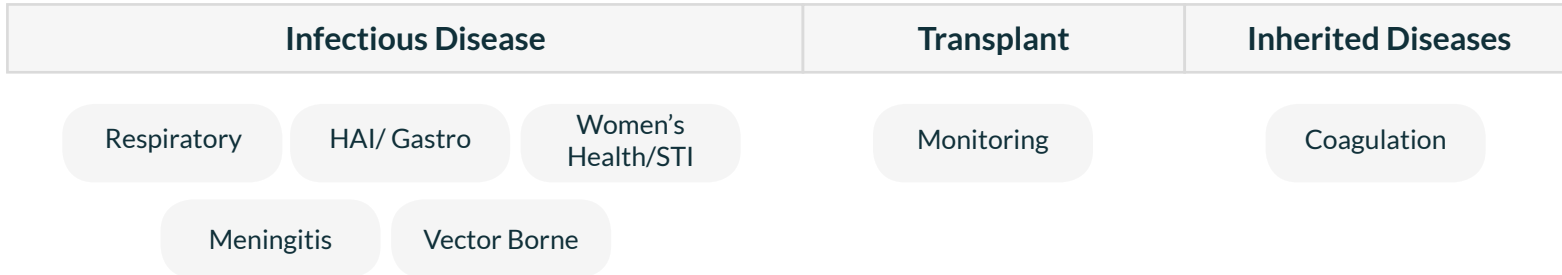
Direct Amplification Disc  
(DAD)

8 reaction well  
Low to Mid Volume

Universal Disc  
(UD)

96 reaction well  
High Volume

# DiaSorin menu positioning



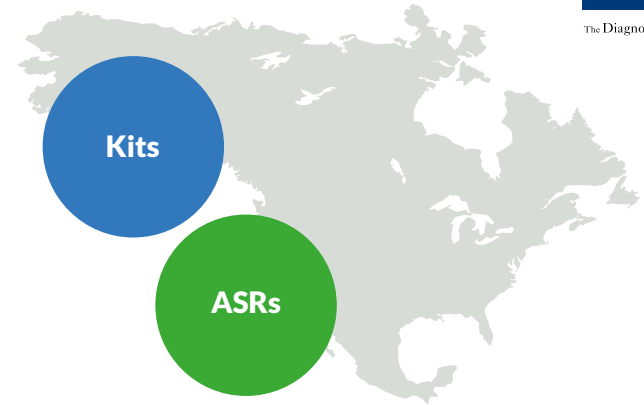
# Molecular kits and ASRs

## Kits

- 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

## ASRs

- Sold as separate components instead of a kit, building blocks or “active ingredients” of LDT
- Manufactured in compliance with cGMPs to help ensure quality



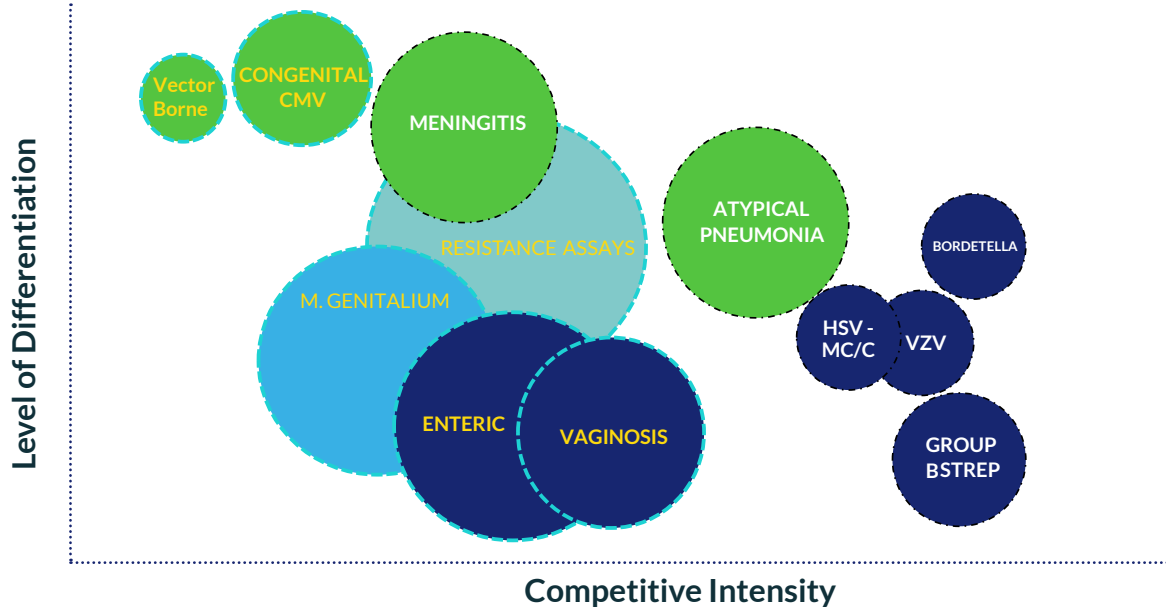
# Molecular Kits Pipeline Strategy



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Avg. # 2 new Kits / Year



Investigational Markers

Differentiating specialties

High volume specialties

Me too tests

3 years pipeline strategy

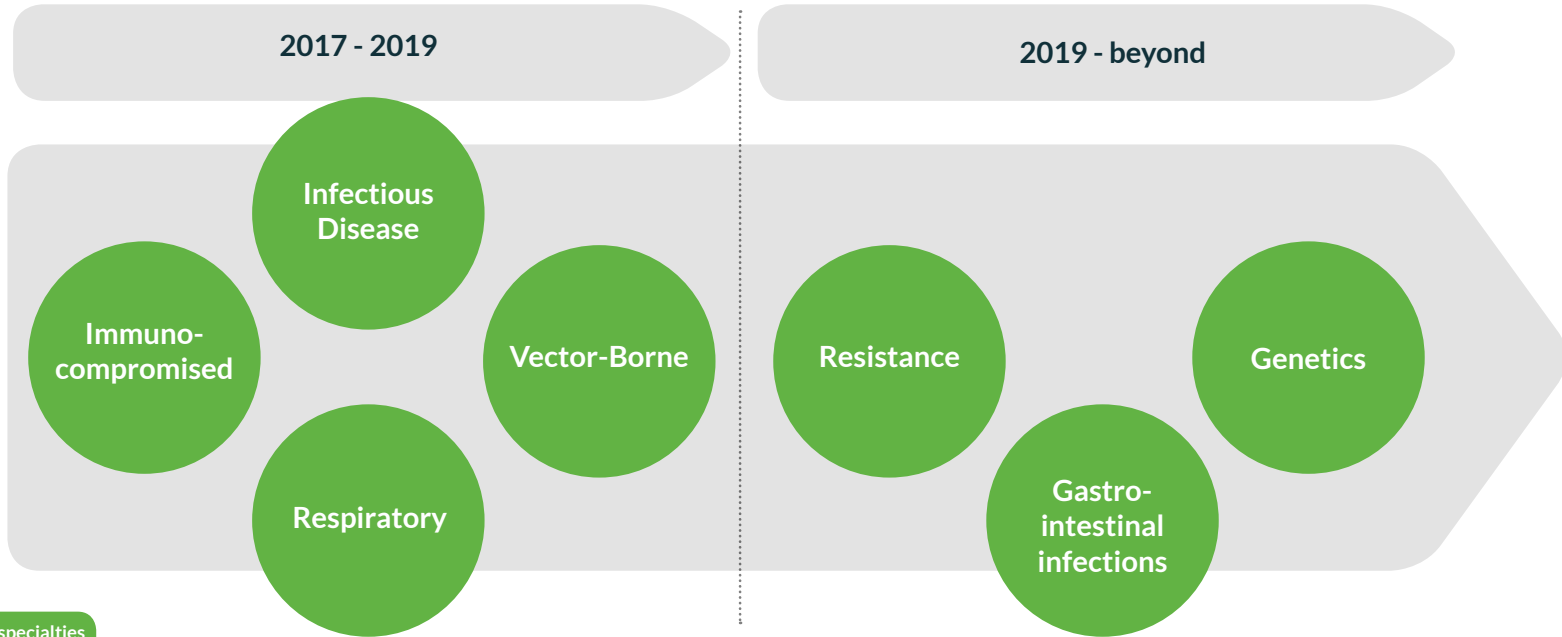
3-5 years pipeline strategy

# ASRs Pipeline Strategy



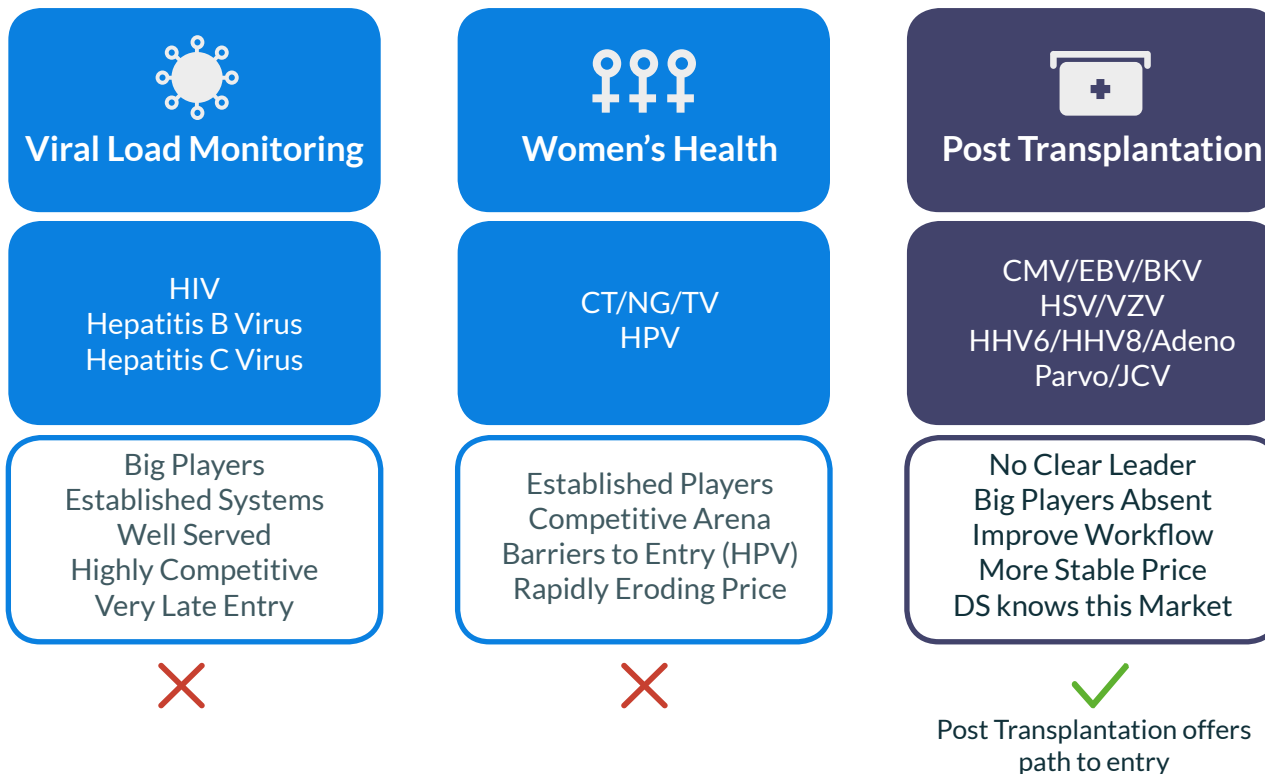
Avg. # 4 new ASRs / Year

Reagents ASRs



Differentiating specialties

# Europe: Options in High Throughput testing





# Europe Molecular Post Transplant

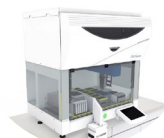


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## Strategy

- Instrument for extraction/PCR set up



- LIAISON MDX for Amplification



- Provide complete transplant menu

### 11 transplant assays

- |       |         |              |
|-------|---------|--------------|
| ■ CMV | ■ HSV 1 | ■ HHV8       |
| ■ EBV | ■ HSV 2 | ■ ADENOVIRUS |
| ■ BKV | ■ VZV   | ■ PARVOVIRUS |
|       | ■ HHV6  | ■ JCV        |



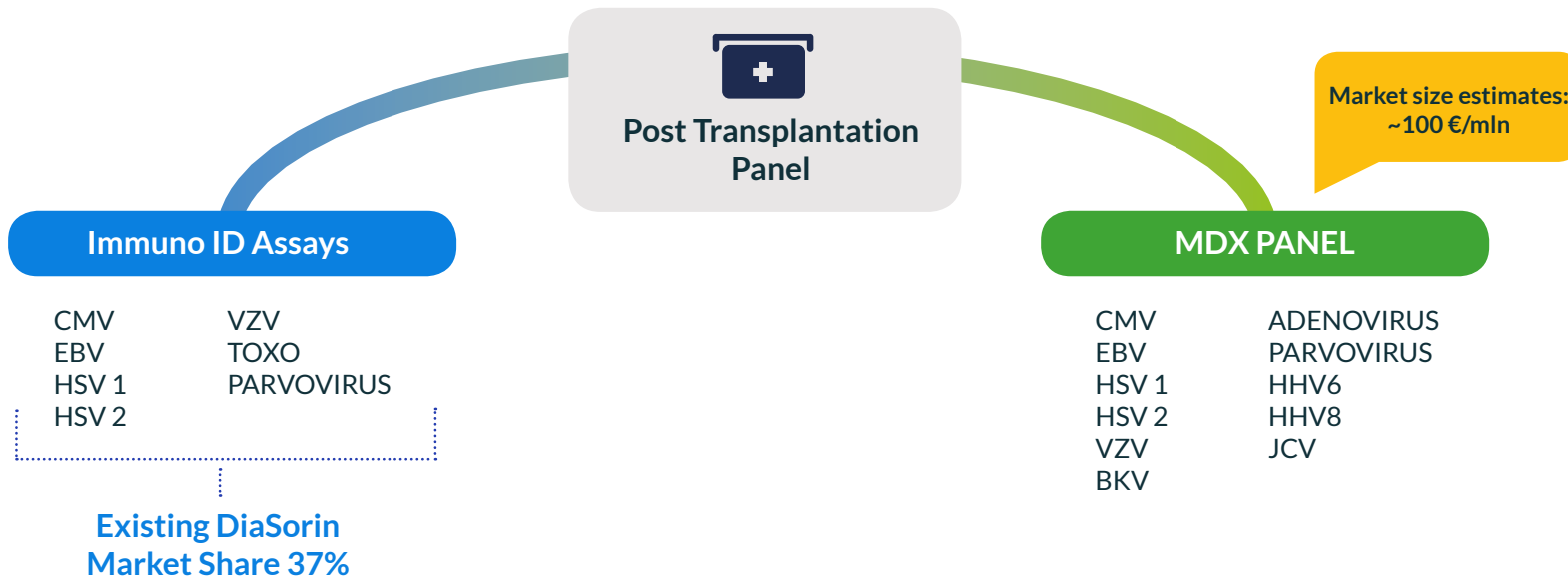
# Europe: IMMUNO - MDX Synergy



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Expand cross selling opportunity IMMUNO-MDX  
with most complete panel





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# Mid-term objectives

# 2019 targets



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- 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/ POLs segment
- 3 QIAGEN partnership demonstrates that DiaSorin is seen well positioned to serve the Specialty market also by other large IVD players
- 4 Conversion of SIEMENS' Elisa customers base to LIAISON XL/XS platforms
- 5 Molecular Diagnostics is a second leg and will offer lots of opportunities to develop Specialty ID products
- 6 Strong financial performance driven by solid margins in both segments (IA and Molecular)
- 7 Committed to targeted bolt on acquisitions to strengthen our product portfolio or allow access to new customers in consolidated markets

## 2019 Company Guidance

**Revenues**  
~ 775 €/mln  
CAGR 16-19: ~ +11%

**EBITDA**  
295-300 €/mln  
EBITDA Margin: ~ 38.5%  
CAGR 16-19: ~ +11%





**NET RESULT**  
160-165 €/mln  
On sales: ~ 21.0%  
CAGR 16-19: ~ +13%

**CUMULATIVE  
FREE CASH FLOW**  
465-475 €/mln

# Business Development, partnerships and M&A



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	2008-2009	2010	2011-2012	2013-2014	2015-2016	2017
 <b>Technological evolution</b>	CLIA menu expansion	LIAISON XL	LIAISON IAM LIAISON IXT		LIAISON MDX	LIAISON XS project (launch in 2019)
 <b>Geographic expansion</b>		Portugal Austria Czech Republic Canada Australia Ireland South Africa Netherlands	India	Switzerland	Poland	
 <b>Partnership</b>		MERIDIAN BIOSCIENCE		ROCHE	BECKMAN COULTER	QIAGEN TECAN
 <b>M&amp;A</b>	BIOTRIN	MUREX (ABBOTT ELISA business)	NORDIAG		FOCUS DIAGNOSTICS	SIEMENS ELISA business



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