

# DiaSorin INVESTOR DAY

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Driving our business  
through innovation

2015-2017



The Diagnostic Specialist

# Disclaimer

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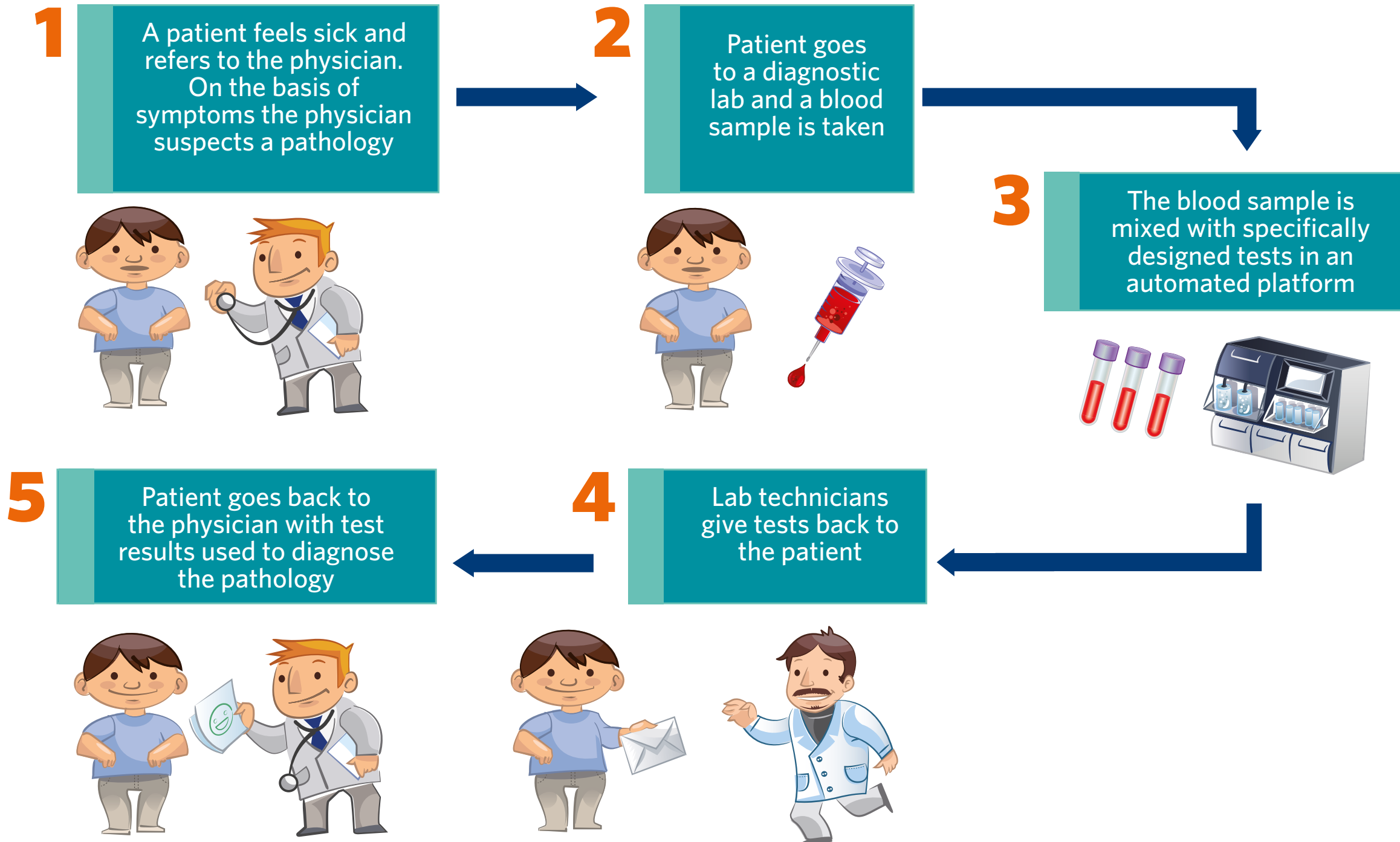
These statements are related, among others, to the intent, belief or current expectations of the customer base, estimates regarding future growth in the different business lines and the global business, market share, financial results and other aspects of the activities and situation relating to the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

Luigi De Angelis, 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.

# What we do



# From 2011-2015 to 2015-2017 Plan



2011-2015

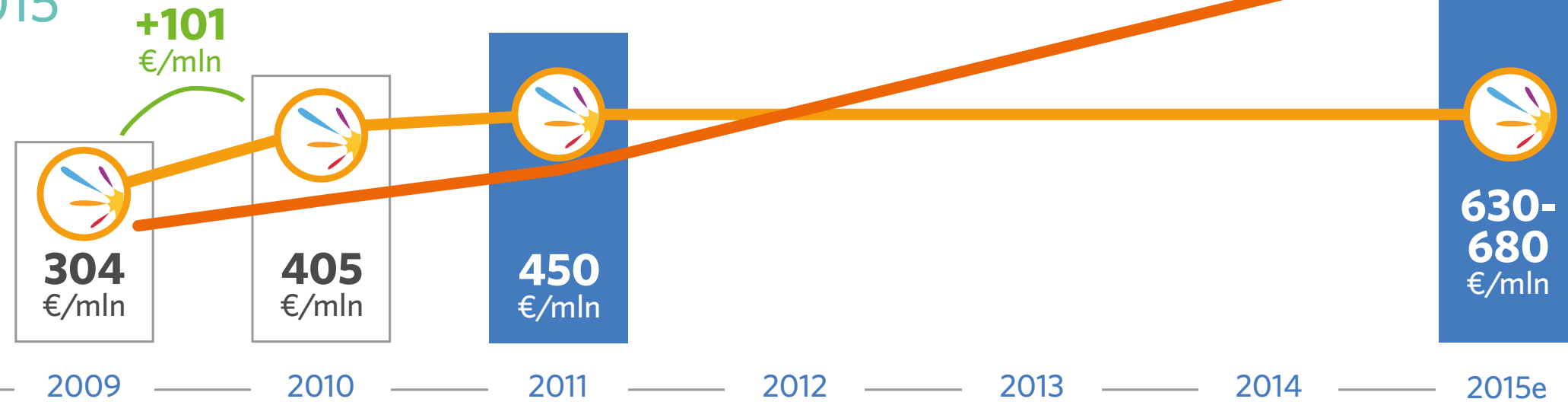


2015-2017

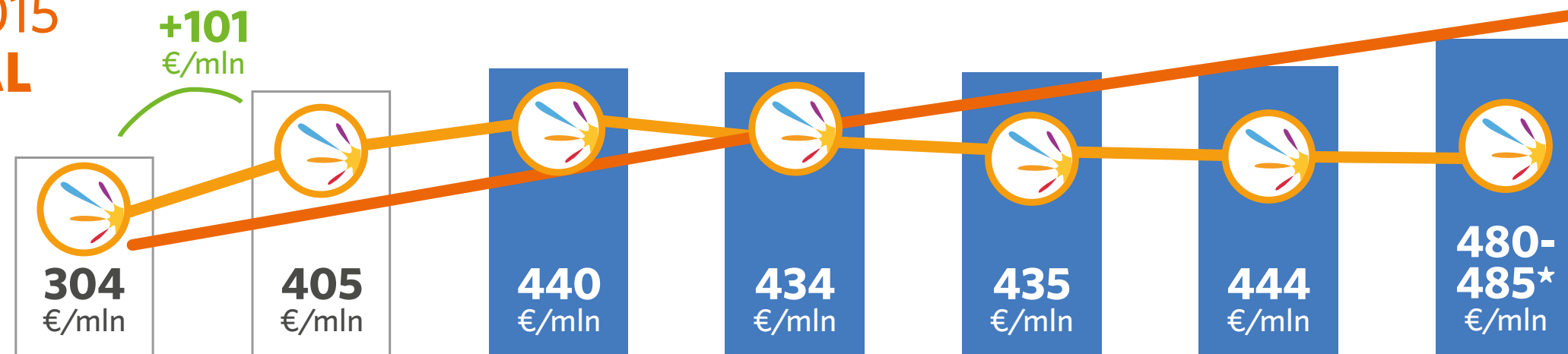


# Revenues comparison between 2011-2015 Plan and Actual

## 2011-2015 PLAN



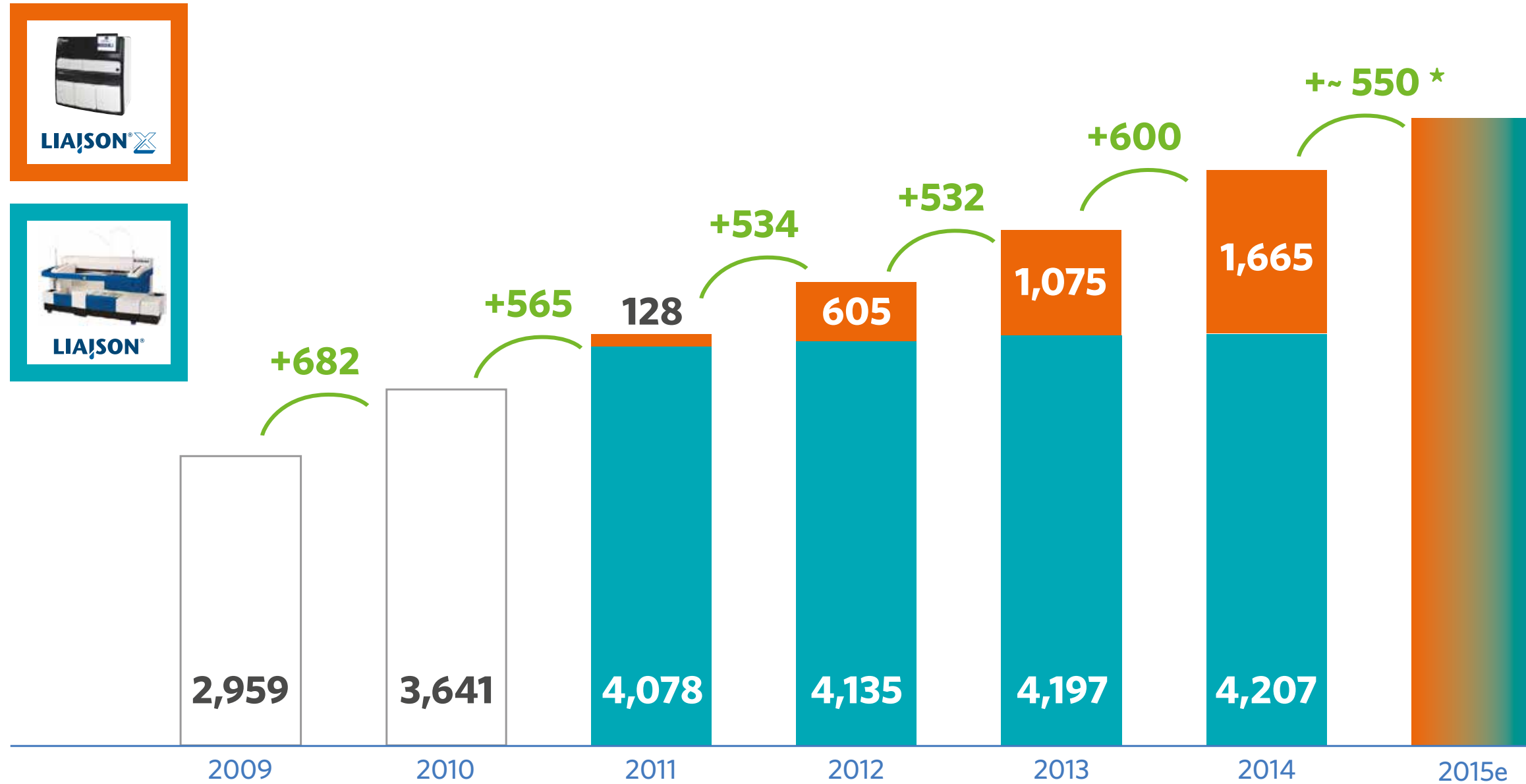
## 2011-2015 ACTUAL



● CHANGE IN REVENUES   
 ● VITAMIN D REVENUES   
 ● CLIA EX VITAMIN D REVENUES

\* Data based on 2015 guidance: Revenues growth at CER +4-5% and on the assumption of exchange rate EUR/USD = 1.15

# Installed base evolution



\* Data based on 2015 guidance

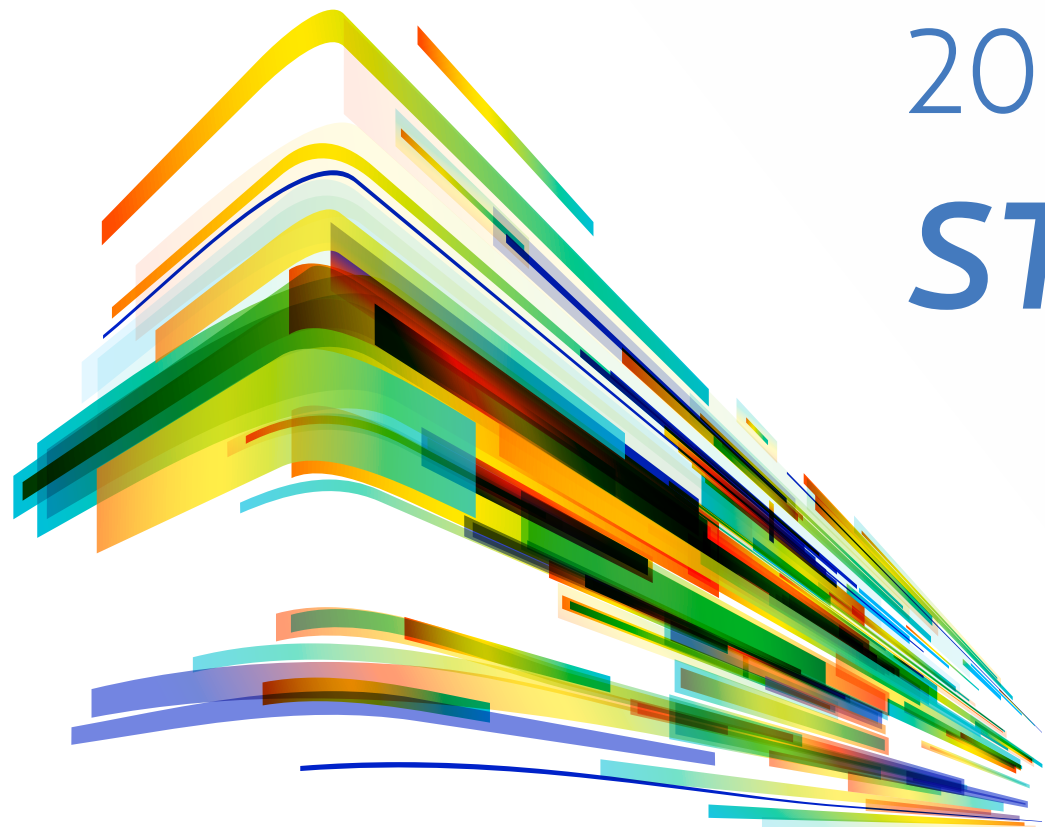
TOTAL INSTALLED BASE GROWTH

# Product Development comparison between 2011-2015 Plan and Actual



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2015-2017 PLAN:  
***STRATEGIC SETTING***





## YESTERDAY



**CONSOLIDATION OF LIAISON INSTALLED BASE, LEVERAGING THE BROAD CLIA MENU AVAILABILITY**

**DEVELOPMENT, LAUNCH AND GROWTH OF LIAISON XL:**

- HIGH THROUGHPUT AND RANDOM ACCESS INSTRUMENT FITTING THE NEEDS OF MID-LARGE LABS
- FULL MENU CONTENT AVAILABLE



**DEVELOPMENT OF AMPLIFICATION TECHNOLOGY (Q-LAMP)**

**LAUNCH OF LIAISON IAM**

**ACQUISITION OF EXTRACTION TECHNOLOGY KNOW-HOW AND LAUNCH OF LIAISON IXT**

## TOMORROW



**MANAGEMENT OF LIAISON INSTALLED BASE**

**CONTINUOUS EXPANSION OF LIAISON XL INSTALLED BASE**

**BUILD ON LIAISON XL LAS CONNECTIVITY:**

- ALONE
- THROUGH PARTNERSHIPS

**DEVELOPMENT OF LIAISON XS**



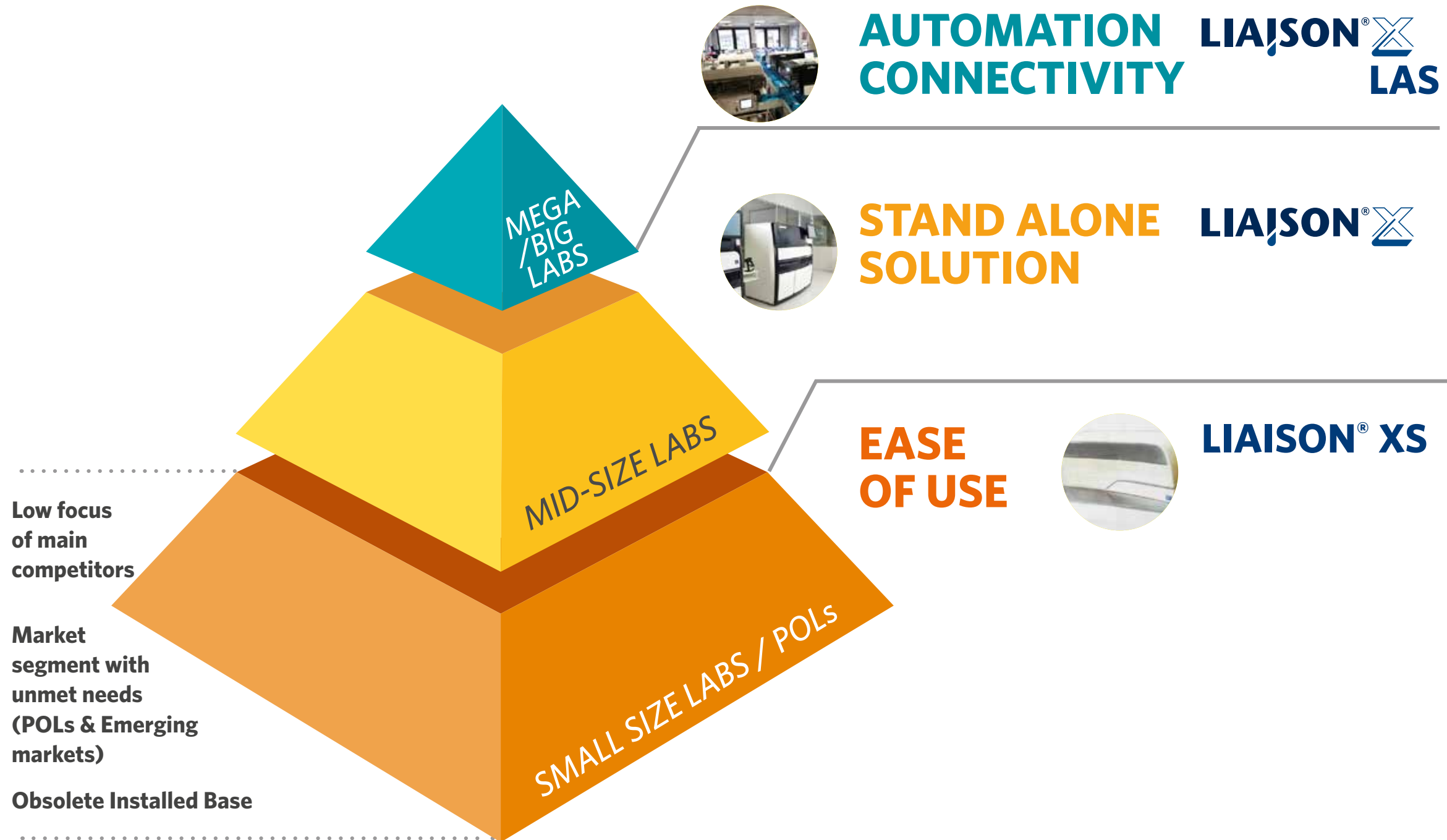
**LIAISON IAM IN ONCO-HAEMATOLOGY**

**CONSOLIDATION OF LIAISON IXT POSITIONING**

**DIASORIN POSITIONING WITH A COMPLETE MOLECULAR SOLUTION**

# Technological full spectrum solution: from small to mega

DiaSorin



# LIAISON XS: Strategic Positioning

**SMALL-SIZE LABS / POLs**  
**< 200,000 TUBES / YEAR**

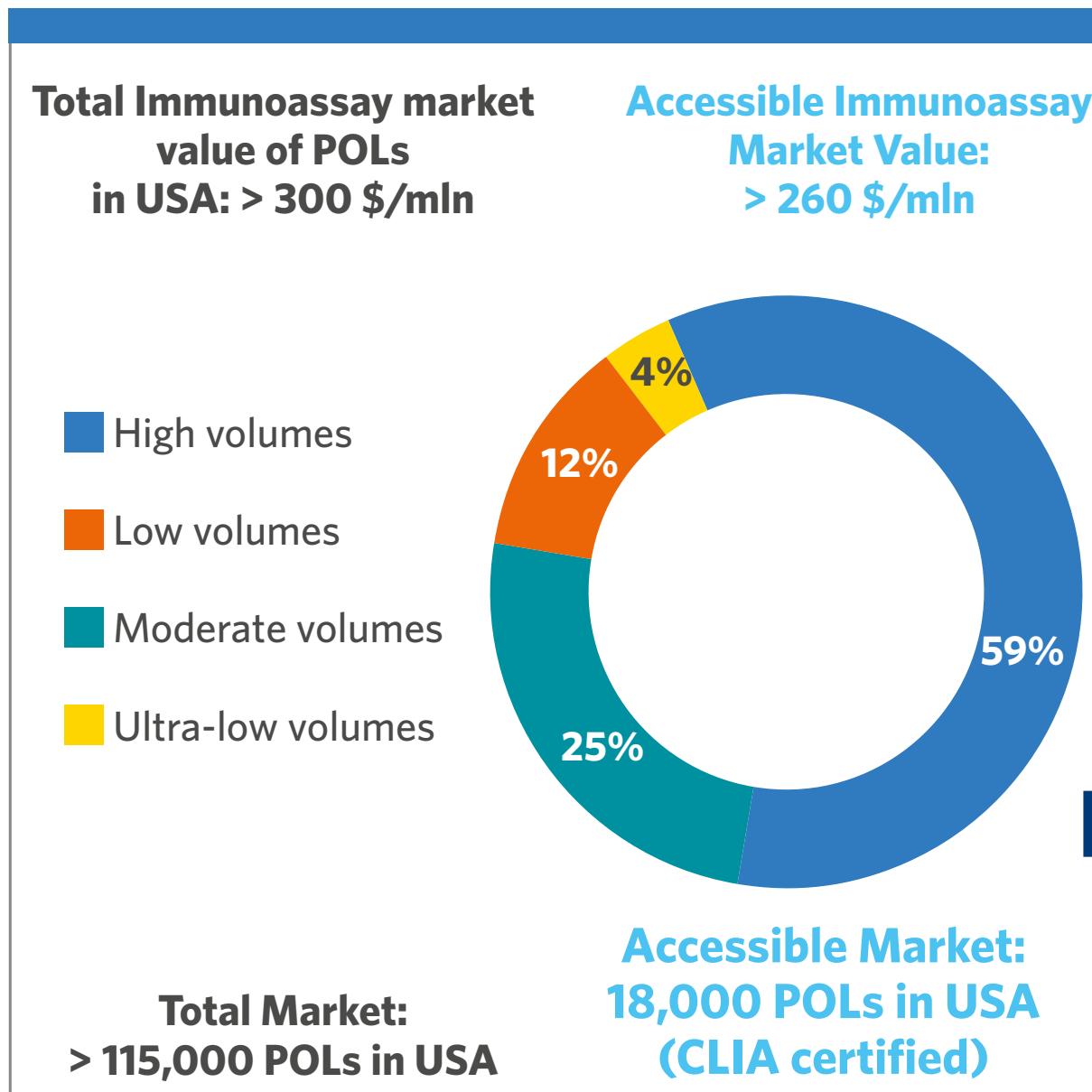


## DIASORIN POSITIONING



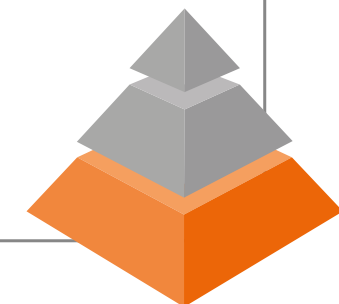
<b>Tests/Year</b>	<b>~12,000-24,000</b>	<b>System Cost</b>	<b>~50% of LIAISON XL</b>
<b>Reagents &amp; consumables</b>	<b>Same of LIAISON XL</b>	<b>Technical functioning and Software</b>	<b>Remote connectivity</b>

# LIAISON XS positioning: POLs in USA



**LIAISON XS** is designed to provide a reliable and efficient solution for **CLIA tests in Labs with low volumes**, depending on the specific needs of analysis with **specialty and routine tests**

## LIAISON XS



Source: Company data

## YESTERDAY



FOCUS ON **SPECIALTY AND HIGH ROUTINE TESTS**

**HOOK AND ME-TOO STRATEGY:** LEVERAGE ON SPECIALTIES TO EXPAND THE OFFER TO HIGH ROUTINE (e.g. HEPATITIS AND RETROVIRUS)

**BROADEST CLIA MENU ON THE MARKET (114 TESTS)**



**INFECTIOUS DISEASES AND QUALITATIVE ONCO-HAEMATOLOGY TESTS**  
**EXTRACTION TESTS**

## TOMORROW



**CONSOLIDATION AS SPECIALTY AND HIGH ROUTINE PLAYER:**

- 130-135 CLIA TESTS ON THE MARKET BY 2017

**FOCUS ON INNOVATION:**

- INNOVATIVE USE OF EXISTING MARKERS

- INNOVATIVE MARKERS



**QUANTITATIVE ONCO-HAEMATOLOGY TESTS**  
**EXTRACTION TESTS**

# Innovative Use of Existing Markers & Innovative Markers

DiaSorin

**Clinical approach strategy to drive market expansion**

**Prescribers, Regulators and Payers demand greater evidence of healthcare value**

**Development of robust and sustained clinical program critical to commercial success**

**Innovative use of existing markers**

**Innovative markers**

## CLINICAL AREAS

- Hypertension
- Heart Failure
- Chronic Kidney Diseases
- Diabetes
- Gastroenterology

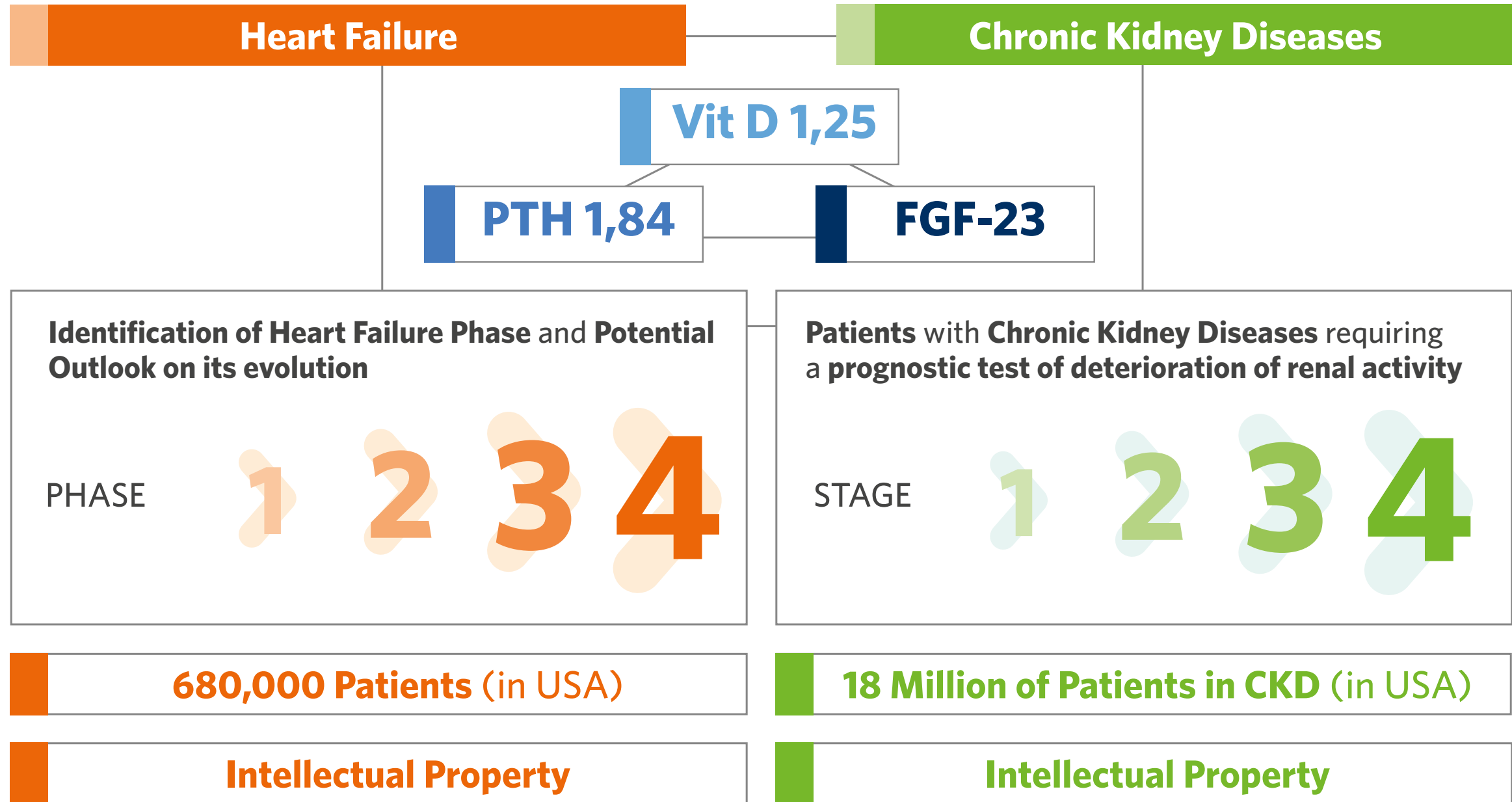
## MARKERS

- Aldosterone, Renin, Infectious Diseases, 1,25 Vitamin D, FGF-23...

## STUDIES IN PIPELINE

- Broader clinical use
- New clinical indications
- Pharma-economic benefits

# Practical Example of innovative use of existing markers





## Existing markers

## Innovative markers

<b>Clinical utility</b>	Accepted	Likely but not yet demonstrated/accepted
<b>Market</b>	Defined and acknowledged	Small/not yet exploited
<b>Competition</b>	High	Low / Not existing
<b>Development</b>	Linear	Challenging
<b>Risk</b>	Limited risk of technical failure	More demanding technical development
<b>IP Protection</b>	Limited / Not existing	Available

## Sclerostin

- A PROTEIN PRODUCED BY OUR BODY THAT REDUCES THE BONE MASS
- ITS DETECTION AND QUANTITATION IN BLOOD MIGHT HAVE A DIAGNOSTIC UTILITY IN HIGH PREVALENCE CLINICAL CONDITIONS CHARACTERIZED BY BONE MASS LOSS (e.g. POSTMENOPAUSAL OSTEOPOROSIS AND CKD)

SCLEROSTIN  
CAN BRING TO:



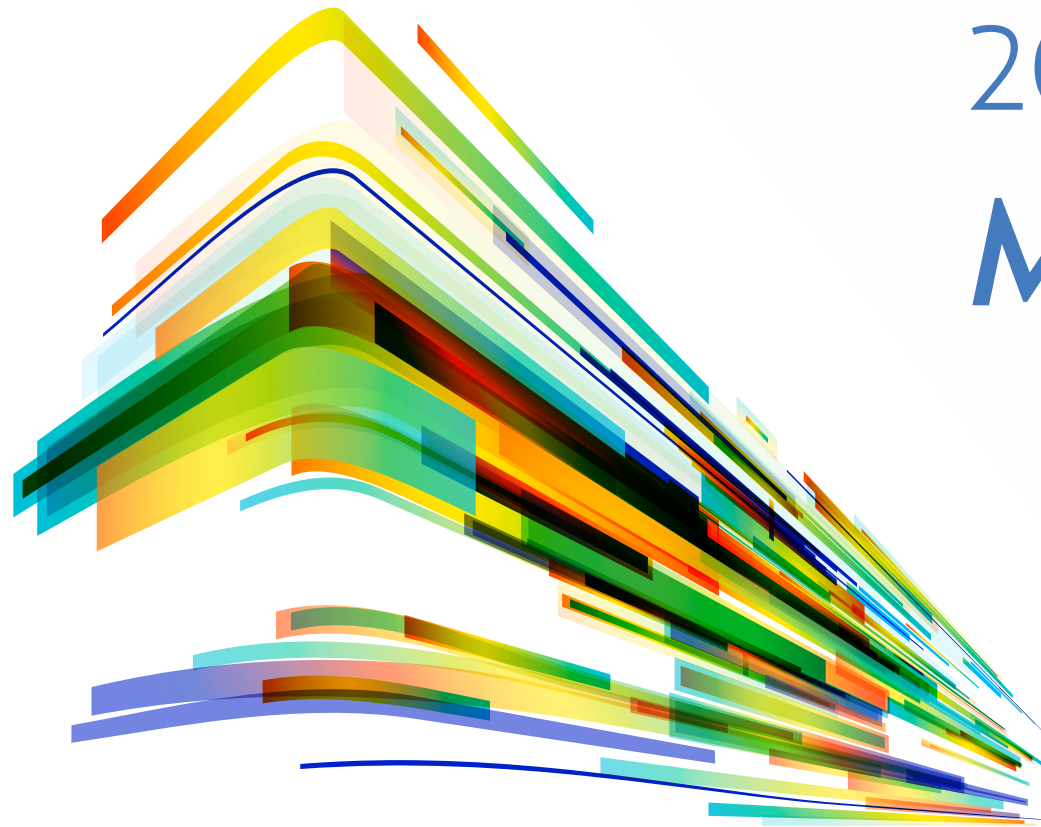
NEW CLINICAL CLAIMS

AGREEMENT WITH  
PHARMA FOR COMPANION  
DIAGNOSTIC



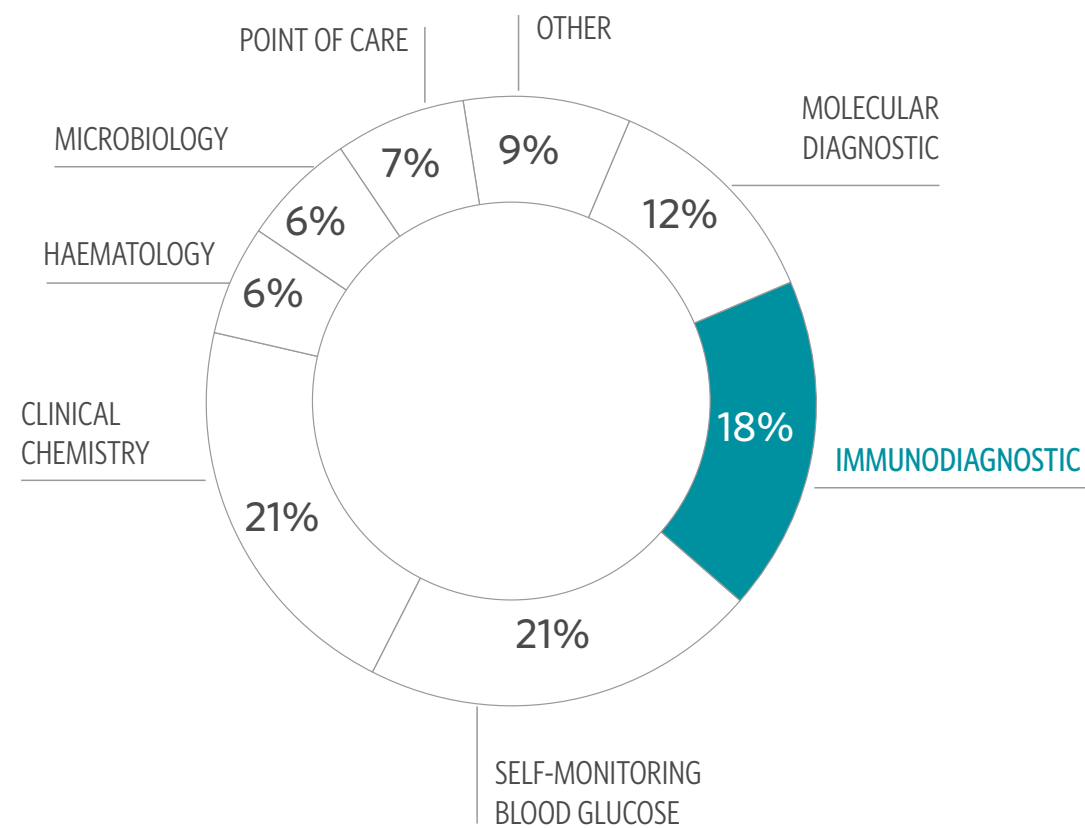
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2015-2017 PLAN:  
***MARKET AND  
PRODUCTS***



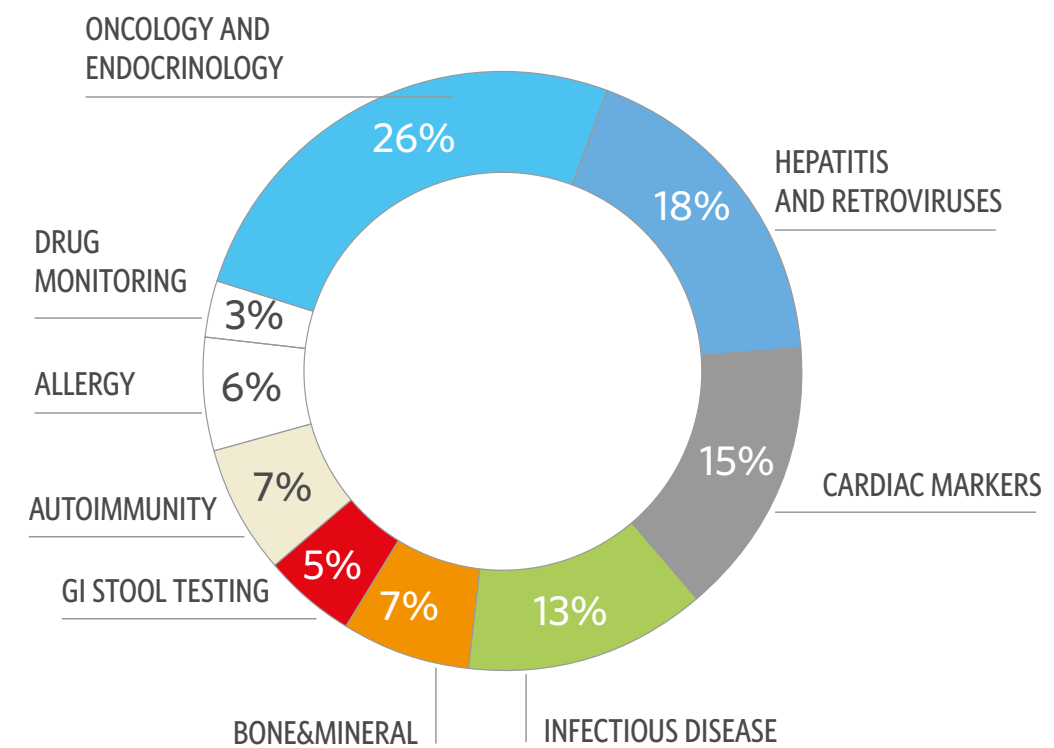
## In Vitro Diagnostic (IVD) Market

Value: ~ € 45 billion



## Immunodiagnostic Market

Value: ~ € 8.1 billion



# Broadest CLIA menu in the world

## 114 TESTS

### 83 High Routine Tests



### 31 Specialty tests



<p><b>TORCH</b> 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 Parvovirus B19 IgG Parvovirus B19 IgM</p>	<p><b>MYCOPLASMA</b> <i>Mycoplasma pneumoniae</i> IgG <i>Mycoplasma pneumoniae</i> IgM</p>	<p><b>VIRAL HEPATITIS AND RETROVIRUSES</b> HBsAg<sup>(2)</sup> HBsAg Quant<sup>(1)</sup> HBsAg Confirmatory test Anti- HBs II Anti- HBs II plus Anti- HBc HBc IgM HBeAg Anti-HBe Anti-HAV HAV IgM HCV Ab<sup>(1)</sup> HIV Ab/Ag<sup>(1)</sup> HIV Ab/Ag HT<sup>(1)</sup> HTLV I/II<sup>(1)</sup></p>	<p><b>REPRODUCTIVE ENDOCRINOLOGY</b> LH FSH Prolactin Progesterone Testosterone Estradiol hCG/<math>\beta</math>-hCG</p>	<p><b>GROWTH</b> hGH IGF-I</p>	<p><b>TUMOUR MARKERS</b> CEA Free PSA Total PSA CA 15-3<sup>™</sup> CA 125 II<sup>™</sup> CA 19-9<sup>™</sup> TPA<sup>®</sup>-M NSE S100 AFP hCG/<math>\beta</math>-hCG Tg <math>\beta</math>2-Microglobulin TK Calcitonin</p>
<p><b>BORRELIA</b> <i>Borrelia burgdorferi</i> IgG <i>Borrelia burgdorferi</i> IgM</p>	<p><b>MEASLES &amp; MUMPS</b> Measles IgG Measles IgM Mumps IgG Mumps IgM</p>	<p><b>CHAGAS</b> Chagas IgG<sup>(1)</sup></p>	<p><b>ANAEMIA</b> Ferritin</p>	<p><b>ADRENAL FUNCTION</b> ACTH Cortisol DHEA-S</p>	<p><b>BONE &amp; MINERAL</b> 25-OH Vitamin D TOTAL N-TACT<sup>™</sup> PTH Gen II 1-84 PTH Osteocalcin BAP OSTASE<sup>®</sup> 1,25 dihydroxyvitamin D<sup>(1)</sup> FGF 23<sup>**</sup> Sclerostin<sup>**</sup></p>
<p><b>VZV</b> VZV IgG VZV IgM</p>	<p><b>BORDETELLA</b> <i>Bordetella pertussis</i> Toxin IgG <i>Bordetella pertussis</i> Toxin IgA</p>	<p><b>SEPSIS</b> BRAHMS PCT<sup>™(2)</sup> BRAHMS PCT<sup>®</sup> II Gen</p>	<p><b>HYPERTENSION</b> Direct Renin Aldosterone</p>	<p><b>THYROID</b> TSH (3rd Gen.) Free T3 Free T4 T3 T4 Tg Anti-Tg Anti-TPO</p>	
<p><b>EBV</b> EBV IgM VCA IgG VCA IgA<sup>**</sup> EBNA IgG EA IgG</p>	<p><b>STOOL DIAGNOSTICS</b> <i>C. difficile</i> GDH<sup>(2)</sup> <i>C. difficile</i> Toxin A and B<sup>(2)</sup> <i>H. pylori</i> SA EHEC<sup>(2)</sup> Rotavirus Adenovirus Calprotectin <i>Campylobacter</i><sup>*</sup></p>	<p><b>TREPONEMA</b> Treponema Screen</p>	<p><b>CARDIAC MARKERS</b> Troponin I<sup>(2)</sup> Myoglobin<sup>(2)</sup> CK-MB<sup>(2)</sup></p>	<p><b>AUTOIMMUNITY</b> ANA Screen<sup>(2)</sup> dsDNA<sup>(2)</sup> tTG IgA<sup>(2)</sup> ENA Screen<sup>(2)</sup> Cardiolipin IgG<sup>(2)</sup> Cardiolipin IgM<sup>(2)</sup></p>	

\*\* Under Development  
1 - Available on LIAISON<sup>®</sup> XL only  
2 - Available on LIAISON<sup>®</sup> only

# Immunodiagnostic Pipeline: 2015-2017



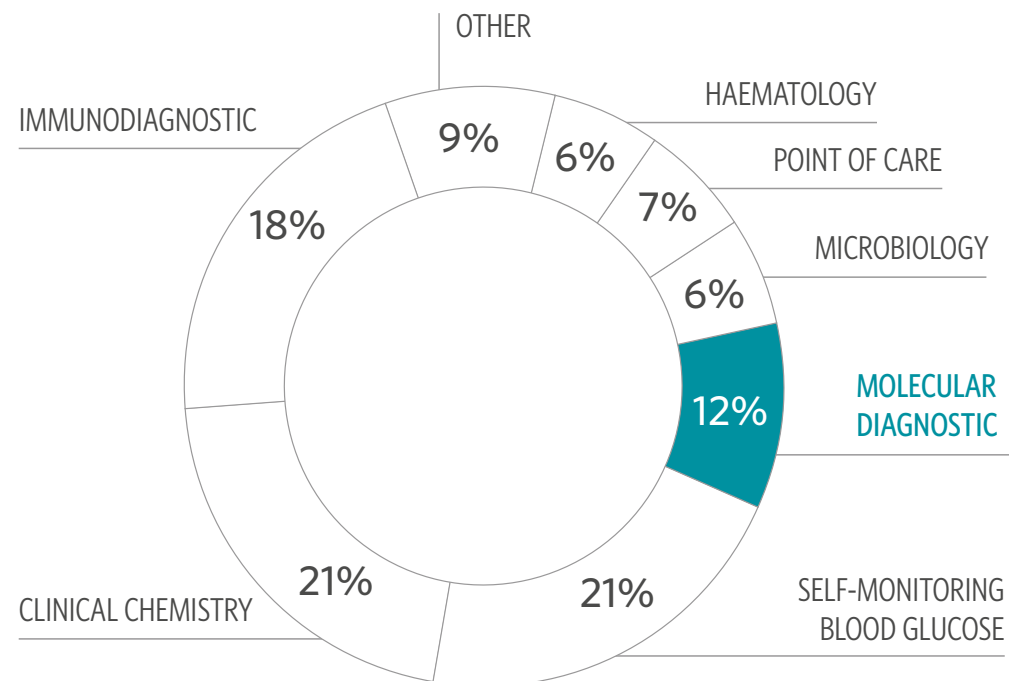
AREA	2015	2016	2017
Bone & Mineral	Sclerostin	6 to 8 Tests	6 to 8 Tests
	FGF-23		
GI Stool Testing	Campylobacter		
Infectious Diseases	Bordetella G*		
	Bordetella A*		
	PCT II*		
	H. Pylori IgG		
Endocrinology	HCV II		

\*Already available on the market

# IVD Market: Molecular Diagnostic

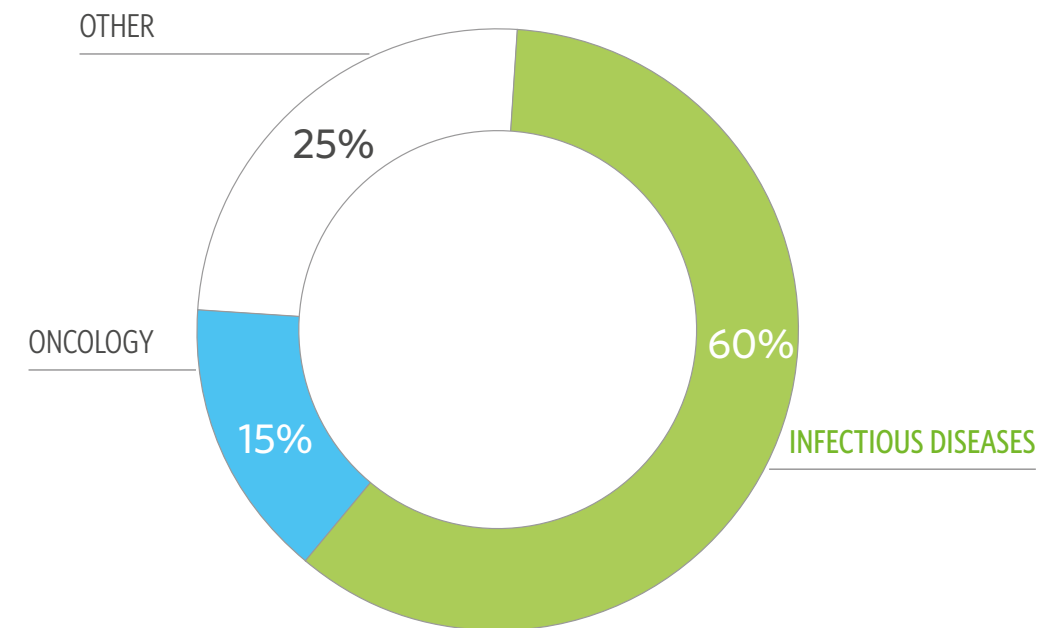
## In Vitro Diagnostic (IVD) Market

Value: ~ € 45 billion



## Molecular Diagnostic Market

Value: ~ € 5.4 billion










## DiaSorin Strategy

- Market Leadership on Specialties in Onco-Haematology
- Development and launch of Qualitative Onco-Haematology tests (e.g. BCR ABL launched in 2014), followed by Quantitative tests
- The most complete menu to diagnose and monitor the different types of Leukemia by 2017
- Leverage the existing portfolio of 6 Infectious Diseases tests

## DiaSorin Tests in this clinical area

	<b>BCR-ABL 190</b>	CHRONIC MYELOID LEUKEMIA ACUTE LYMPHOBLASTIC LEUKEMIA
	<b>PML-RARa</b>	ACUTE PROMYELOCYTIC LEUKEMIA
	<b>BCR-ABL 210</b>	CHRONIC MYELOID LEUKEMIA
	<b>AML1-ETO</b>	ACUTE MYELOID LEUKEMIA
	<b>CBFB-MYH11</b>	ACUTE MYELOID LEUKEMIA

## Positioning of LIAISON IAM



**LIAISON<sup>®</sup> Iam**

Development of Molecular amplification technology (Q-LAMP)

Assays differentiating the current methodology (PCR)

Easier to use

Rapid diagnostic response

Sensitivity, accuracy and reliability

# Molecular Diagnostic Pipeline: 2015-2017

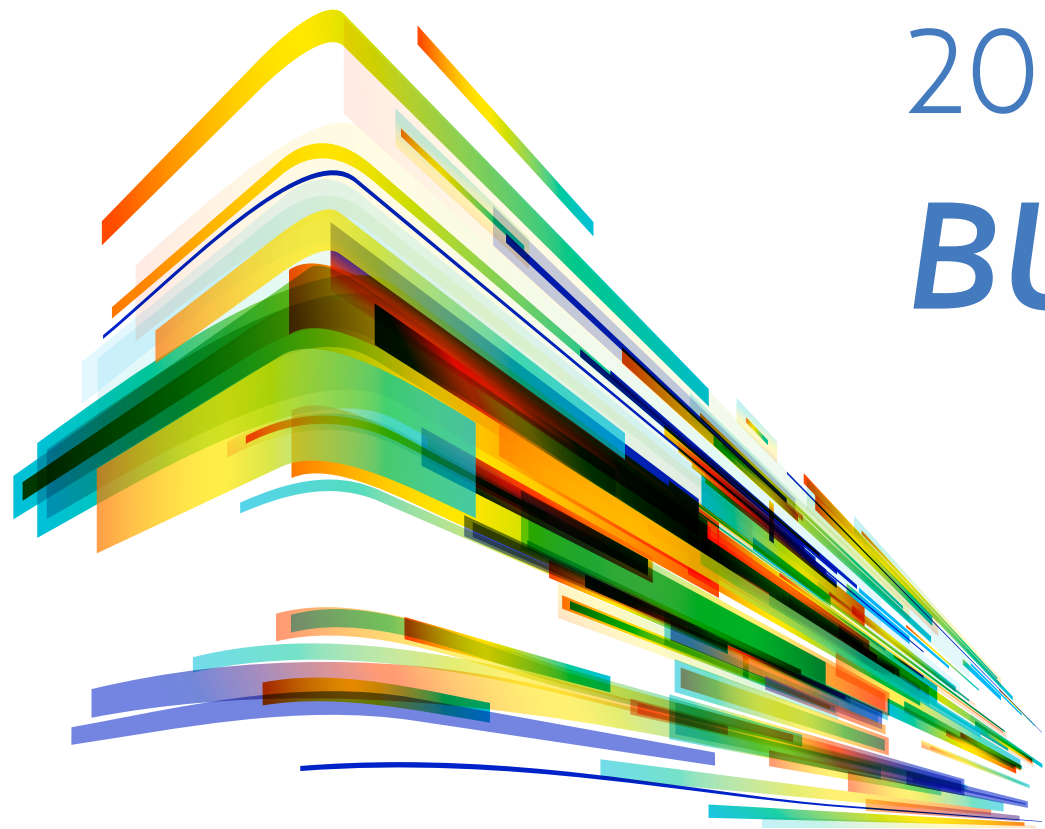


AREA	2015	2016	2017
Qualitative Onco-Haematology	PML-RAR 1-3	AML-ETO 1	
	PML-RAR 2	CBF D-E	
		CBF A	
Quantitative Onco-Haematology		BCR-ABL P210	BCR-ABL P190 + ABL
		BCR-ABL ABL	PML-RAR 1 + ABL
			PML-RAR 2 + ABL
			PML-RAR 3 + ABL

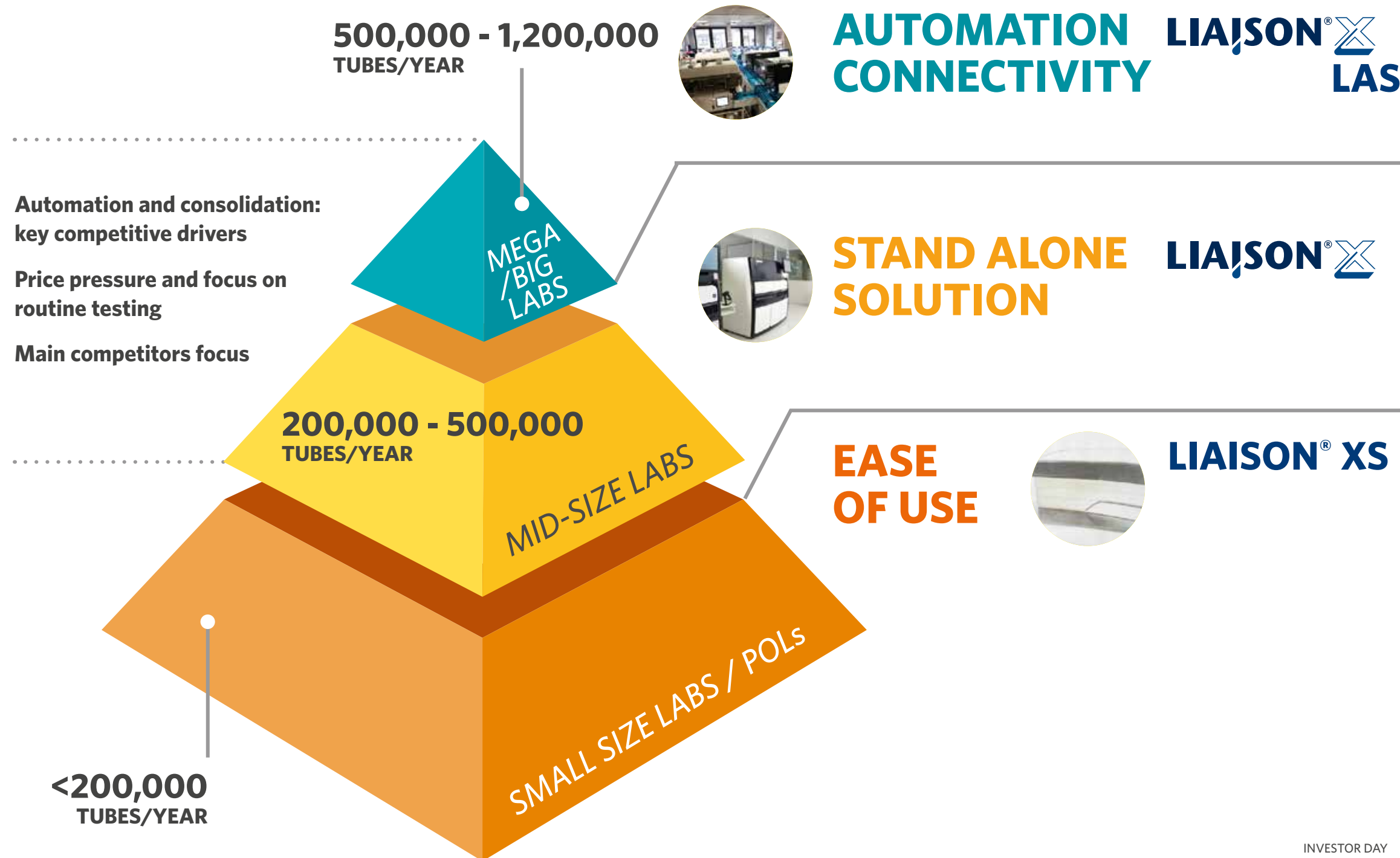
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2015-2017 PLAN:

***BUSINESS EXECUTION***



# Technological full spectrum solution: from small to mega



# LIAISON XL: stand alone

**MID-SIZE LABS WORLDWIDE**  
**200,000 - 500,000 TUBES / YEAR**



**DIASORIN POSITIONING**

**> 1,600 LIAISON XL installed at worldwide level,  
(ex mega/big labs)**

**> 70% of LIAISON XL future intallations**



# LIAISON XL: automation and connectivity

DiaSorin

**MEGA-BIG LABS WORLDWIDE**  
500,000-1,200,000 TUBES / YEAR

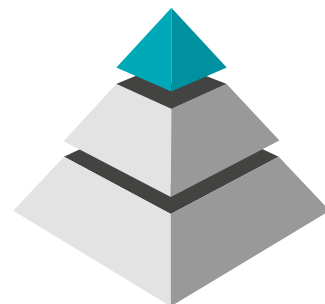
LABCORP

QUEST  
DIAGNOSTICS

ROCHE

SONIC  
HEALTHCARE

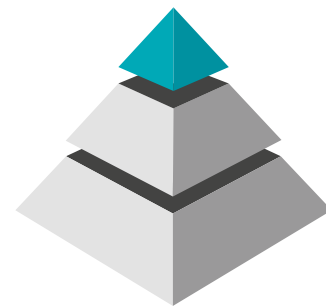
NEW STRATEGIC  
PARTNER



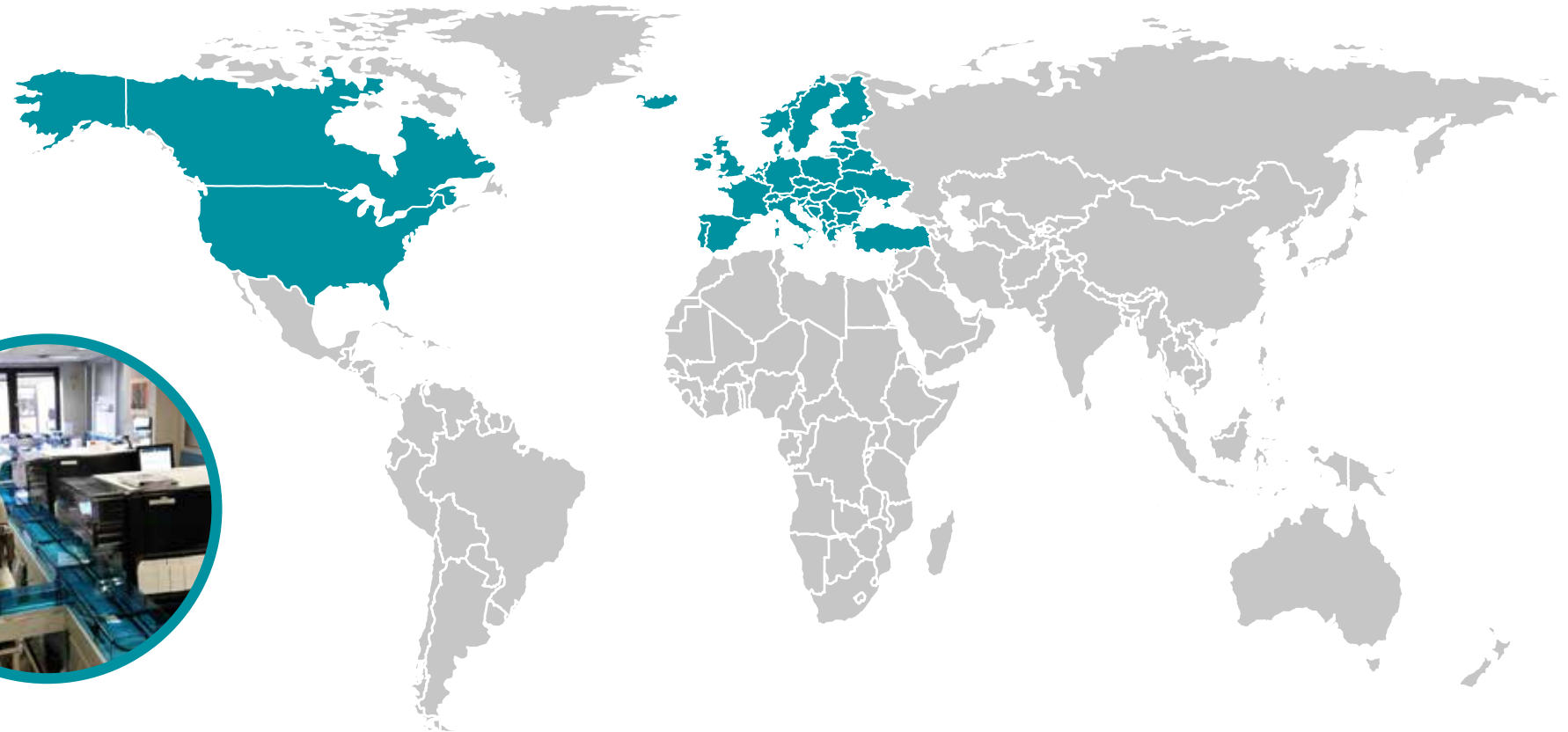
## **DIASORIN POSITIONING**

**Alone through LIAISON XL: Specialties**

**In partnership through the connection of the  
LIAISON XL LAS: Specialties + High Routine**



MEGA-BIG LABS  
WORLDWIDE



### TYPE OF AGREEMENT

WORLDWIDE EX CHINA AND JAPAN COOPERATION AGREEMENT, WITH CO-EXCLUSIVITY ON MOSTLY DIASORIN SPECIALTY TESTS

### # TESTS

~ 40

### CLINICAL AREAS

ENDOCRINOLOGY, HYPERTENSION, INFECTIOUS DISEASES, BONE & METABOLISM

### AVAILABLE MARKET

>1,000 MEGA LABS BY 2020  
POTENTIALLY ADDRESSABLE BY COBAS 8100

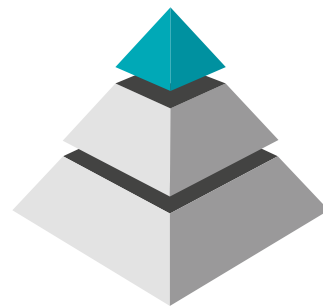
### # YEARS

5

### TYPE OF TESTS

SPECIALTIES / UNIQUE

# NEW STRATEGIC PARTNER



MEGA-BIG LABS  
WORLDWIDE



## TYPE OF AGREEMENT

DISTRIBUTION AGREEMENT IN CHINA

## # TESTS

10

## CLINICAL AREAS

HEPATITIS AND RETROVIRUSES

## AVAILABLE MARKET

ANY LABORATORY SERVED BY AN AUTOMATED  
PLATFORM OF THE STRATEGIC PARTNER

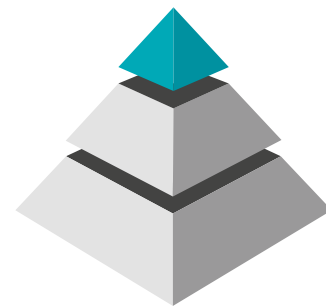
## # YEARS

10

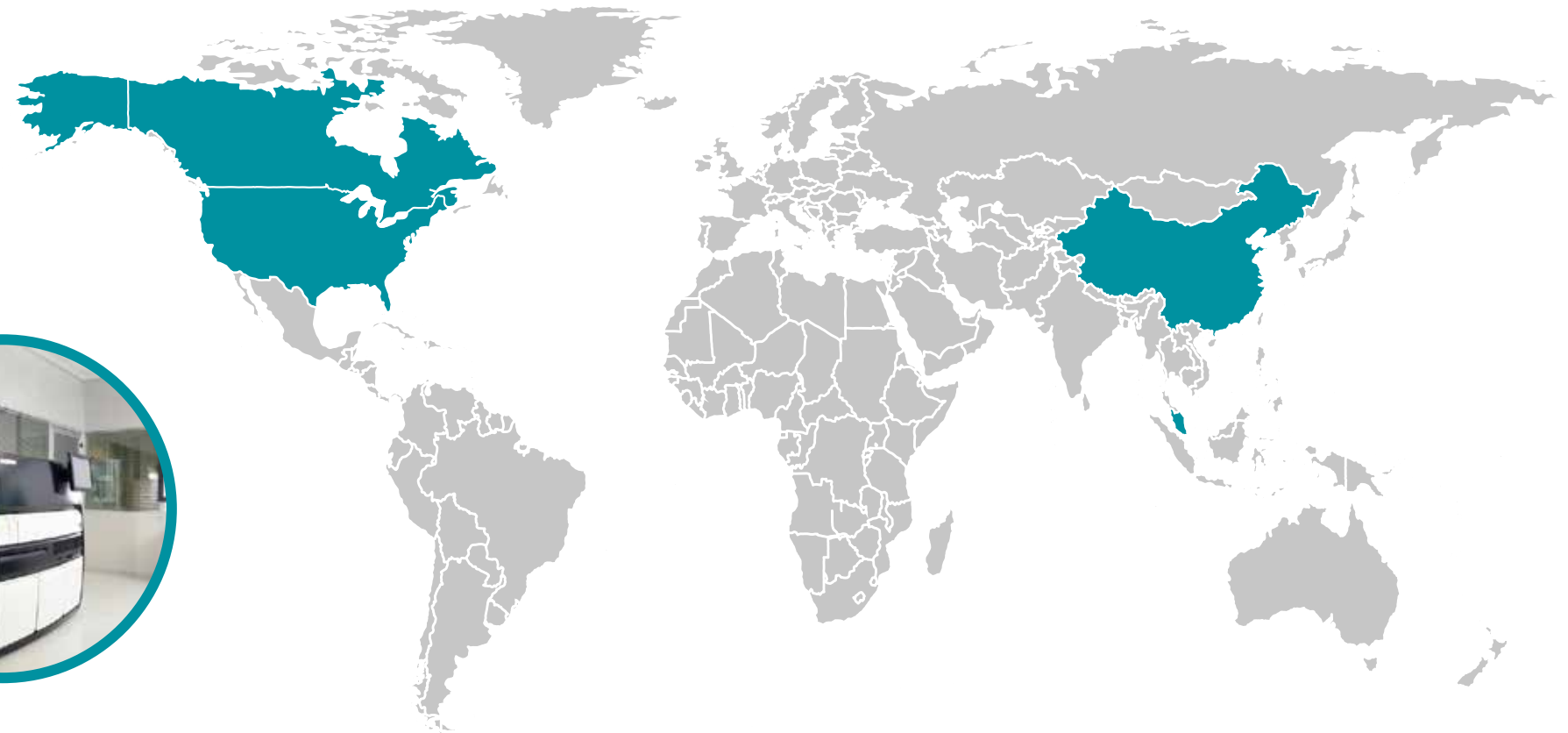
## TYPE OF TESTS

HIGH ROUTINE WITH LIAISON XL  
LAS CONNECTIVITY





MEGA-BIG LABS  
WORLDWIDE



**TYPE OF AGREEMENT**

EXCLUSIVE SUPPLY AGREEMENT

**# TESTS**

16

**CLINICAL AREAS**

VITAMIN D + INFECTIOUS DISEASES +  
ENDOCRINOLOGY

**# LIAISON XL**

> 50 AT WORLDWIDE LEVEL

**AVAILABLE MARKET**

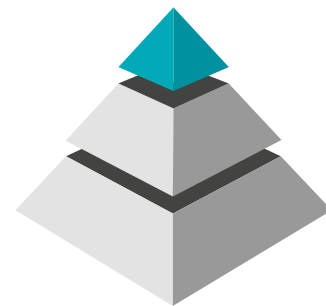
WORLDWIDE LABORATORIES OF LABCORP

**# YEARS**

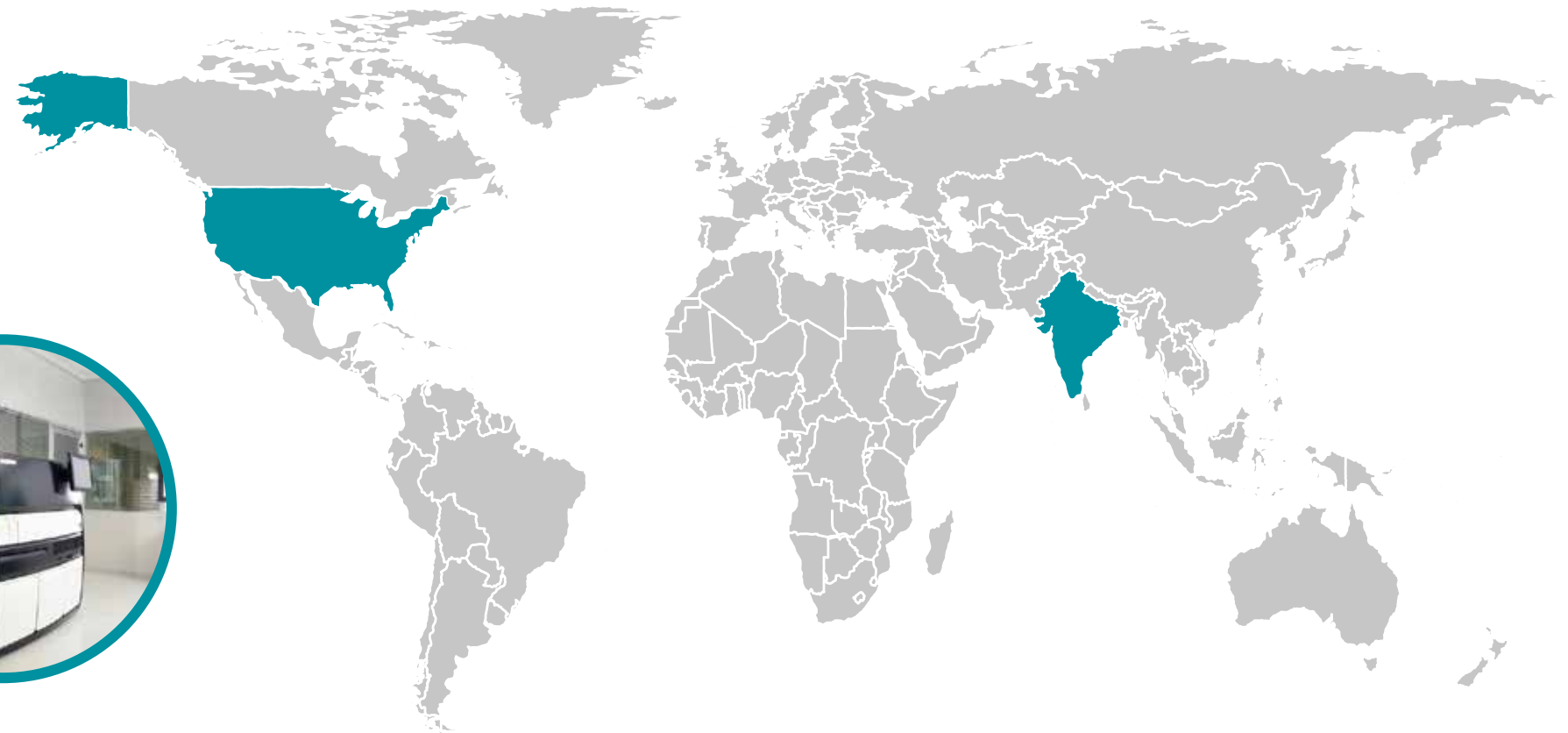
5+

**TYPE OF TESTS**

SPECIALTIES



MEGA-BIG LABS  
WORLDWIDE



**TYPE OF AGREEMENT**

SUPPLY AGREEMENT

**# TESTS**

STARTING WITH 1

**CLINICAL AREAS**

BONE & MINERAL

**# LIAISON XL**

> 50 AT WORLDWIDE LEVEL

**AVAILABLE MARKET**

LABORATORIES OF QUEST

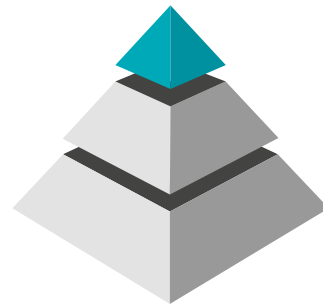
**# YEARS**

5

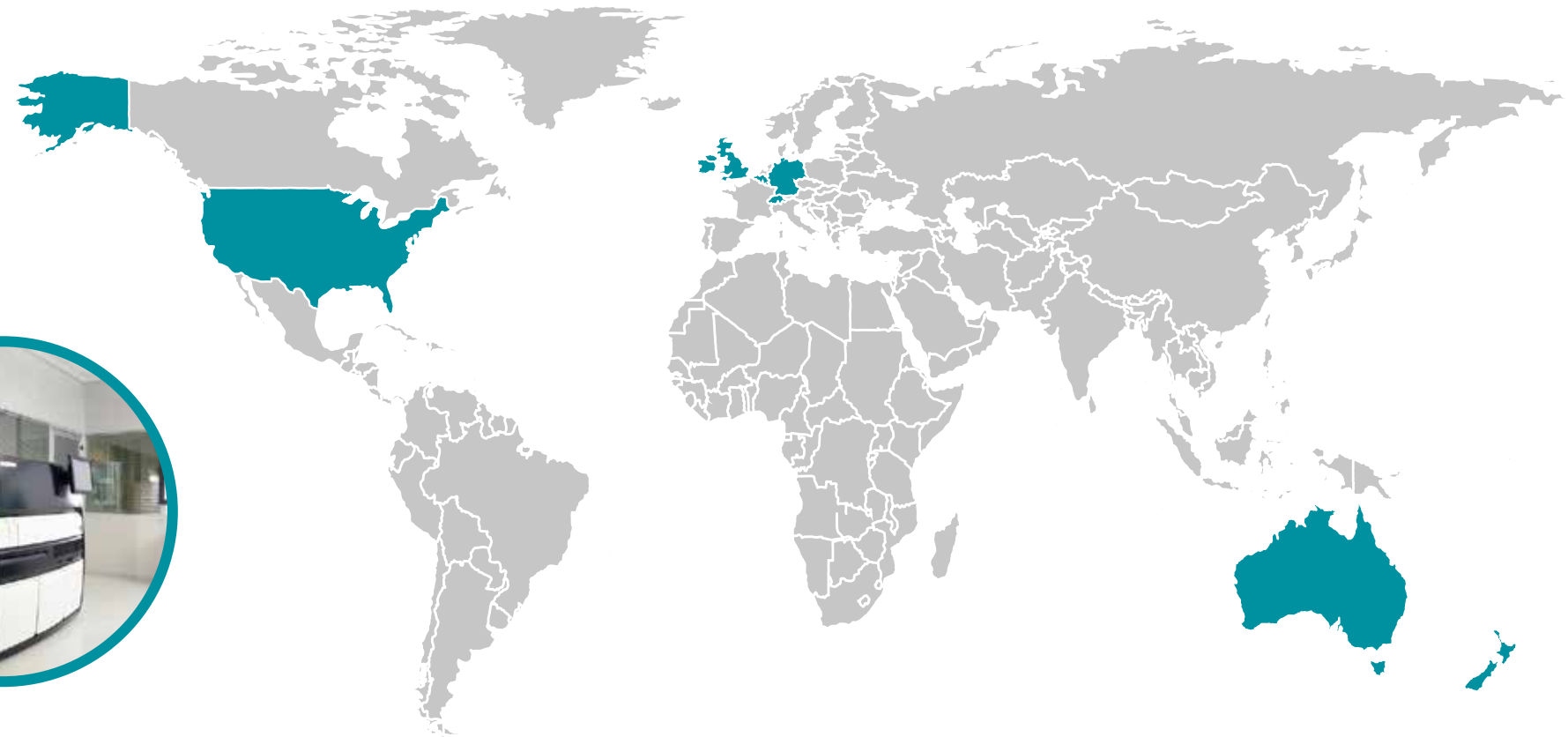
**TYPE OF TESTS**

VITAMIN D

# SONIC HEALTHCARE



MEGA-BIG LABS  
WORLDWIDE



## TYPE OF AGREEMENT

WORLDWIDE SUPPLY AGREEMENT

## # TESTS

> 15

## CLINICAL AREAS

BONE & MINERAL + INFECTIOUS DI-  
SEASES + ENDOCRINOLOGY

## # LIAISON XL

MULTIPLES FOR EVERY LAB +  
CONNECTIVITY

## AVAILABLE MARKET

SONIC HEALTHCARE LABORATORIES

## # YEARS

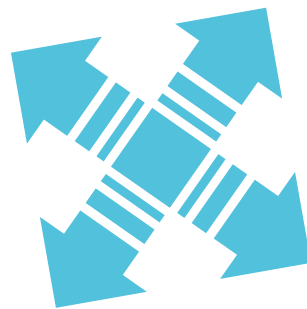
3+

## TYPE OF TESTS

SPECIALTIES

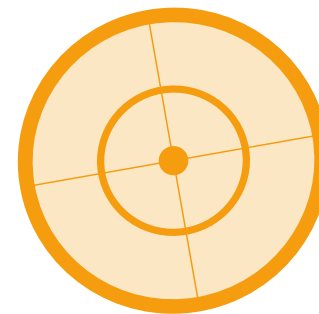
## YESTERDAY

- **GEOGRAPHIC EXPANSION AND CONTINUOUS CONSOLIDATION** THROUGHOUT ALL THE REGIONS (E.G. AUSTRALIA, AUSTRIA, BRAZIL, CANADA, CZECH REPUBLIC, IRELAND, ISRAEL, MEXICO, NETHERLANDS, PORTUGAL, SOUTH AFRICA, SWITZERLAND)



## TOMORROW

- **STRATEGIC FOCUS ON SOME KEY GEOGRAPHIES**
- **SOME GEOGRAPHIC EXPANSION IN MARKETS BECOMING RELEVANT** (e.g. POLAND)





## MARKET

- Mature, stable and highly competitive
- Ever growing consolidation
- Opportunities in both high-routine and specialties throughout all clinical areas
- Mainly driven by Germany, Italy, France, Spain and the UK
- Growing opportunities in the smaller countries

## DIASORIN

### CURRENT POSITIONING

- Full menu CE marked
- Large installed base: >2,200 (~ 50% LIAISON XL)
- Over 20 different tests used on 50% of the stand-alone installed base
- Direct presence in all major countries

### STRATEGY

- Managing the turnover of LIAISON customers to LIAISON XL with larger and longer commitments
- Add-on strategy of newly developed tests on the existing installed base (e.g. Infectious Diseases tests)
- Entering new markets segments such as Stool testing
- Addressing mega lab connectivity needs with Roche
- Working with customers on high value tests and cost-in-use (e.g. Vitamin D 1,25)



## MARKET

- Growing in the range of 2-3% by volumes
- So far, out of 43 million non-insured people, Obama Care Program enrolled 12 million
- Prices under pressure as reimbursement is cut throughout the health system
- LabCorp + Quest Diagnostics + Sonic Healthcare > 30% market share
- ~ 120 Regional Reference Labs
- > 4,000 medium and small size hospitals
- ~ 18,000 POLs

## DIASORIN

### CURRENT POSITIONING

- Strategic relationship and secure business within LabCorp, Quest Diagnostics and Sonic Healthcare with specialty tests
- Presence in most of the regional reference laboratories
- 70% market share on Vitamin D
- ~ 40 Tests FDA approved
- Large portion of installed base with <10 tests per instrument

### STRATEGY

- Managing the turnover of LIAISON customers with few tests to LIAISON XL with broader tests menu and longer commitments
- Add-on strategy of newly FDA approved tests on the existing Vitamin D installed base (e.g. Infectious Diseases tests)
- Addressing the opportunity of medium-size hospitals and large POLs with the LIAISON XL and the newly expanded menu
- Addressing mega lab connectivity needs with Roche
- Working with customers on high value tests and cost-in-use (e.g. Vitamin D 1,25)



## MARKET

- ~ 10,000 CLASS II and III hospitals
- International players are mainly targeting the ~ 8,000 CLASS III and IIA hospitals
- Local players are targeting smaller CLASS I and II hospitals
- CLIA technology and full lab automation are gaining ground
- Market is still growing double digits

## DIASORIN

### CURRENT POSITIONING

- Strong positioning in pre-natal screening: full menu best-in-class
- Leadership in blood bank imported testing
- A wide product menu offer
- ~ 650 instruments installed, of which ~ 150 LIAISON XL targeting mainly CLASS III and IIA hospitals

### STRATEGY

- Continue market leadership in Pre-Natal screening
- Growth from Hypertension and Hepatitis & Retrovirus recently registered tests
- Strategic commercial agreement with local manufacturer which will act as a distributor to address CLASS II and I hospitals in relevant areas
- Strategic partnership with an international player to target CLASS III and IIA hospitals, offering a complementary product menu

# Japan: VITAMIN D approved



DiaSorin

## MARKET

- Calcium and Vitamin D deficiency more prevalent than in the US and Europe
- Low exposure to sunlight
- With a population of ~ 125 million, there are ~ 13 million cases of osteoporosis
- Until recently no approval and no reimbursement for Vitamin D testing
- If 2-4% market penetration within 5 years, total available market will be 2.5-5 million tests

## DIASORIN

### CURRENT POSITIONING

- DiaSorin CLIA Vitamin D test approved in Japan in April 2015
- Within 6 months, reimbursement will be defined and tests can be prescribed
- LIAISON XL already installed in the 3 largest private reference laboratories

### STRATEGY

- Market awareness and education on Vitamin D testing in order to increase prescriptions related to the approved reimbursement claim (co-marketing with the 3 main reference labs and their networks)
- Capture the send-out market

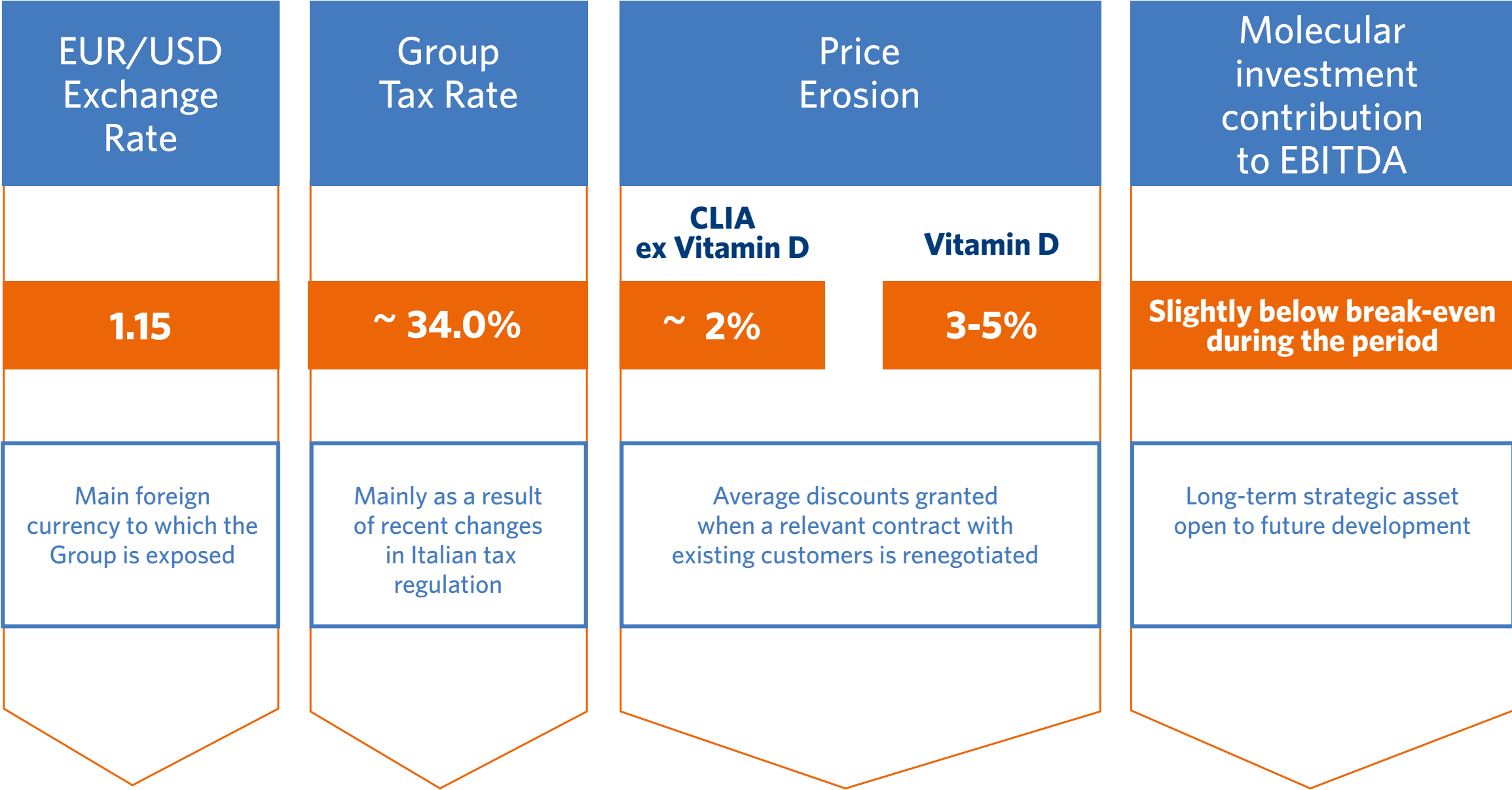


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2015-2017 PLAN:  
***FINANCIALS***



# 2015-2017 Plan Main Assumptions



# Guidance 2015-2017

€/MLN	2014a	2017	CAGR
<b>REVENUES</b>	<b>444</b>	<b>550-570</b>	<b>~ +8.0%</b>
CLIA ex Vitamin D			~ +16.0%
Vitamin D			~ +2.0%
ELISA / RIA			~ -8.0%
Instruments & other			~ +4.0%
Molecular Diagnostics			~ +30.0%
<b>EBITDA</b>	<b>160</b>	<b>205-215</b>	<b>~ +9.5%</b>
EBITDA Margin	36.1%	~ 37.5%	
<b>NET RESULT</b>	<b>84</b>	<b>110-114</b>	<b>~ +10.0%</b>
% on Revenues	18.9%	~ 20.0%	
<b>FCF</b>	<b>91</b>	<b>280-300 (*)</b>	
			(*) Cumulative 2015-2017
<b>EPS</b>	<b>€ 1.55</b>	<b>€ 2.00-2.08</b>	

# M&A: potential targets

OPPORTUNITIES  
IN THE MARKET

LISTED AND/OR PRIVATE COMPANIES

SIZE OF THE TARGET

DEPENDING ON THE OPPORTUNITY

## MARKET EXPANSION

**COMPANIES WITH A DEVELOPED CUSTOMER  
BASE ACCESSIBLE WITH THE COMBINED MENU**  
(DiaSorin + Target Company)

## GEOGRAPHICAL EXPANSION

**ACQUISITION OF LOCAL DISTRIBUTORS WHEN  
THE MARKET BECOMES RELEVANT (> 5 €/MLN)**  
(e.g. Switzerland in 2014, Poland in 2015)

## CONTENT DRIVEN

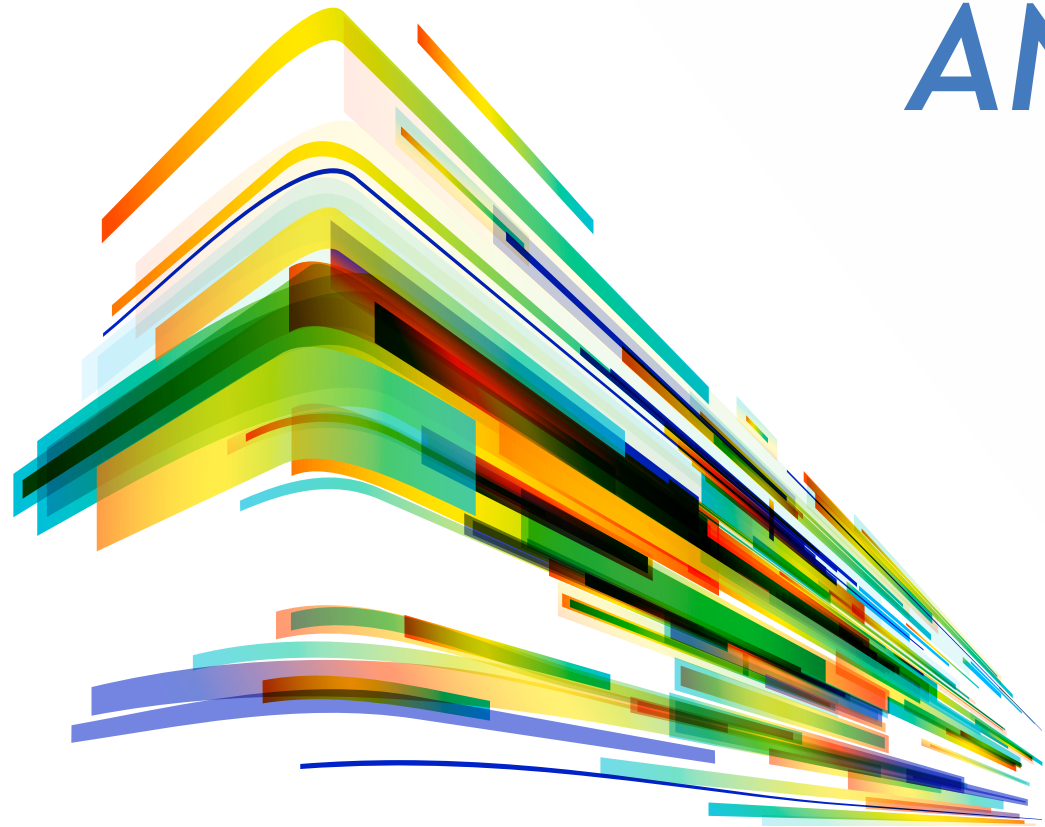
**COMPANIES WITH CLIA MARKERS/RAW  
MATERIAL PROTECTED BY IP** (e.g. Biotrin with  
Parvovirus test)

## TECHNOLOGICAL CONVERSION

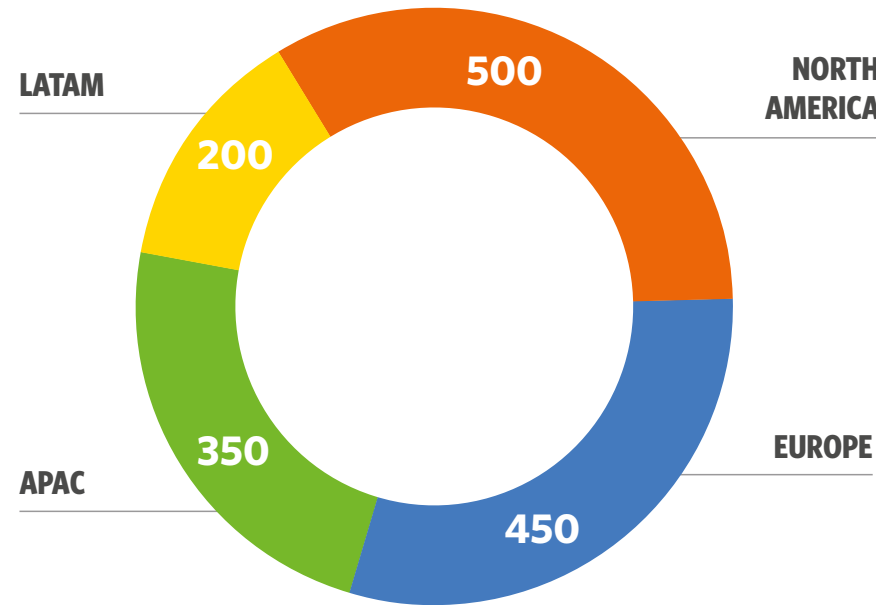
**COMPANIES RUNNING TESTS ON OLD  
TECHNOLOGIES WHICH CAN BE CONVERTED  
TO CLIA** (e.g. Murex with Hepatitis and  
Retrovirus tests on ELISA converted to CLIA)

---

# *ANNEXES*



## MARKET



WW: € 1.5 Billion

## VOLUMES TREND

Increase in volumes as a result of population growth, patients who access the diagnosis of these tests and urbanization in emerging markets

## PRICE TREND

Hepatitis C price erosion following the expiry of the patent. The number of HCV tests will increase following the availability of the new treatment

## DIASORIN TESTS IN THE CLINICAL AREA



### VIRAL HEPATITIS AND RETROVIRUSES

- HBsAg<sup>(2)</sup>
- HBsAg Quant<sup>(1)</sup>
- HBsAg Confirmatory test
- Anti- HBs II
- Anti- HBs II plus
- Anti- HBc
- HBc IgM
- HBeAg
- Anti-HBe

- Anti-HAV
- HAV IgM
- HCV Ab<sup>(1)</sup>
- HIV Ab/Ag<sup>(1)</sup>
- HIV Ab/Ag HT<sup>(1)</sup>
- HTLV I/II<sup>(1)</sup>



### CHAGAS

- Chagas IgG<sup>(1)</sup>

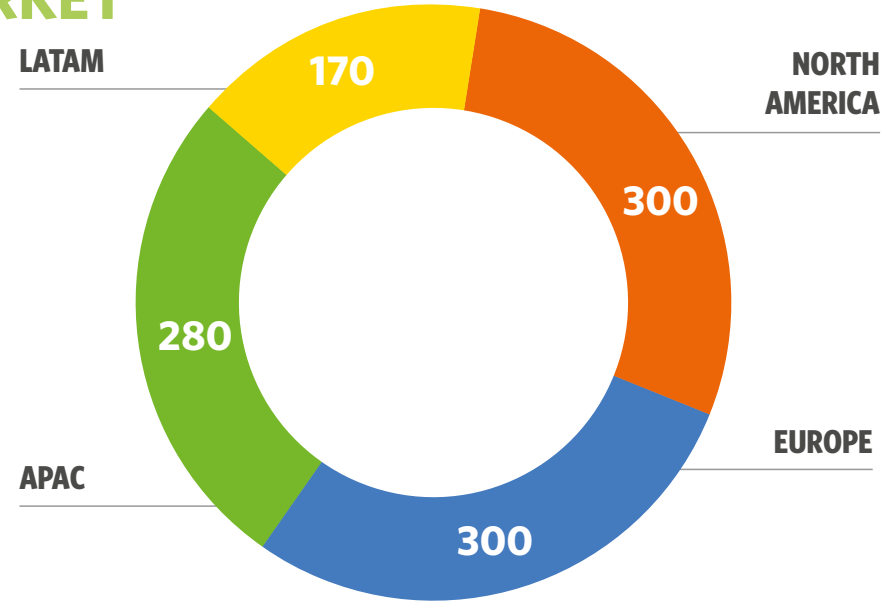
## DIASORIN STRATEGY

- Leverage on **Infectious Diseases** menu
- **LIAISON XL** to get access to **mid-size Labs**
- **Full menu on LIAISON XL** (HCV, HBV, HIV, HIV HT, HTLV, SYPHILIS e CHAGAS)
- **Significant installed base** in key markets (> 5,000) in clinical labs
- Leverage on the **MUREX** brand
- **Strategic Partnership in China**
- Registration of tests **in key markets (China and Brazil)**

\*\* Under Development - 1. Available on LIAISON® XL only - 2. Available on LIAISON® only

# Infectious Diseases (ex Hepatitis and Retrovirus)

## MARKET



## VOLUMES TREND

Infectious Diseases increasing in the world as a result of population growth, especially in the US and LATAM (3-5%) as well as in China (>10%)

## PRICE TREND

Price pressure following increasing competition and reimbursements' cuts

## DIASORIN TESTS IN THE CLINICAL AREA



### 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  
Parvovirus B19 IgG  
Parvovirus B19 IgM



### BORRELIA

*Borrelia burgdorferi* IgG  
*Borrelia burgdorferi* IgM



### VZV

VZV IgG  
VZV IgM



### EBV

EBV IgM  
VCA IgG  
VCA IgA\*\*  
EBNA IgG  
EA IgG



### MEASLES & MUMPS

Measles IgG  
Measles IgM  
Mumps IgG  
Mumps IgM



### CHLAMYDIA

*Chlamydia T.* IgG  
*Chlamydia T.* IgA



### SEPSIS

BRAHMS PCT<sup>(\*)</sup>  
BRAHMS PCT<sup>(\*)</sup> II Gen



### TREPONEMA

Treponema Screen



### BORDETELLA

*Bordetella pertussis* Toxin IgG  
*Bordetella pertussis* Toxin IgA



### MYCOPLASMA

*Mycoplasma pneumoniae* IgG  
*Mycoplasma pneumoniae* IgM

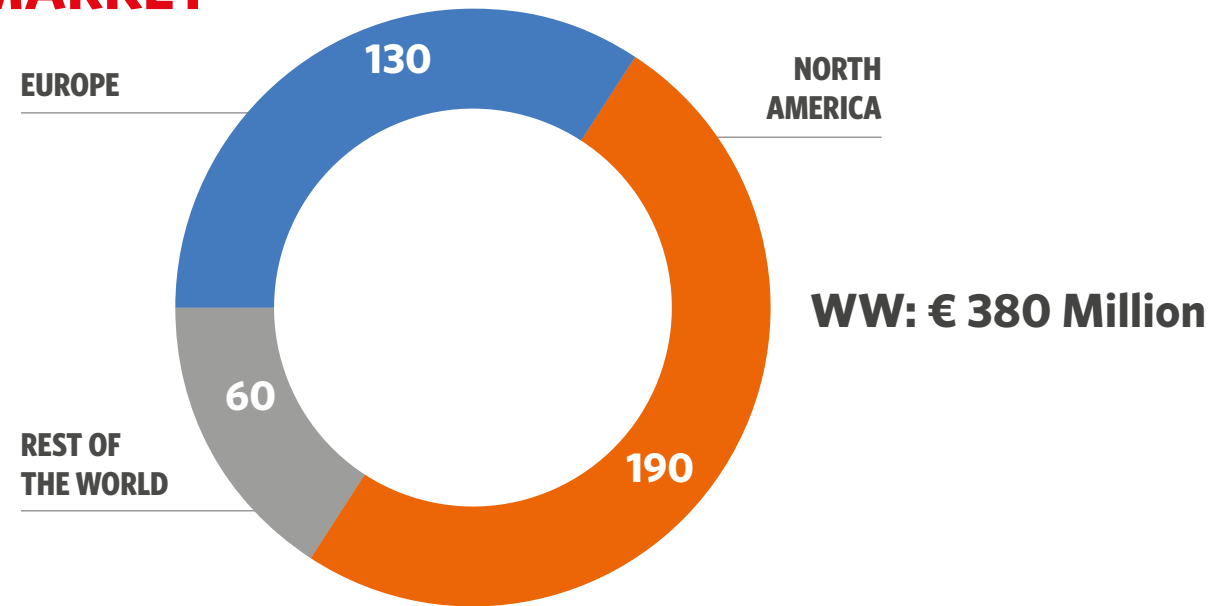
## DIASORIN STRATEGY

### Use of LIAISON XL to:

- Get access to Clinical Mid-size Labs
- Accelerate the conversion from dated technologies to CLIA
- Consolidate the Infectious Diseases market with Hepatitis and Retrovirus CLIA tests
- Strategic Partnership with ROCHE**
- Broad Menu to gain new clients, leveraging on some «key» products** (e.g. Parvovirus, Mycoplasma, Bordetella, Chlamydia and MMRV panel in the US)

\*\* Under Development - 1. Available on LIAISON® XL only - 2. Available on LIAISON® only

## MARKET



## VOLUMES TREND

Volumes growing at 5-10% CAGR  
 H. Pylori and Calprotectin markets growing  
 C. Difficile and Norovirus tests on PCR are worth € 100 Million  
 Fecal Occult Blood Test (FOBT) is worth € 50 Million

## PRICE TREND

Premium Price on "Specialty" tests

## DIASORIN TESTS IN THE CLINICAL AREA



### STOOL DIAGNOSTICS

- C. difficile* GDH<sup>(2)</sup>
- C. difficile* Toxin A and B<sup>(2)</sup>
- H. pylori* SA
- EHEC<sup>(2)</sup>
- Rotavirus
- Adenovirus
- Calprotectin
- Campylobacter*\*

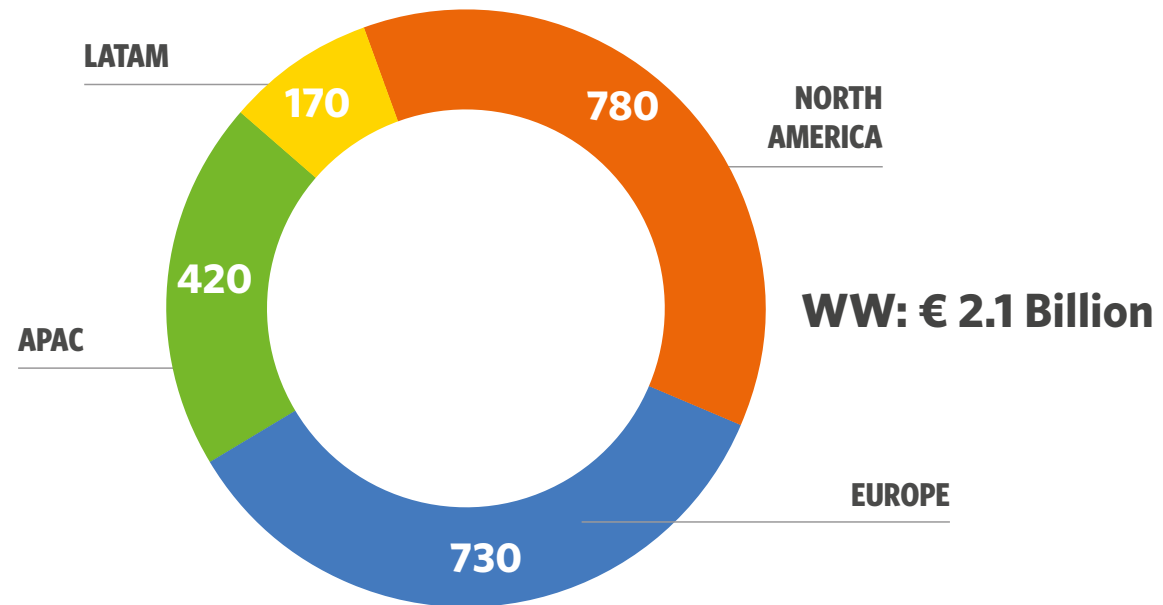
## DIASORIN STRATEGY

- Supply of an **automated «full» panel** for gastrointestinal tests on LIAISON and LIAISON XL
- Leverage on Infectious Diseases business
- **Agreement** with a leading player **to co-develop a gastro-intestinal panel** to sell worldwide, ex North America and UK
- Goal of positioning DiaSorin in the **microbiology segment**

\*\* Under Development - 1. Available on LIAISON® XL only - 2. Available on LIAISON® only



## MARKET



## VOLUMES TREND

Increase of volumes due to higher prevalence of diseases, population ageing and lifestyles in urban areas

## PRICE TREND

Routine tests: low and stable prices  
Specialty tests: high prices (e.g. Aldosterone and Renin)

## DIASORIN TESTS IN THE CLINICAL AREA



### REPRODUCTIVE ENDOCRINOLOGY

LH  
FSH  
Prolactin  
Progesterone  
Testosterone  
Estradiol  
hCG/β-hCG



### ANAEMIA

Ferritin



### HYPERTENSION

Direct Renin  
Aldosterone



### DIABETES

C-Peptide  
Insulin



### GROWTH

hGH  
IGF-I



### ADRENAL FUNCTION

ACTH  
Cortisol  
DHEA-S



### THYROID

TSH (3rd Gen.)  
Free T3  
Free T4  
T3  
T4  
Tg  
Anti-Tg  
Anti-TPO



### TUMOUR MARKERS

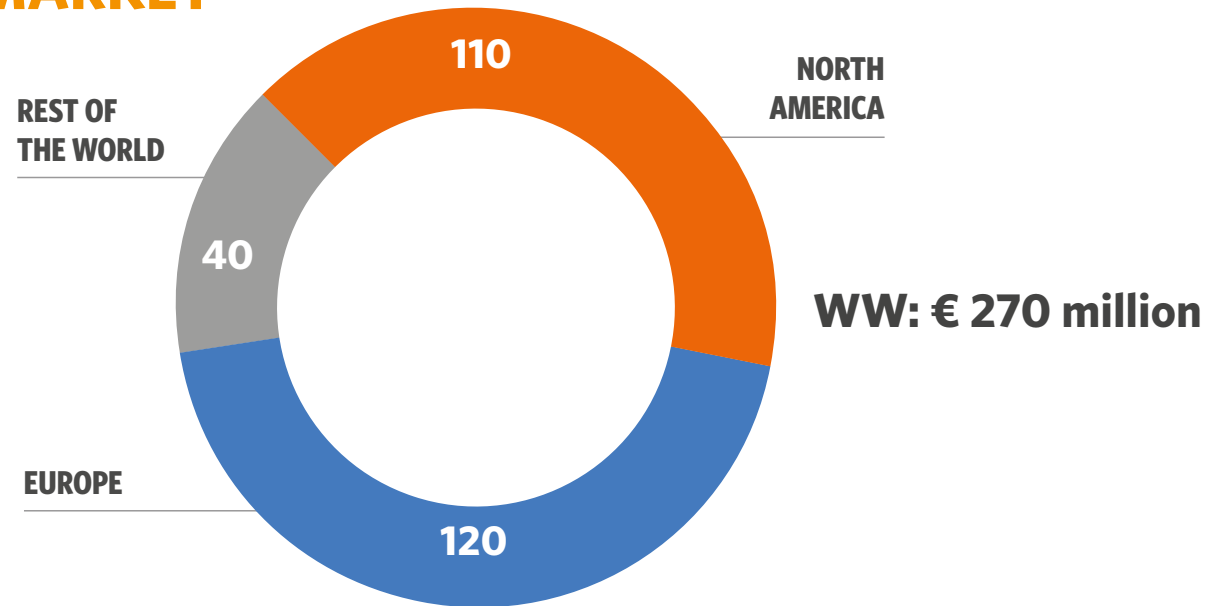
CEA  
Free PSA  
Total PSA  
CA 15-3\*  
CA 125 II™  
CA 19-9™  
TPA™-M  
NSE  
S100  
AFP  
hCG/β-hCG  
Tg  
β2-Microglobulin  
TK  
Calcitonin

## DIASORIN STRATEGY

- Use of **LIAISON XL** and **XLINE** in **medium-large size Labs**
- **Endocrinology specialties** (e.g. Direct Renin and Aldosterone for hypertension) to reinforce the reputation of «specialist» and place new analyzers
- **Expansion of the US Menu** to consolidate the positioning of the LIAISON Family and, at the same time, to strengthen the leadership position on the Vitamin D panel (Vitamin D 25 OH + 1,25 OH Vitamin D)
- Registration in **China** of **Oncology** and **Endocrinology** tests

\*\* Under Development - 1. Available on LIAISON® XL only - 2. Available on LIAISON® only

## MARKET



## VOLUMES TREND

Expected growth on average of 6% CAGR mostly due to the penetration of the 1,25 OH Vitamin D, following the clinical evidence of its usage and the necessity of follow up for patients

## PRICE TREND

Routine tests: stable (e.g. 1-84 PTH, Osteocalcin and BAP Ostase)  
 Specialty tests: Premium Price, overall for 1,25 OH Vitamin D

## DIASORIN TESTS IN THE CLINICAL AREA



### BONE & MINERAL

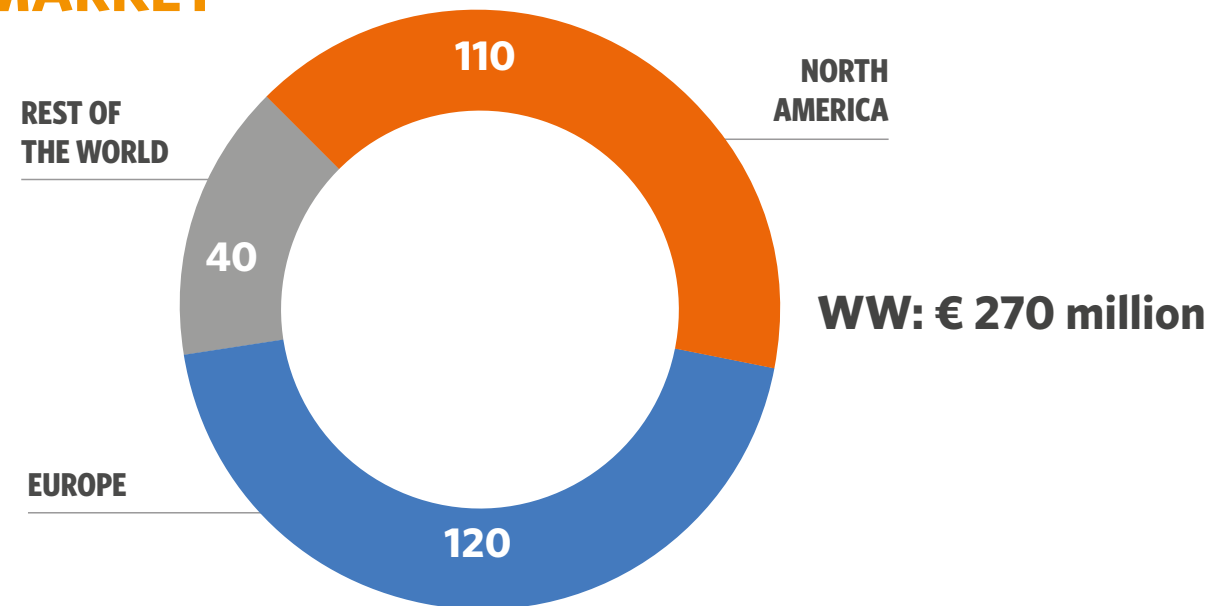
- N-TACT® PTH Gen II
- 1-84 PTH
- Osteocalcin
- BAP OSTASE®
- 1,25 dihydroxyvitamin D<sup>(1)</sup>
- FGF 23<sup>\*\*</sup>
- Sclerostin<sup>\*\*</sup>

## DIASORIN STRATEGY

- **1,25 OH Vitamin D** mostly **driving the strategy** on this clinical area
- **High-level technology** from a scientific point of view
- **Premium Price** of the test
- Ongoing **conversion** of the customers **from RIA to CLIA**
- US market targeted after the Food and Drug Administration approval
- Development of the WW Market through **clinical studies** highlighting the necessity of the test at "time zero" and in the consequent follow up of the patient

\*\* Under Development - 1. Available on LIAISON® XL only - 2. Available on LIAISON® only

## MARKET



## VOLUMES TREND

Expected growth on average of 3% CAGR mostly due to unpenetrated markets

## PRICE TREND

Price Erosion in the US and in Europe due to the increased competitiveness and to reimbursement cuts in some countries

## DIASORIN TESTS IN THE CLINICAL AREA



**BONE & MINERAL**  
25-OH Vitamin D TOTAL

## DIASORIN STRATEGY

- **Synergy with other tests of the menu:**
  - Securing the CLIA Vitamin D 25 OH market leveraging on the richness/completeness of the menu available on the LIAISON and LIAISON XL
- **New geographies:**
  - Opportunities for expansion into new markets (e.g. China and Japan)

\*\* Under Development - 1. Available on LIAISON® XL only - 2. Available on LIAISON® only



The Diagnostic Specialist

