

The Diagnostic Specialist

## 2018 Roadshow Presentation

#### **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.

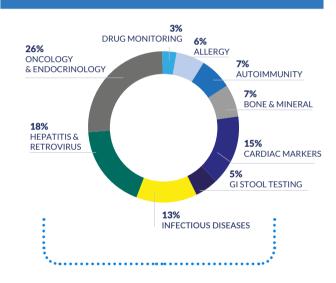
Piergiorgio Pedron, the Officer Responsible for the preparation of corporate financial reports of DiaSorin S.p.A.,

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.

### We operate in two IVD segments

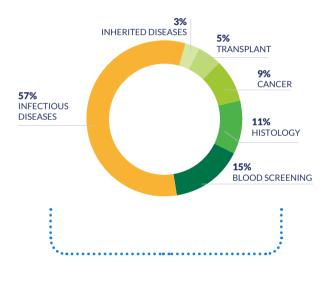


#### **Immunodiagnostics:** ~ 18% of IVD market





#### **Molecular Diagnostics:** ~ 12% of IVD market





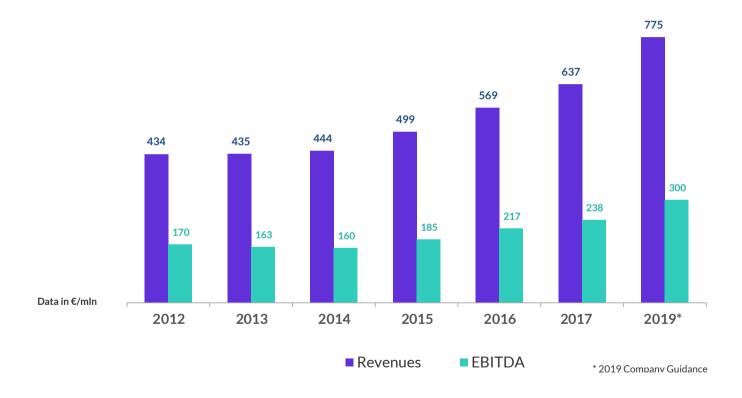
#### Where we are





#### **Revenues and EBITDA**





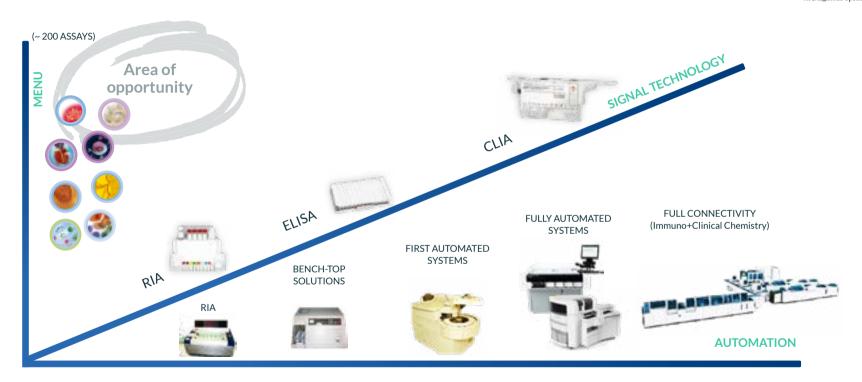


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# **Immunodiagnostics**

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





### **LIAISON** family platforms



Each test has 100 samples Same raw material its specific cartridge for each cartridge for routine and specialty tests Calibrators ..... Diluent Magnetic particles ..... New in 2019 LIAJSON° X LIAISON -LIAISON **LIAISON°** 

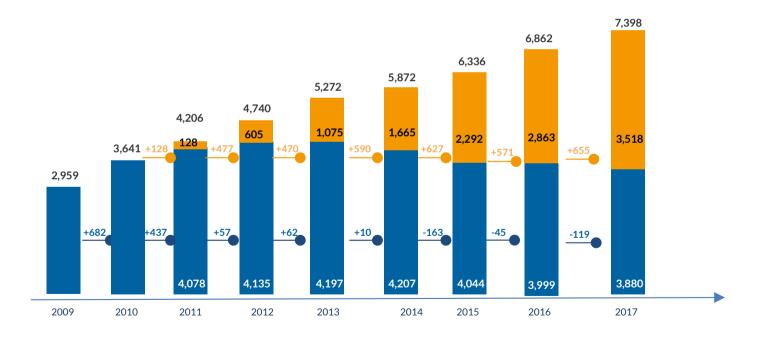
#### **Installed base evolution**











#### Menu positioning: 118 tests - the broadest CLIA menu



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## NSE AFP

ONCOLOGY TUMOUR MARKERS Free PSA Total PSA CA 15-3 CA 125 II CA 19-9 TPA-M S100 Tg Tg Gen II(\*) hCG/ß-hCG

: ß2-Microglobulin TK Calcitonin

**○**ENDOCRINOLOGY

THYROID TSH (3rd Gen.) Free T3 Free T4 Т3 T4 Tg

To Gen II DIABETES C-Peptide Anti-To Insulin · Anti-TPO

: GROWTH : REPRODUCTIVE **ENDOCRINOLOGY** 

ADRENAL FUNCTION

hGH

IGE-I

ACTH

Cortisol

DHEA-S

Ferritin

Folate(\*)

ANAEMIA

Vitamin B12(\*)

CHRONIC KIDNEY

DISEASE

1-84 PTH

Osteocalcin

BAP OSTASE

**○**ENDOCRINOLOGY

HYPERTENSION

Direct Renin

Aldosterone

1.25 dihvdroxy Vitamin D

FSH Prolactin Progesterone Testosterone Estradiol hCG/ß-hCG Androstenedione

SHRG

○BONE & MINERAL 25-OH Vitamin D TOTAL N-TACT PTH II

OINFECTIOUS DISEASE

EBV FBV IgM VCA IgG EBNA IgG

EA IgG H.PYLORI H. Pvlori 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 lgG HSV-1 IgG HSV-2 lgG

HSV-1/2 IgM **BORRELIA** Borrelia burgdorferi IgG Borrelia burgdorferi IgM MEASIES & MUMPS Measles IgG

Mumps IgG Mumps IgM VZV VZV IgG VZV IgM

Measles IgM

HBc IgM

HBeAg

Anti-HBe

Anti-HAV

HAV IgM

HCV Ab

HIV Ab/Ag

CHAGAS

HT HTLV I/II

Chagas IgG

**OVIRAL HEPATITIS** & RETROVIRUSES HBsAg HBsAg Ouant

HBsAg Confirmatory test Anti- HRs II Anti- HBs II plus Anti- HBc

OSTOOL DIAGNOSTICS C. difficile GDH C. difficile Toxin A and B H. pylori SA FHFC Rotavirus Adenovirus Calprotectin Campylobacter

**OINFECTIOUS DISEASE** Zika IgM PARVOVIRUS Parvovirus B19 IgG Parvovirus B19 IgM

BORDETELLA Bordetella pertussis Toxin IgG

Plus (\*)

Bordetella pertussis Toxin IgA MYCOPI ASMA Mycoplasma pneumoniae

IgG Mycoplasma pneumoniae **CHLAMYDIA** 

Chlamydia T. IgG OVIRAL HEPATITIS Chlamydia T. IgA QuantiFFRQN & RETROVIRUSES OuantiFERON TB Gold Anti-HDV(\*)

CHRONIC KIDNEY DISEASES

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

\* Under development

### Menu positioning: 118 tests - the broadest CLIA menu











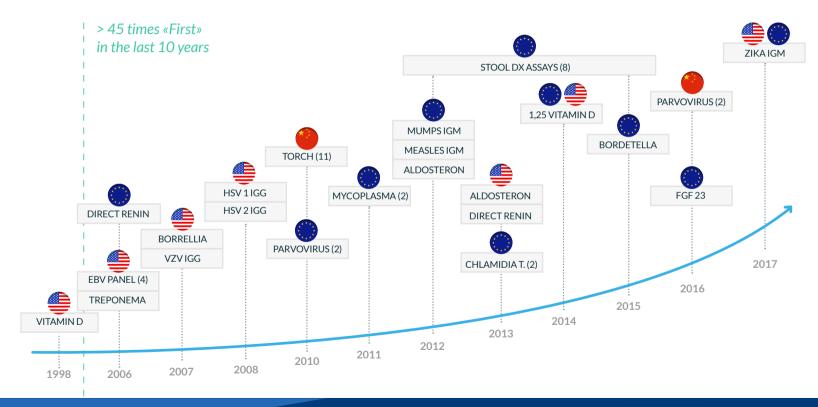
### Where we plan to invest R&D money





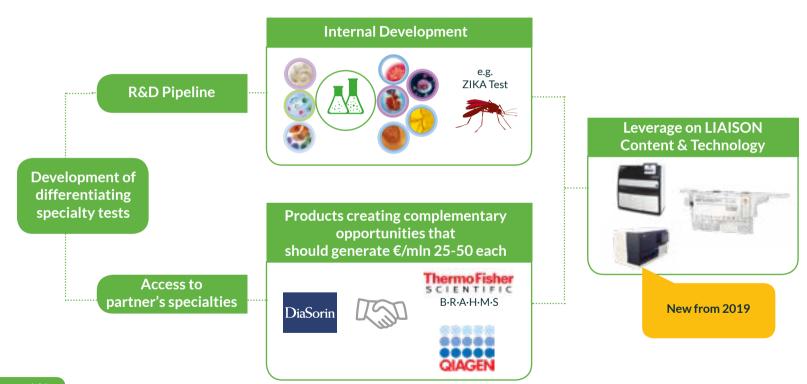
### DiaSorin «First»: Fully Automated CLIA assays





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





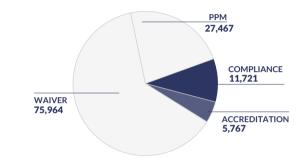
Differentiating specialties

#### **LIAISON XS: the opportunity**





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

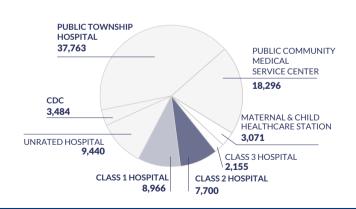




#### LIAISON 💥





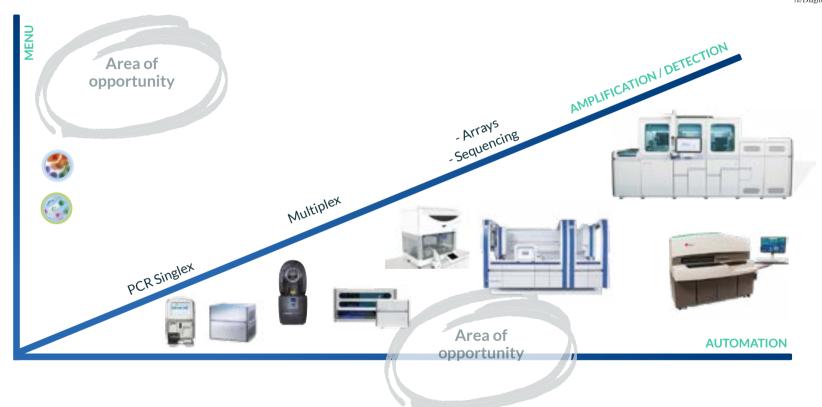




## **Molecular Diagnostics**

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





#### Platforms in the Molecular Diagnostic Market



**Point of Care systems Benchtop systems** High throughput systems CLIA Limited menu Multiplex Total Lab Limited menu Single (HCV, HIV, HBV, HPV, CT/NG) (e.g. FLU) waived Automation target X X Direct Amplification Disc (DAD) Multiplex Disc Universal Disc (UD) **New Project** DiaSorin positioning

#### **Our technology: Liaison MDX**







PCR Based ASRs & Kits

#### Compact. Powerful. Expandable.

Unique technology developed by 3M, with no extraction required





Versatile Same platform, multiple discs

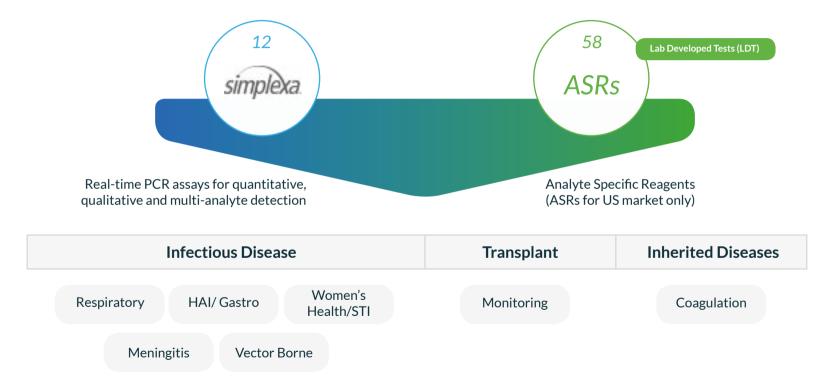
Direct Amplification Disc (DAD)

8 reaction well Low to Mid Volume Universal Disc (UD)

96 reaction well High Volume

## **DiaSorin menu positioning**





#### Molecular kits and ASRs

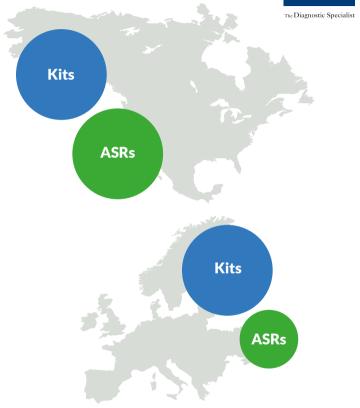
DiaSorin

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

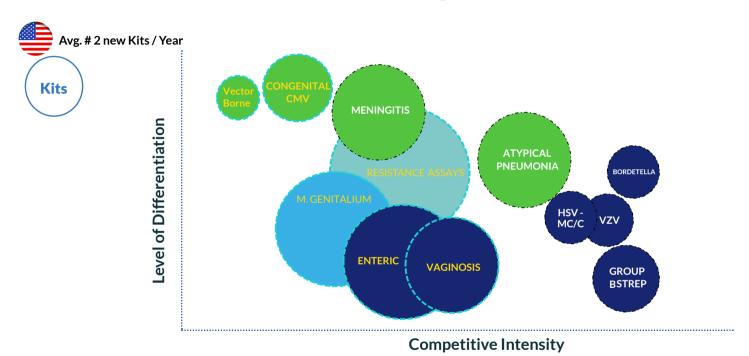
**ASRs** 

- 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**





investigational Markers

Differentiating specialties

High volume specialties

Me too tests

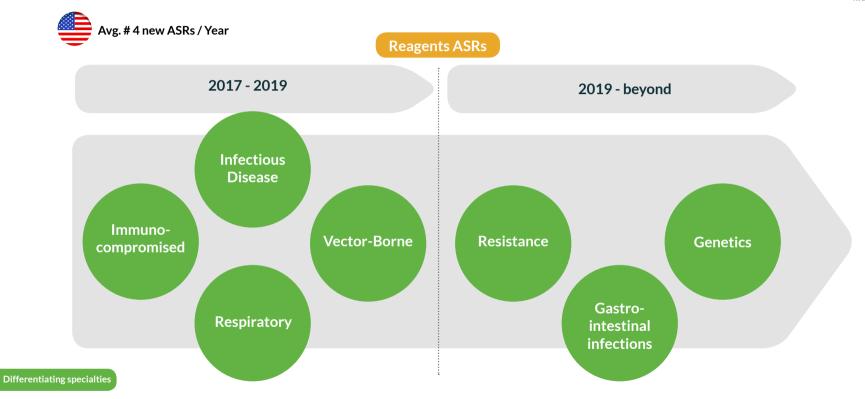
3 years pipeline strategy



3-5 years pipeline strategy

### **ASRs Pipeline Strategy**





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







**Viral Load Monitoring** 

HIV Hepatitis B Virus Hepatitis C Virus

Big Players Established Systems Well Served Highly Competitive Very Late Entry





CT/NG/TV HPV

Established Players Competitive Arena Barriers to Entry (HPV) Rapidly Eroding Price





CMV/EBV/BKV HSV/VZV HHV6/HHV8/Adeno Parvo/JCV

No Clear Leader Big Players Absent Improve Workflow More Stable Price DS knows this Market



Post Transplantation offers path to entry

#### **Europe Molecular Post Transplant**





#### Strategy

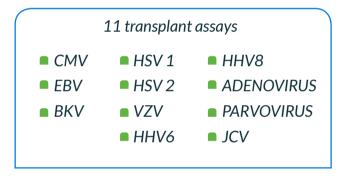
Instrument for extraction/PCR set up



 LIAISON MDX for Amplification



Provide complete transplant menu



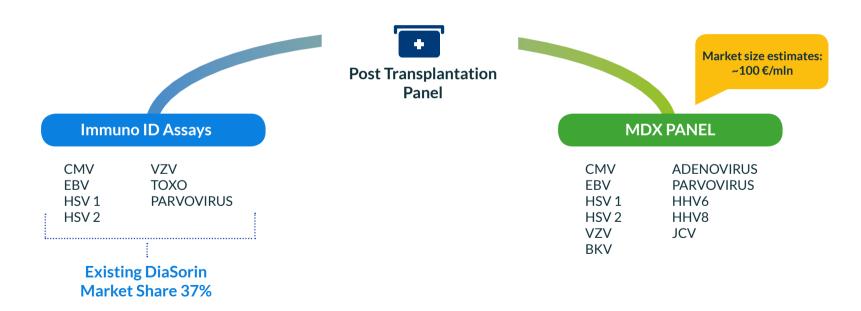


### **Europe: IMMUNO - MDX Synergy**





Expand cross selling opportunity IMMUNO-MDX with most complete panel





# Mid-term objectives

#### 2019 targets



- Solid growth of the Immunoassay franchise with addition of innovative and differentiating new products
- Launch of Liaison XS allows penetration of the small labs/ POLs segment
- QIAGEN partnership demonstrates that DiaSorin is seen well positioned to serve the Specialty market also by other large IVD players
- Conversion of SIEMENS' Elisa customers base to LIAISON XL/XS platforms
- Molecular Diagnostics is a second leg and will offer lots of opportunities to develop Specialty ID products
- Strong financial performance driven by solid margins in both segments (IA and Molecular)
- 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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Technological
evolution

2008-2009

2010

2011-2012

2013-2014

2015-2016

2017



CLIA menu expansion

LIAISON XI

**HAISON IAM LIAISON IXT** 

**LIAISON MDX** 

**LIAISON XS** project



Geographic expansion



M&A

**BIOTRIN** 

Portugal Austria Czech Republic Canada Australia Ireland South Africa

Netherlands

**MERIDIAN** 

**BIOSCIENCE** 

MURFX

(ABBOTT ELISA

business)

India

**NORDIAG** 

Switzerland

**ROCHE** 

**BECKMAN** COULTER

**FOCUS DIAGNOSTICS**  (launch in 2019)

Poland

**QIAGEN** 

**TECAN** 

SIFMENS FLISA business



## Q1 2018 Results



DiaSorin	1
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LIAISON & LIAISON XL PLACEMENTS	Q1'18	@ March 31, 2018
LIAISON XL	+116	3,634
LIAISON	-13	3,867
TOTAL	+103	7,501

Product	Deve	lopment
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#### MOLECULAR

Infectious Disease 

HSV (US market)

Extended cutaneous and mucocutaneous lesion swabs claims to cerebrospinal fluid (CSF) and genital lesion swab

	Q1	'18	
REVENUES	€/mln :	164.5 <sup>(*)</sup>	
REVEROES	+4.4%	+11.2% (**)	
CLIA ex Vit D 25 OH	+9.1%	+13.8% (**)	
▶ Vit D 25 OH	-11.5%	-2.6% (**)	
▶ ELISA tests	+18.2%	+24.4% (**)	
Molecular tests	+4.8%	+19.1% (**)	
Instruments & other revenues	-1.6%	+3.3% (**)	
EBITDA	€/mlr	63.3	
	+1.3%	+9.3% (**)	
EBITDA MARGIN	+38.5% -120 bps	+39.0%(**) -70 bps	
NET RESULT	€/mlr	38.3	
	+16	.6%	
% OF REVENUES	+23.3%		
FCF	€/mln 27.8		
NFP	+€/mln 168.6		

<sup>\*</sup> Revenues includes the contribution of Siemens's ELISA business, consolidated as of September 2017

<sup>\*\* @</sup> constant exchange rates

### Q1'18 Revenues



		Q1'18 vs. Q1'17
	@ current	+4.4%
Revenues	@ CER	+11.2%

#### **Growth driven by**

- all CLIA tests, net of Vitamin D 25 OH, with particular evidence on:
- Infectious Diseases
- Hepatitis
- Torch
- Gastro-Intestinal Testing
- Vitamin D 1.25
- molecular tests, with a strong flu season
- positive contribution coming from Siemens's **ELISA business** acquired in September 2017

partially offsets by forex negative impact amounting to €/mln 10.7





			Q1'18 vs. Q1'17
	CLIA ex Vitamin D	@ current	+9.1%
CLIA	25 OH tests	@ CER	+13.8%
CL	Vitamin D	@ current	-11.5%
	25 OH test (CLIA)	@ CER	-2.6%
	ELISA tests <sup>(1)</sup>	@ current	+18.2%
		@ CER	+24.4%
	Molecular Diagnostic	@ current	+4.8%
	tests	@ CER	19.1%
	Instruments &	@ current	-1.6%
	Consumables	@ CER	+3.3%

 $<sup>^{\</sup>ast}$  Includes the contribution of Siemens's ELISA business, consolidated as of September 2017

### Q1'18 Revenues\*: breakdown by geography



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+16.4%
+23.5%
nal testing, Vitamin D 1,25
+10.4% Vitamin D 1,25 and PCT tests. pward trend in Vit D 25.
+15.0%
OH tests.
+5.0%
+4.3%

<sup>-</sup> Molecular tests also thanks to a strong flu season; \*Managerial outlook on data reported; Change Q1'18 on Q1'17 @ CER

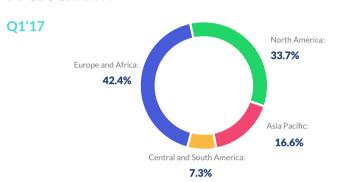
	Q1'18 vs. Q1'17				
ASIA PACIFIC	+15.8%				
China	+0.9%				
Growth in CLIA tests (+17.8%) dr and thyroid tests, partially offset and Murex sales (high Q1'17).	iven by Hepatitis, Prenatal diseases by lower Instruments				
Australia	+21.0%				
Upward trend in CLIA tests, mainly driven by Gastro-Intestinal testing, Vit. D 25 OH test and Siemens' ELISA business acquisition.					
Vit. D 25 OH test and Siemens' El	LISA business acquisition. +37.4% owth in CLIA tests, Siemens' ELISA				
Vit. D 25 OH test and Siemens' El  Distributors  Performance underpinned by gro	LISA business acquisition. +37.4% owth in CLIA tests, Siemens' ELISA				
Vit. D 25 OH test and Siemens' El  Distributors  Performance underpinned by grobusiness positive contribution an	+37.4%  owth in CLIA tests, Siemens' ELISA d instruments sales.				
Vit. D 25 OH test and Siemens' El  Distributors  Performance underpinned by grobusiness positive contribution an  LATIN AMERICA  Brazil	+37.4%  owth in CLIA tests, Siemens' ELISA d instruments sales.				
Vit. D 25 OH test and Siemens' El  Distributors  Performance underpinned by grobusiness positive contribution an  LATIN AMERICA  Brazil  Positive performance of CLIA test	+37.4%  with in CLIA tests, Siemens' ELISA d instruments sales.  -0.1%  +6.5%				

in instruments sales.

#### Q1'18 Revenues Breakdown

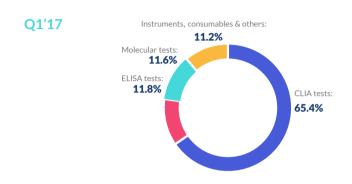


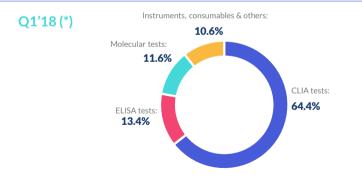






#### **BY TECHNOLOGY**

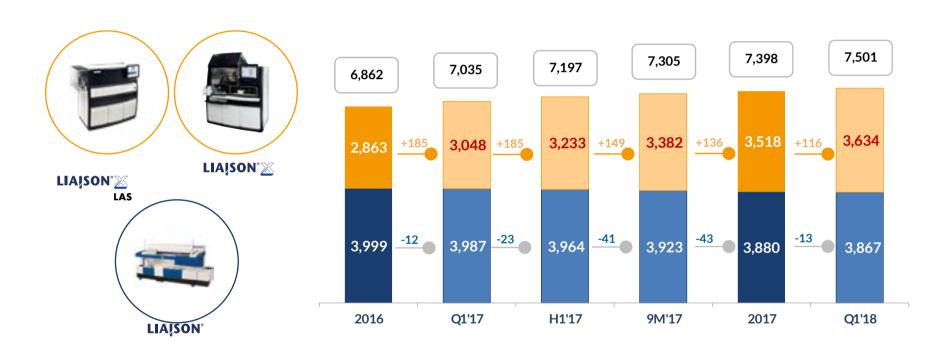




(\*) Revenues include Siemens' ELISA business acquired on Sept 29, 2017

### **Installed base expansion**





#### **Q1'18 EBITDA\***





#### Variance versus Q1'17 mainly driven by:

- higher sales as a consequence of:
  - growth of immunodiagnostic products, mainly driven by CLIA ex Vitamin D
  - growth in molecular sales also thanks to a strong flu season
  - Siemens ELISA business contribution

partially offset by a negative FOREX impact (-€/mln 5.0)

#### **EBITDA Margin:**

- strong margin in the quarter (39% @CER)
- comparison versus Q1'17 affected by some favorable OPEX phasing recorded in 2017

<sup>\*</sup>Financials as reported



## **Business Development**

### **Business and product development**



		PARTNERSHIPS	i	PORTFOLIO ACQUISITION	NEW PRODUCT CO-DEVELOPMENT	NEW PLATFORM	S DEVELOPMENT
	Roche	in China	in the US	SIEMENS	QIAGEN	LIAISON	●TECAN•
Rationale	Increase penetration in big labs	Increase penetration in big Iabs	Launch Hepatitis & Retroviruses panel	Market share: conversion from ELISA to CLIA	New market opportunities leveraging on QFT technology	Access to new mkt segment: POLs (US) Class I-II hospitals (China) Hub and Spoke (EU)	Extraction for European post transplantation strategy
Technology	Immuno (CLIA)	Immuno (CLIA)	Immuno (CLIA)	Immuno (ELISA)	Immuno (CLIA)	Immuno (CLIA)	Molecular (Extraction)
Impact on revenues							
2017							
2018							
2019							
Beyond 2019							



# FY 2018 Company Guidance

### **FY 2018 Company Guidance**





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#### **2017-2019** guidance



#### 2017-2019 STRATEGIC GOALS

- Solid growth of Immunoassay franchise with addition of innovative and differentiatingnew products
- 2 Launch of LIAISON XS allows penetration of the small labs/POLs segment
- 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
- 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 (Immunoassay and Molecular)
- Committed to targeted bolt on acquisitions to strengthen our product portfolioor allow access to new customers in consolidated markets

	<b>ACTUAL</b> DATA IN			ANCE N €/MLN
	2016	2017	2018	2019
				REVENUES
Revenues	569.3	637.5 +12.0% reported +13.1% @ CER	~ <b>+11%</b> @ CER 2017	3-years plan guidance confirmed
		2016		
		237.9 +9.5% reported +11.5% @ CER	~+13% @ CER 2017	EBITDA
EBITDA	217.3	2016  ADJUSTED EBITDA(*)		3-years plan guidance confirmed
		241.2 +11.0% reported +13.0% @ CER 2016		

(\*) Managerial outlook on reported data: net of positive contribution from acquisition of Siemens' ELISA business and non recurring costs related to closing of Irish facility



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## Annexes





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	Q1		Change	
Data in € million			Cila	
	2017	2018	amount	%
Net revenues	157.5	164.5	+7.0	+4.4%
Gross profit	107.9	111.2	+3.3	+3.0%
Gross Margin	68.5%	67.6%	-93 bps	
S&M	(29.8)	(31.7)	-1.9	+6.3%
R&D	(10.2)	(11.7)	-1.5	+14.7%
G&A	(16.0)	(15.1)	+0.9	-5.7%
Total operating expenses	(56.0)	(58.5)	-2.5	+4.4%
% on sales	(35.6)%	(35.5)%	+1 bps	
Other operating income (expense)	(2.0)	(2.0)	-0.0	+1.3%
EBIT	50.0	50.7	+0.8	+1.5%
EBIT margin	31.7%	30.9%	-89 bps	
Net financial income (expense)	(1.6)	(0.9)	+0.7	-42.6%
Profit before taxes	48.4	49.8	+1.4	+3.0%
Income taxes	(15.5)	(11.5)	+4.0	-26.0%
Net result	32.9	38.3	+5.5	+16.6%
EBITDA	62.5	63.3	+0.8	+1.3%
EBITDA margin	39.7%	38.5%	+120 bps	





Data in € million	12/31/2017	3/31/2018	Change
Goodwill and intangibles assets	347.1	344.6	-2.5
Property, plant and equipment	92.4	90.8	-1.6
Other non-current assets	23.8	24.5	+0.7
Net working capital	191.9	206.8	+14.9
Other non-current liabilities	(62.5)	(63.7)	-1.2
Net Invested Capital	592.7	603.0	+10.3
Net Financial Position	149.3	168.6	+19.3
Total Shareholders' equity	742.0	771.6	+29.7





D. J. O. 100	Q1		
Data in € million	2017	2018	Change
Cash and cash equivalents at the beginning of the period	130.5	159.3	+28.9
Operating activities	51.2	37.6	-13.6
Investing activities	(8.0)	(10.0)	-2.1
Financing activities	(0.8)	(3.5)	-2.7
Acquisitions of companies and business operations	(0.1)	(3.8)	-3.6
Net change in cash and cash equivalents before investments in financial assets	42.3	20.3	-22.0
Divestment/(Investments) in financial assets	0.0	(7.3)	-7.3
Net change in cash and cash equivalents	42.3	13.0	-29.3
Cash and cash equivalents at the end of the period	172.8	172.3	-0.4



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