
Leading the way in Integrated Diagnostics Solutions

Roland Diggelmann
CEO Roche Diagnostics

Chicago, 31 July 2018



HY 2018 Group results

Diagnostics

HY 2018 overview

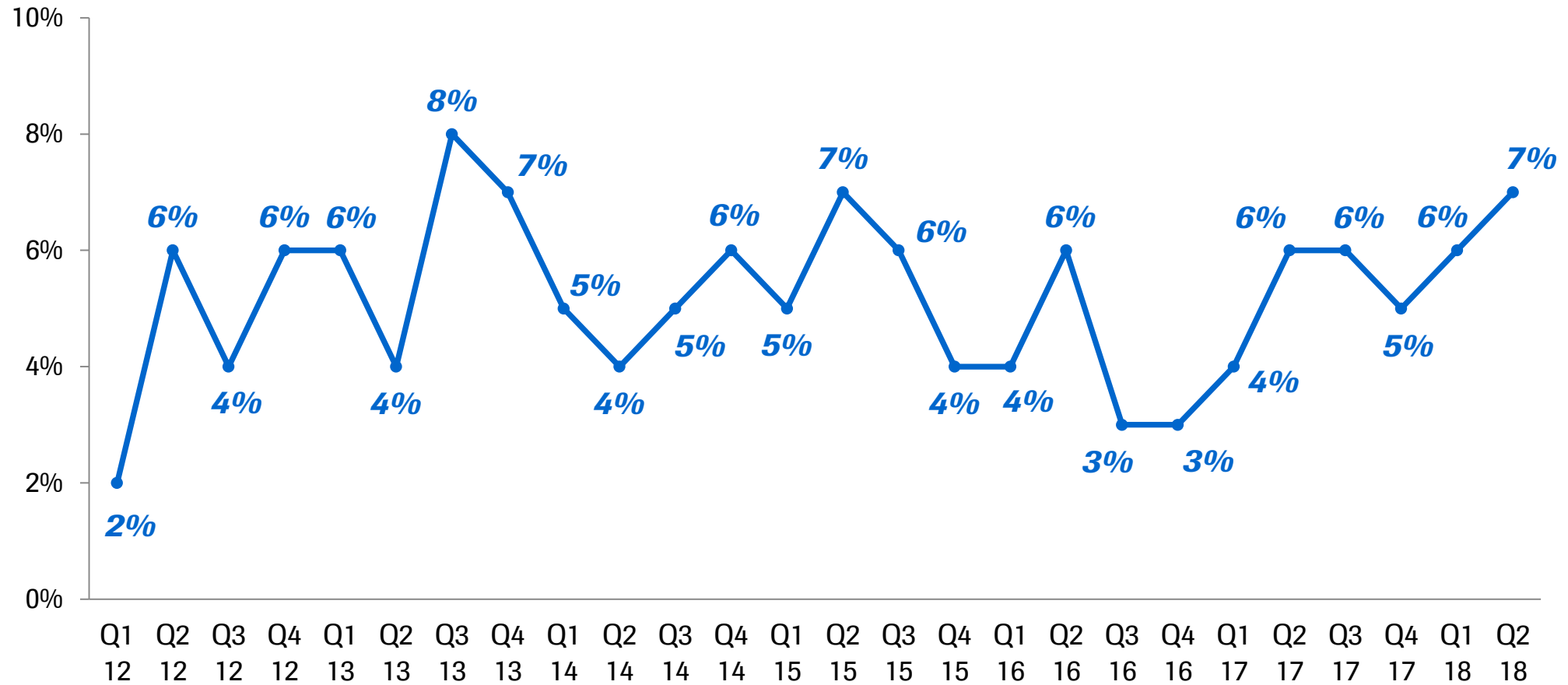
Newsflow & Innovation

Outlook

HY 2018: Very strong sales growth in both divisions

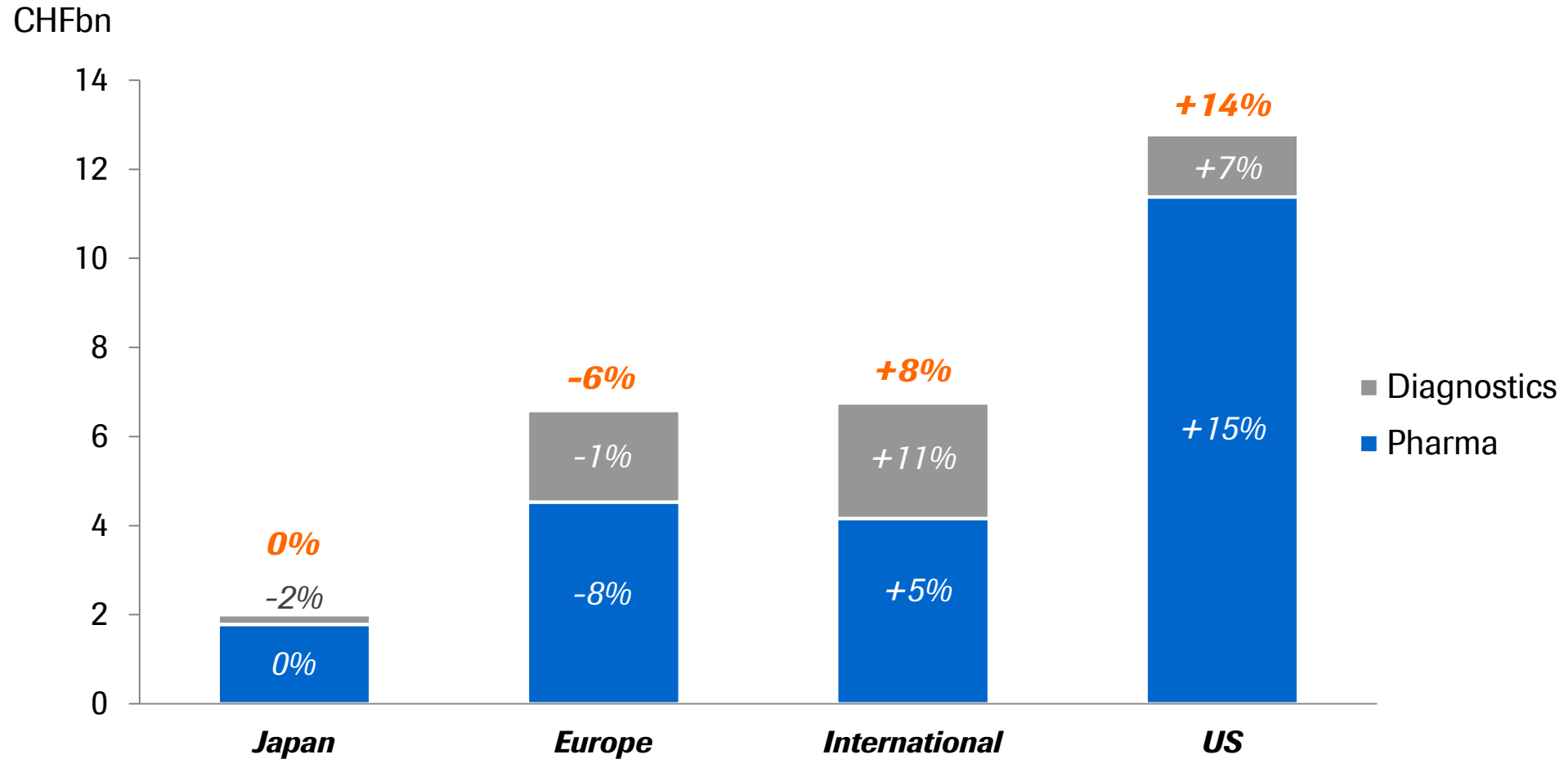
	HY 2018	HY 2017	Change in %	
	CHFbn	CHFbn	CHF	CER
Pharmaceuticals Division	21.8	20.5	6	7
Diagnostics Division	6.3	5.8	8	6
Roche Group	28.1	26.3	7	7

Q2 2018: Sales growth for the seventh consecutive year



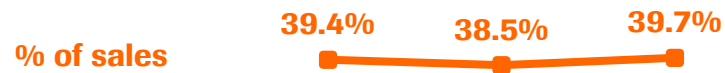
All growth rates at Constant Exchange Rates (CER)

HY 2018: Strong sales growth in US and International



HY 2018: Strong Core results, significant operating free cash flow

Operating profit

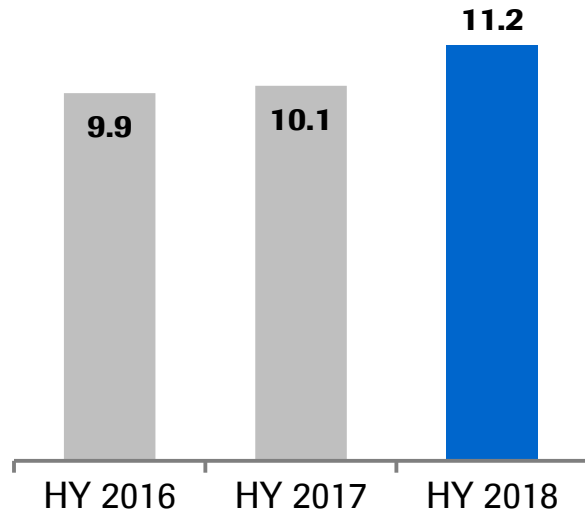


EPS

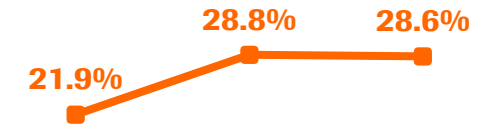
CHF

+10% at CER

CHFbn

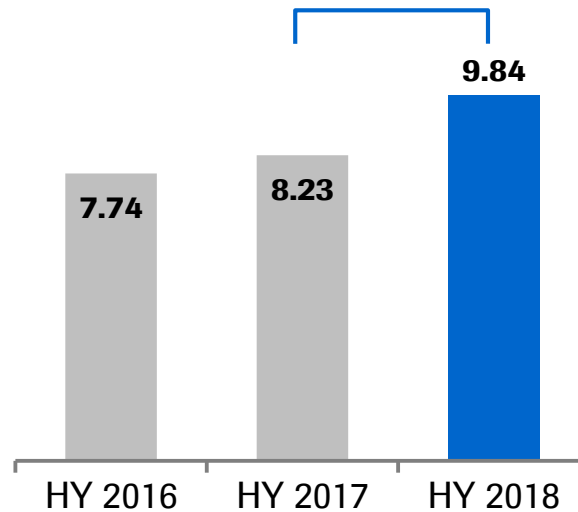


Operating free cash flow

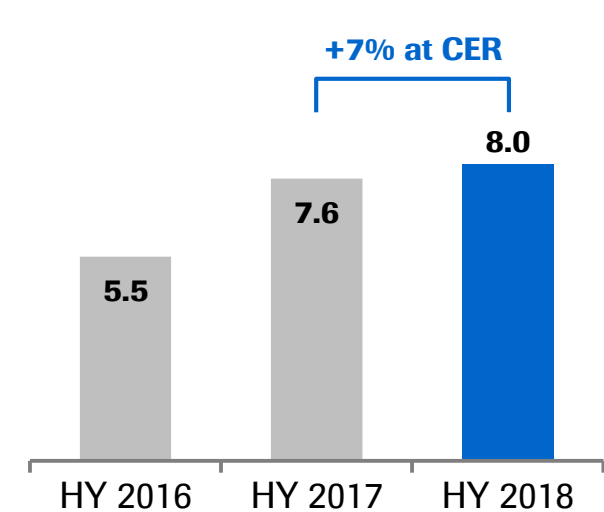


+19%¹ at CER

CHFbn



+7% at CER



CER=Constant Exchange Rates
¹+8% at CER excl. US tax reform

Roche significantly advancing patient care

BTD's and Priority reviews reflecting the quality of our research

22 Breakthrough Therapy Designations

Year	Molecule	Indication
2018	Tecentriq + Avastin	(HCC)
	Hemlibra	(Hemophilia A non-inhibitors)
	entrectinib	(ROS1+ NTRK+ solid tumors)
	balovaptan	(Autism spectrum disorders)
2017	polatuzumab vedotin + BR	(R/R DLBCL)
	Venclexta + LDAC	(1L unfit AML)
	Zelboraf	(BRAF-mutated ECD)
	Rituxan	(Pemphigus vulgaris)
2016	Actemra	(Giant cell arteritis)
	Alecensa	(1L ALK+ NSCLC)
	Ocrevus	(PPMS)
	Venclexta + HMA	(1L unfit AML)
	Venclexta + Rituxan	(R/R CLL)
2015	Actemra	(Systemic sclerosis)
	Tecentriq	(NSCLC)
	Venclexta	(R/R CLL 17p del)
	Hemlibra	(Hemophilia A inhibitors)
2014	Esbriet	(IPF)
	Lucentis	(Diabetic retinopathy)
	Tecentriq	(Bladder)
2013	Alecensa	(2L ALK+ NSCLC)
	Gazyva	(1L CLL)

5 Current priority reviews granted

Year	Molecule	Indication
HY 2018	MabThera	(Pemphigus vulgaris)
	Hemlibra	(Hemophilia A non-inhibitors)
	baloxavir marboxil	(Influenza)
	Tecentriq + Avastin	(1L NSCLC)
	Xolair	(Pre filled syringe)

1 Breakthrough Device Designation

Year	Device	Indication
2018	Elecsys® β-Amyloid (1-42) Elecsys® Phospho-Tau (181P) Cerebro Spinal Fluid assays	(Alzheimer's disease)

Replace and extend the business

Through continuously improving standard of care

Replace existing businesses

MabThera/Rituxan	Gazyva, Venclexta, polatuzumab vedotin, Subcutaneous
Herceptin	Perjeta, Kadcyla, Subcutaneous
Avastin	Tecentriq, entrectinib
Lucentis	VA2, Port Delivery System
Tamiflu	baloxavir marboxil

Entering new franchises

MS: Ocrevus
Hemophilia: Hemlibra
CNS: SMA, Autism, Huntington's, Alzheimer's

Achievements HY 2018

Ocrevus:	EU approval (RMS, PPMS)
Gazyva:	CLL11 (iNHL): OS vs Rituxan met
Hemlibra:	US/EU/Japan launch (inhibitor patients) HAVEN 3 (non-inhibitors) & 4 (Q4W) at WFH
Tecentriq:	IMpower150 (1L NSCLC): OS met IMpower130 (1L NSCLC): OS & PFS met IMpower131 (1L NSCLC): PFS met IMpower132 (1L NSCLC): PFS met IMpower133 (1L ES-SCLC): OS & PFS met IMmotion151 (1L mRCC): PFS met IMpassion130 (1L TNBC): PFS met; OS benefit
Perjeta:	EU approval eBC (APHINITY)
Venclexta:	US approval in R/R CLL, 1L AML early filing
baloxavir marboxil:	US filing, Ph III CAPSTONE2 positive
VA2:	Strong Ph II (BOULEVARD) data in DME
Port delivery:	Strong Ph II (LADDER) in wAMD

2018 outlook further raised

Sales growth to ‘mid single digit’ from ‘low single digit’ & EPS growth to ‘mid teens’ from ‘high single digit’

Group sales growth¹

- Mid single digit (from low single digit)

Core EPS growth¹

- Broadly in line with sales, excl. US tax reform benefit
- Mid teens incl. US tax reform (from high single digit)

Dividend outlook

- Further increase dividend in Swiss francs

¹ At Constant Exchange Rates (CER)

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Outlook

HY 2018: Diagnostics Division sales

Strong growth driven by Centralised and Point of Care Solutions

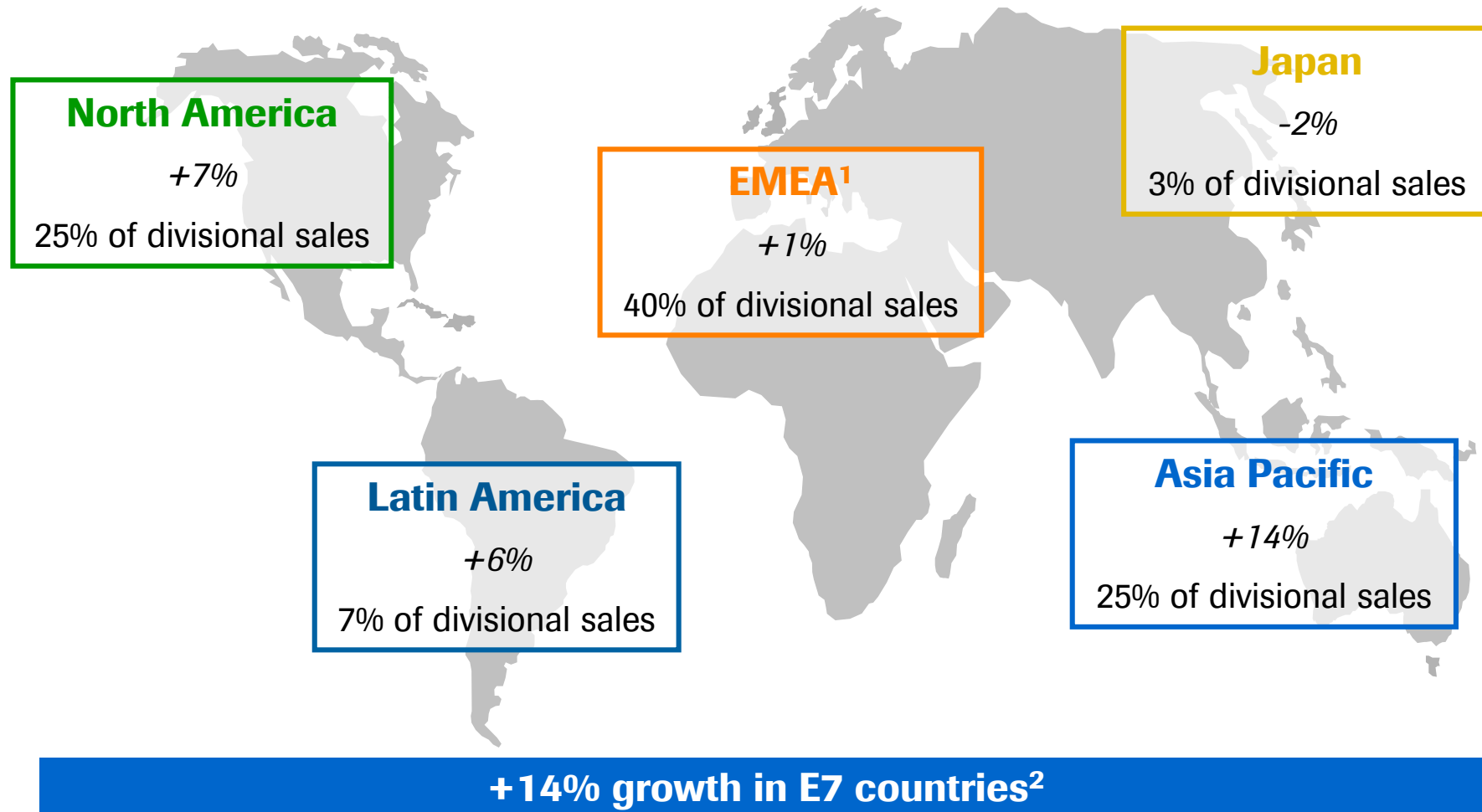
	HY 2018 CHFm	HY 2017 CHFm	Change in %	
			CHF	CER
Diagnostics Division	6,264	5,823	8	6
Centralised and Point of Care Solutions	3,755	3,456	9	6
Diabetes Care	991	962	3	1
Molecular Diagnostics	979	920	6	5
Tissue Diagnostics	539	485	11	11

CER=Constant Exchange Rates

Underlying growth of Molecular Diagnostics excluding sequencing business: +6%

HY 2018: Diagnostics regional sales

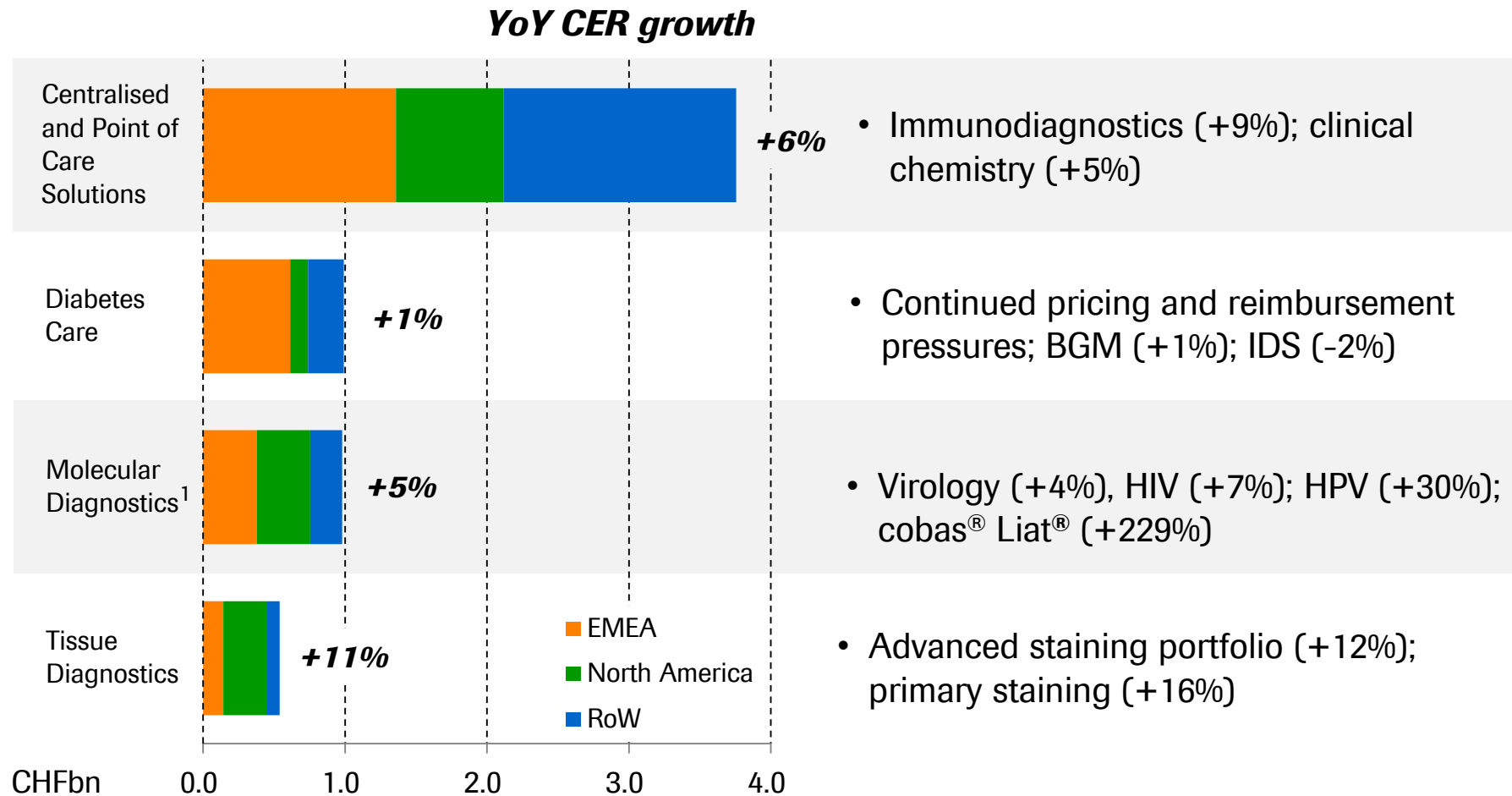
Growth driven by Asia Pacific and North America



¹ Europe, Middle East and Africa; ² Brazil, China, India, Mexico, Russia, South Korea, Turkey
 All growth rates at Constant Exchange Rates

HY 2018: Diagnostics Division highlights

Strong growth driven by Centralised and Point of Care Solutions

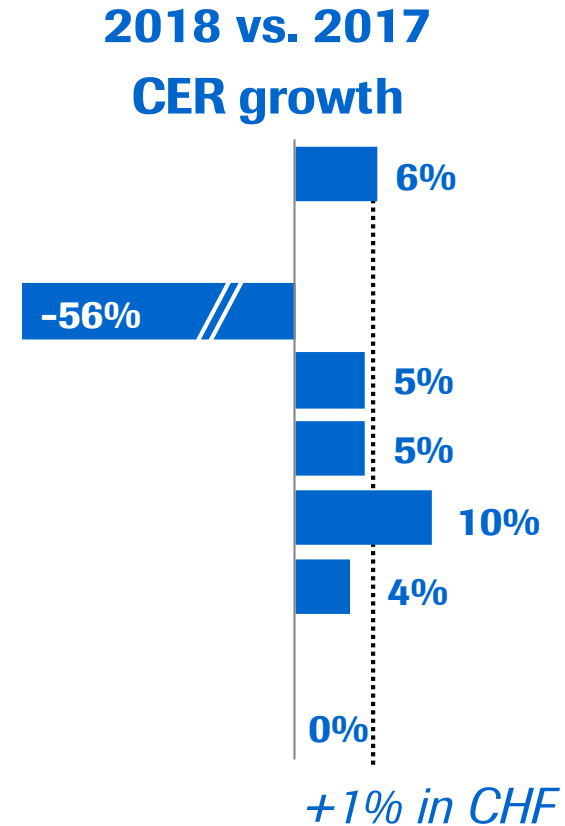


¹ Underlying growth of Molecular Diagnostics excluding sequencing business: +6%
 CER=Constant Exchange Rates; EMEA=Europe, Middle East and Africa

HY 2018: Diagnostics Division

Core operating profit stable despite lower royalty income in HY1 2018

	HY 2018	
	CHFm	% sales
Sales	6,264	100.0
Royalties & other op. inc.	39	0.6
Cost of sales	-2,846	-45.5
M & D	-1,429	-22.8
R & D	-715	-11.4
G & A	-239	-3.8
Core operating profit	1,074	17.1



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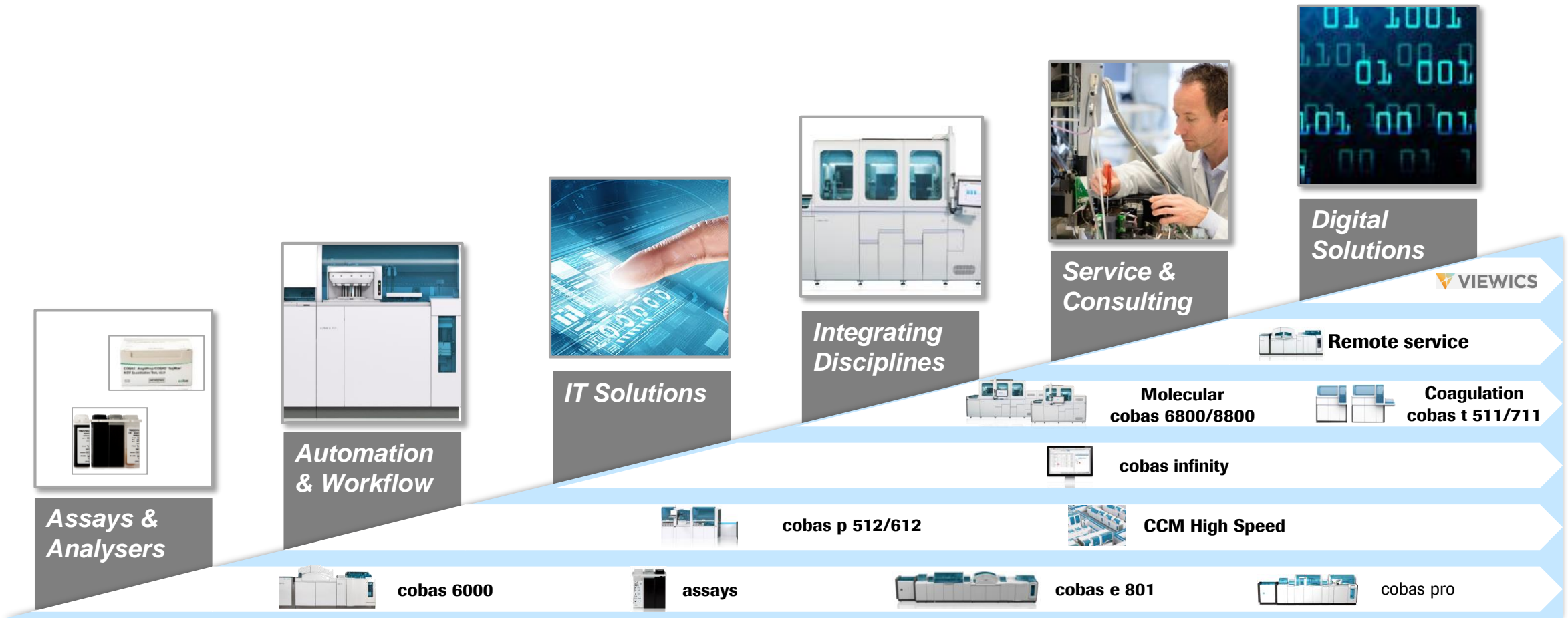
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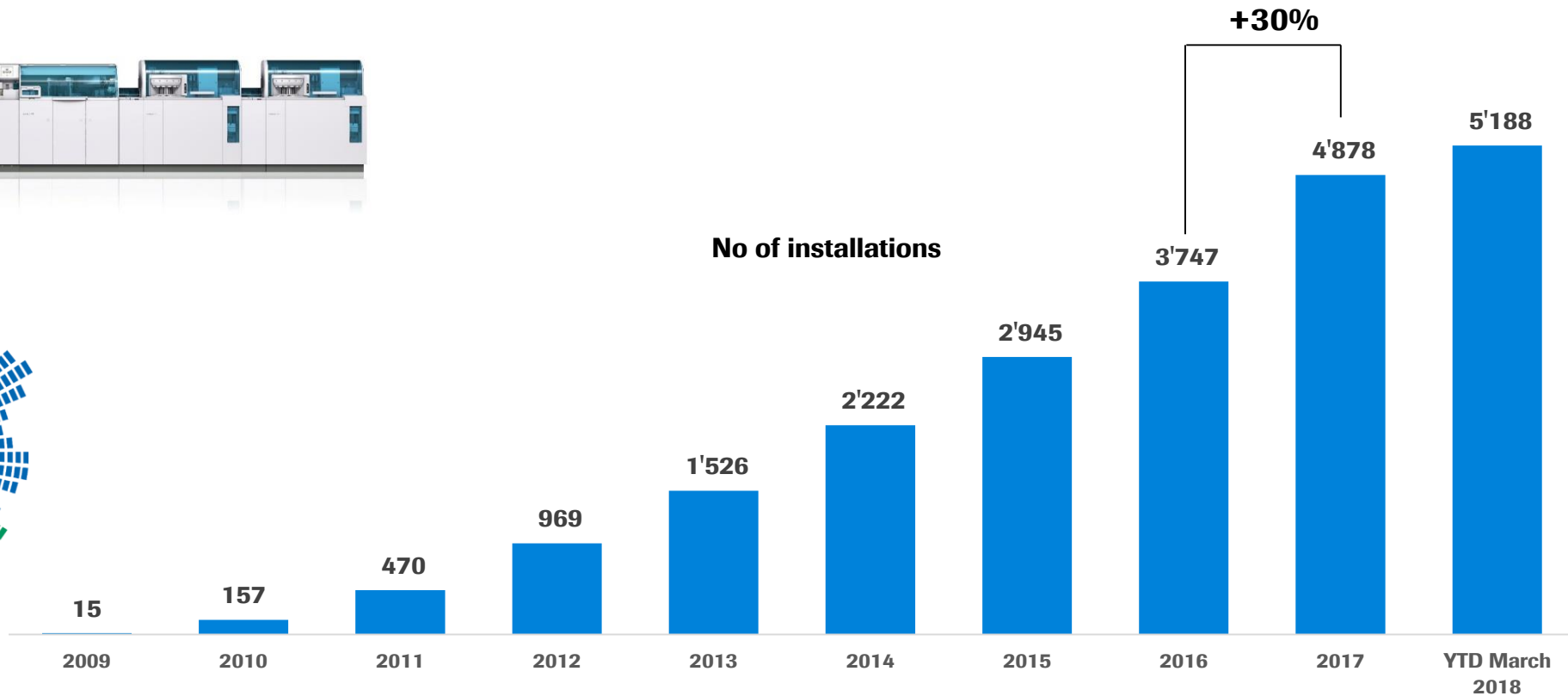
Integrated Core Lab

Expansion with integrated solutions and entering new disciplines



5,000 installations of cobas® 8000 modular analyzer series

Performing 15m tests/day



Preparing the launch of cobas® pro integrated solutions¹

Next generation medium throughput SWA solution



- Seamless integration into the Roche Integrated Core Lab
- Targeting medium to high throughput laboratories
- New clinical chemistry module cobas c 503 in combination with immunochemistry module cobas e 801
- Focus on simplification of laboratory routine while delivering excellent quality

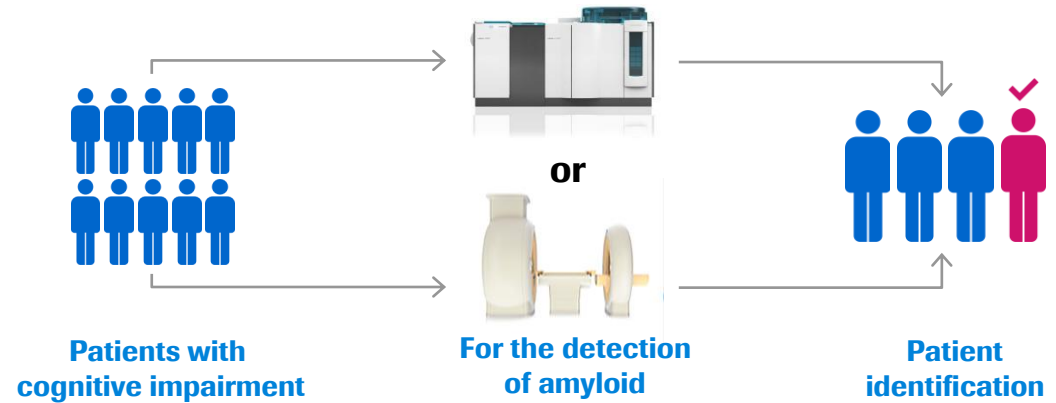
¹ cobas® pro integrated solutions is launching in CE mark countries in Q3

Alzheimer's Disease IVD tests¹ receive Breakthrough Device Designation from the FDA

PET Concordance Claim:

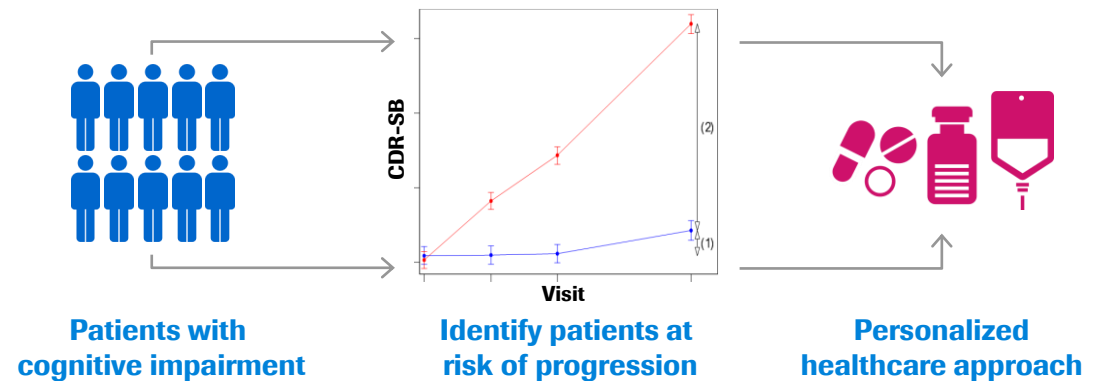
Elecsys® pTau/Abeta42 ratio is a reliable alternative to amyloid PET scan for amyloid detection with benefits of:

- **broader testing availability** via lab
- significant **cost benefit**



Progression Claim:

Identify patients at higher risk of progression of cognitive decline²



¹ Elecsys® β-Amyloid(1-42) (Abeta42) and Elecsys® Phospho-Tau (181P) (pTau) CSF (CSF=Cerebrospinal Fluid) assays; ² defined by change in clinical score within a 2 year period
 PET= Positron Emission Tomography, CDR-SB= clinical dementia ratio – sum of boxes

cobas[®] 6800/8800 systems driving growth in molecular

Main menu completion in 2018

Blood Screening		Infectious Diseases		Women's Health	
MPX	✓	HIV-1	✓	HPV (CE-IVD, US-IVD in 2019)	✓
WNV	✓	HBV, HCV	✓	CT/NG	✓
DPX	✓	CMV	✓	TV/MG (CE-IVD, US-IVD in 2019)	✓
HEV (Not available in the US)	✓	HIV-1/2 Qual (CE-IVD, US-IVD in 2019)	✓		
CHIKV/DENV (Not available in the US)	✓	MTB	Launch 2018		
Zika (US-IVD)	✓	MAI	Launch 2018		
Babesia (US-IND)	✓	RIF/INH	Launch 2019		
Babesia (US-IVD)	Launch 2019	EBV	Launch 2019		
		BKV	Launch 2019		



Installed instrument base: ~500

Launch of cobas® Plasma Separation Card

For testing and monitoring of HIV patients in resource limited settings



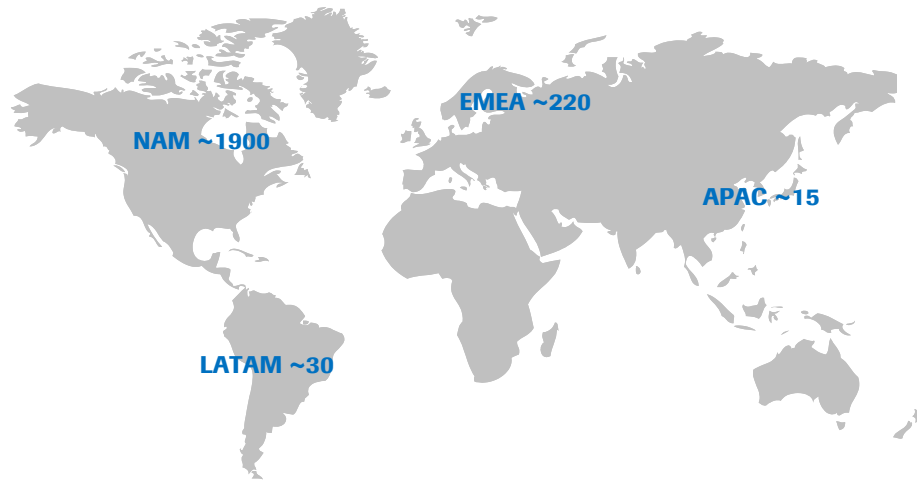
Global Access Program
take aim
at HIV

- No refrigeration needed for patient plasma samples during transport to the lab
- Only card that meets the WHO sensitivity requirement for determining HIV treatment
- Compatible with HIV-1 viral load testing on the cobas® 6800/8800 and cobas® AmpliPrep/TaqMan systems

Strong Flu season driving cobas[®] Liat[®] System sales

Pediatric and emergency room focus segments

Growing number of placements worldwide



**cobas[®] Liat[®]
Analyzer**



**cobas[®] Liat[®]
assay tube**

- Easy to use with less than one minute hands on time
- Lab quality performance in 20 minutes or less

Suitable for testing in a variety of settings



Menu of assays available

	CE	US
cobas[®] Influenza A/B	✓	✓
cobas[®] Strep A	✓	✓
cobas[®] Influenza A/B & RSV	✓	✓
cobas[®] Cdiff	✓	

Launch of Ventana DP 200¹ slide scanner for digital pathology

Provides a foundation in offering a comprehensive, high quality digital pathology portfolio

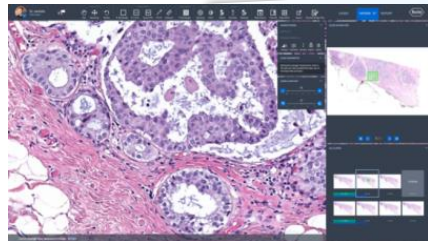
VENTANA DP 200
slide scanner



Launch¹ in Q1 2018

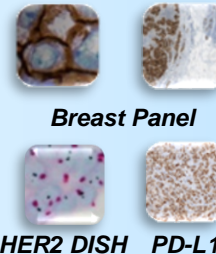


uPATH
Workflow Software

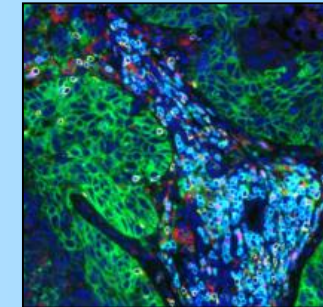


Launch² planned Q4 2018

Enabler of **high**
medical value assays



Deliver a fully **digitised**
pathology lab



Provides a foundation for a future menu of
Roche **image analysis algorithms**³

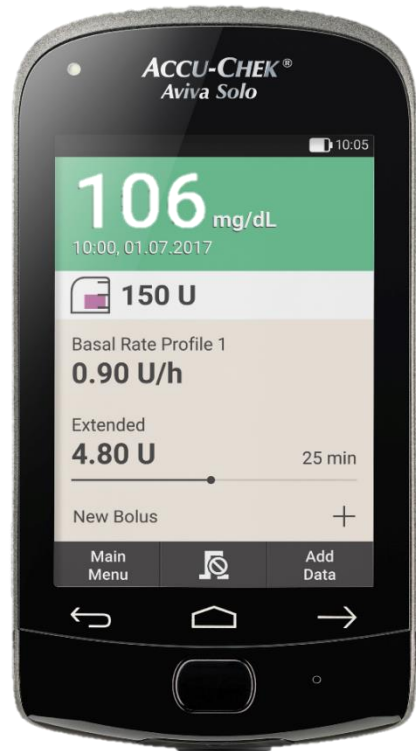
Image Analysis
Algorithms³

Multiplex Algorithms³

1) CE marked for IVD use; approved in the US for research use only
2) Currently in development, launch planned with CE mark and US
3) Currently in development

Accu-Chek® Solo micropump received CE mark

Taking discreet and tube-free insulin pump therapy to the next level



Features and Benefits

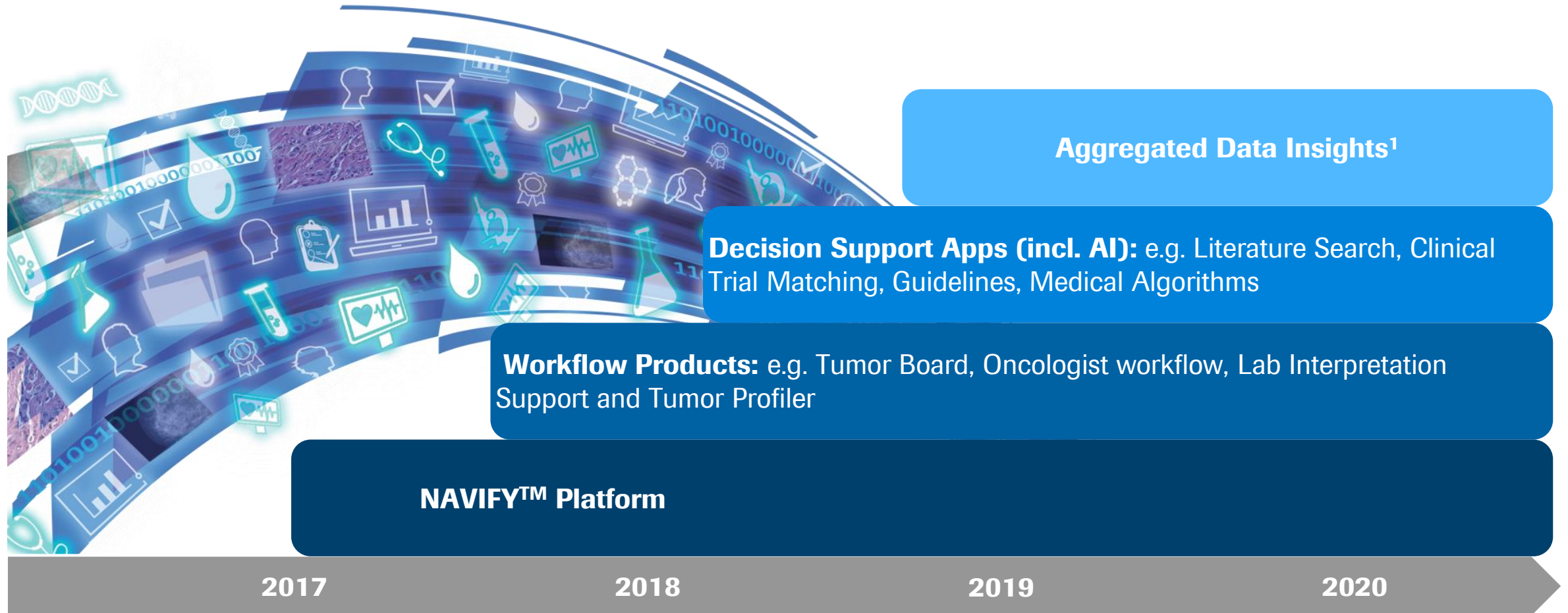
- Modular design to detach and re-attach the pump
- Bolus buttons on the micropump for flexible bolus insulin delivery
- Handheld includes blood glucose monitoring and proven bolus advisor
- Quick access to key data via status screen on colored touch display
- Connecting to digital solutions as e.g. Accu-Chek Smart Pix

Market

- Insulin pump market worldwide growing at +3% (FY 2017)
- Patch pump segment showing strong growth with +29% (FY 2017)

Growing a portfolio of decision support solutions

NAVIFY Portfolio and Platform



¹ Aggregated data sets and Insights as a Service. Feedback loop to Decision Support Apps.

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Key launches 2018



	Area	Product	Market
Instruments/ Devices	Central Laboratory	cobas pro integrated solution – Serum Work Area solution for medium throughput to lower high throughput labs	CE
	Specialty Testing	cobas m 511 – World's first fully digital morphology analyzer and cell counter	US ✓
	Workflow	CCM connectivity to cobas c513 – Connection of cobas c 513 to CCM Automation System for high volume HbA1c testing	WW
	Tissue Dx	BenchMark ULTRA Plus – New and differentiated Advanced Staining System	CE
	Digital Pathology	VENTANA DP200 – Reliable low-volume scanner with superior image quality	CE ✓
	Diabetes Care	Accu-Chek Solo micropump – Small and tubeless insulin delivery device operated through a remote control which includes a blood glucose meter	CE ✓
Tests/ Assays	Endocrinology	IGFBP3 – Completion of the existing growth hormone menu of hGH and IGF-1	CE
	Infectious Diseases	Zika IgG – Highly specific immunoassay for the in vitro qualitative detection of IgG antibodies to Zika virus in human serum and plasma	CE ✓
	Microbiology	cobas CT/NG – Highest throughput CT/NG test on the market with workflow efficiency benefits	US ✓
		cobas 6800/8800 MTB/MAI – High volume solution for MTB/MAI testing; efficient approach to disease management (mixed testing) for infectious disease	CE
	Virology	Plasma Separation Card – Card-like sample collection device; separates plasma from whole blood; for use with CAP/CTM HIV-1 & cobas HIV-1 (6800/8800)	CE ✓
Sequencing	AVENIO FFPET RUO oncology kits – 3 separate tissue based assay kits for solid tumors	WW	
Software	Decision Support	NAVIFY Tumor Board v 1.x – EMR integration	WW ✓

Outlook

Investing into future growth

- Continued strong growth in serum work area
 - Focus on implementation of next generation platforms, e.g. cobas pro
 - Continued investment into development of new technologies (e.g. sequencing, mass spectrometry)
 - Investing into data driven decision support solutions
 - Strengthen leading presence in emerging markets
-

Doing now what patients need next