

# Roche Diagnostics Innovating to improve healthcare

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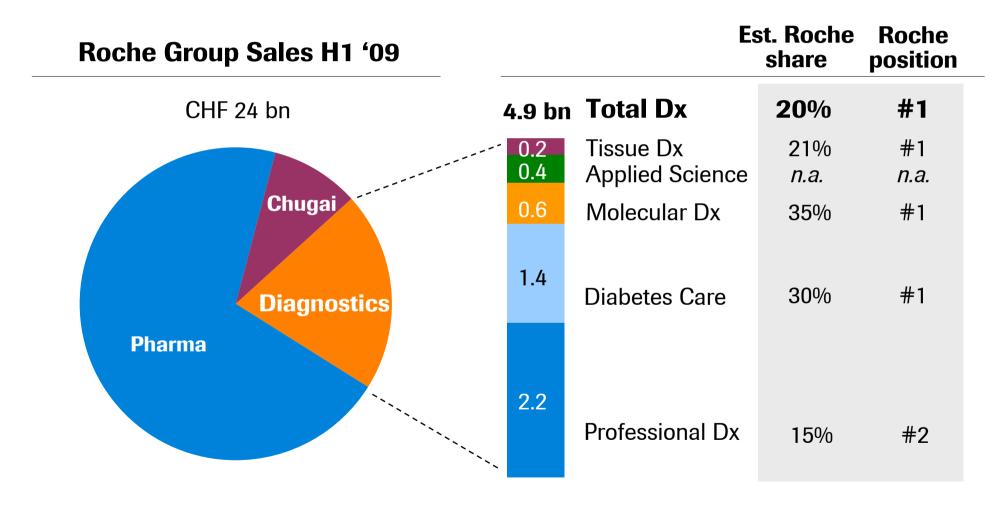
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- 2 legislative and regulatory developments and economic conditions;
- 3 delay or inability in obtaining regulatory approvals or bringing products to market;
- 4 fluctuations in currency exchange rates and general financial market conditions;
- 5 uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
- 6 increased government pricing pressures;
- 7 interruptions in production
- 8 loss of or inability to obtain adequate protection for intellectual property rights;
- 9 litigation;
- 10 loss of key executives or other employees; and
- 11 adverse publicity and news coverage.

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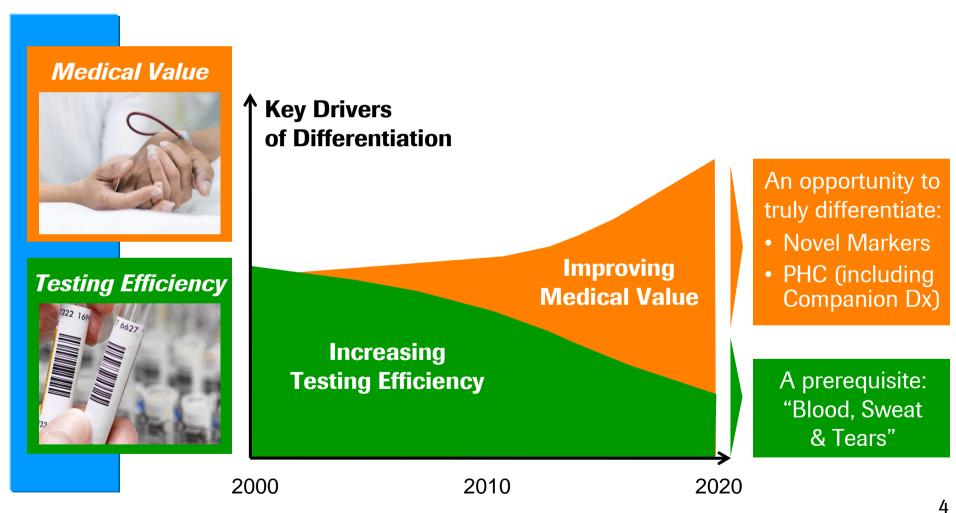
# Diagnostics Division: 20% of Roche Group Sales Leading IVD company with 20% market share





## **Roche Diagnostics Strategy**

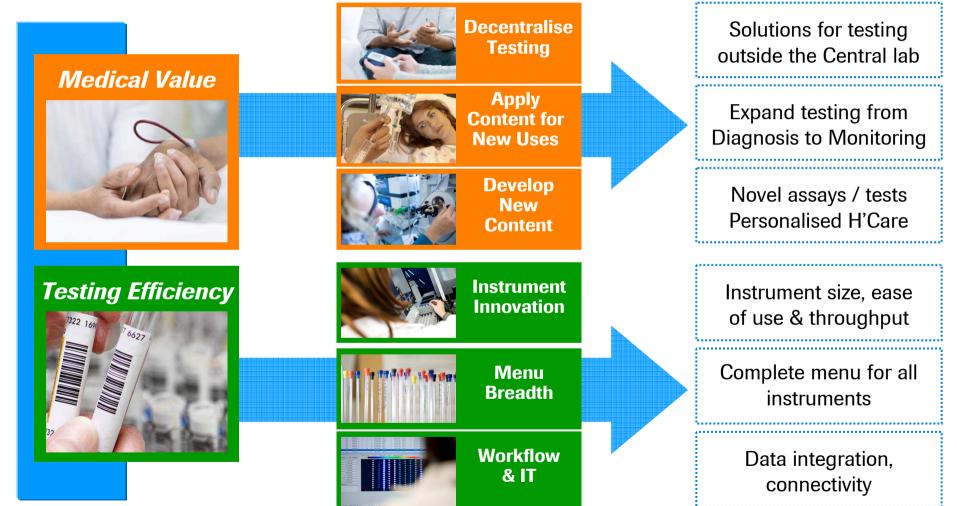
Accessing novel content is a key driver of differentiation





### **Innovating to improve Healthcare**

## In testing efficiency and in adding medical value





# Testing Efficiency – solutions across all business areas

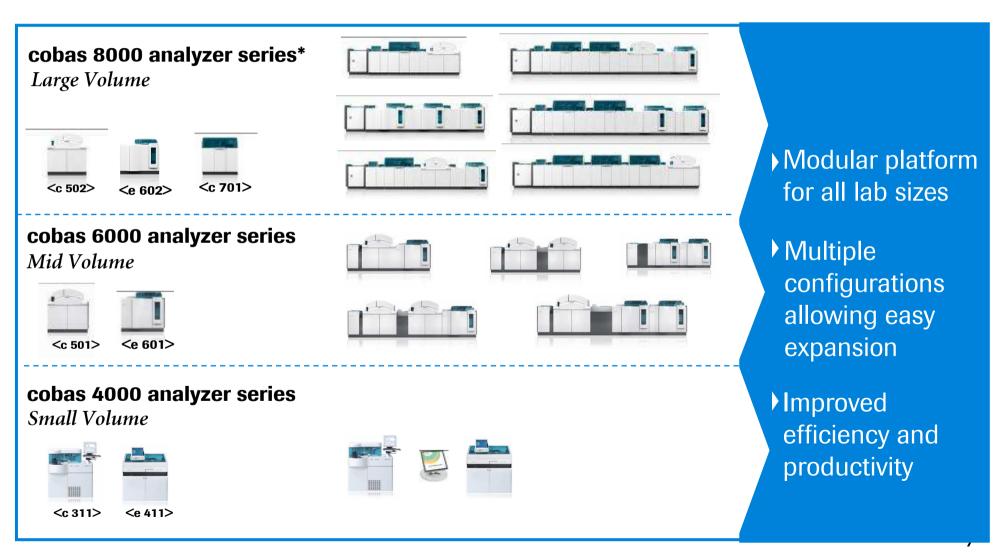
# Projects and initiatives to increase testing efficiency

	Applied Science	Molecular Dx	Tissue Dx	Professional Dx
Instrument Innovation	<ul><li>Sequencing</li><li>Array systems</li><li>LC 1536 for high-throughput PCR</li><li>ACEA x-Celligence</li></ul>	• New Gen	<ul><li>Benchmark Ultra (IHC/ISH)</li><li>Symphony (H&amp;E)</li><li>NexGen</li></ul>	<ul> <li>cobas e801 (double channels &amp; throughput)</li> <li>cobas b123 (blood gas analysis)</li> </ul>
Menu Breadth	<ul><li>"PCR on demand"</li><li>Biomarker / Pathway</li></ul>	<ul> <li>Virology: CMV, EBV</li> <li>Microbiology: MRSA, C difficile, VRE</li> </ul>	<ul> <li>Continuous         expansion of         antibody and         molecular menu</li> </ul>	<ul><li>Infectious Disease Menu Completion</li><li>Cardiac Menu Expansion</li></ul>
Workflow & IT	Bioinformatic support for sequencing	<ul><li> Modular software cobas 4800</li><li> CAP/ CTM 2nd Gen</li></ul>	<ul> <li>Vantage (Lab Workflow management solution)</li> </ul>	<ul> <li>Data manager c8000 (integrated IT middleware)</li> <li>Automated Storage &amp; Retrieval Module</li> </ul>



## **Testing Efficiency - cobas modular platforms**

Strengthening our portfolio to address all laboratory segments



<sup>\*</sup> Launch in first markets planned H2 '09



# Testing Efficiency – breadth immunoassay menu Broadest menu on a single platform

#### **Endocrinology**

Thyroid
TSH, FT4, FT3, T4, T3, TUptake, anti-TPO, anti-TG,
TG, anti-TSH receptor

#### **Fertility**

LH, FSH, Prolactin, Estradiol, Testosterone, Progesterone, SHBG, HCG, HCG+beta, DHEA-S

# Other Hormones C-Peptide, Insulin, Cortisol ACTH, hGH

#### **Sepsis**

IL 6, Procalcitonin

#### **Others**

IgE, S-100

#### **Anemia**

Ferritin, B12, Folate (+ RBC)

#### **Oncology**

PSA (total), PSA (free), AFP, CEA, Cyfra, NSE, CA 15-3, CA 19-9, CA 125-5, CA 72-4

#### **Cardiac**

CK-MB, Myoglobin, Digoxin, Digitoxin, Trop-T, NT-proBNP, hs Trop-T, Trop-I

#### **Rheumatoid Arthritis**

Anti CCP

#### **Bone**

PTH, N-MID Osteocalcin, ß-CrossLaps; P1NP, Vit. D

#### Retrovirology

HIV Ag HIV antigen Conf. HIV combi

#### **Hepatitis**

Anti-HAV, HAV-IgM, HBsAg, anti-HBs, anti-HBc, anti-HBc-IgM, HBeAg, anti-HBe, anti-HCV

#### **TORCH**

Toxo IgG/M Rubella IgG/M CMV IgG/M

#### Preg. Survellance

Free ß hCG, PAPP-A PIGF/ SFlt1









# **Medical Value – innovative new products** *Projects and initiatives to improve medical value*

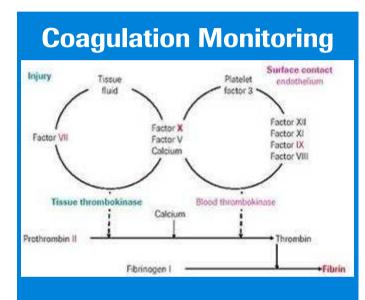
	Applied Science	Molecular Dx	Tissue Dx	Professional Dx
Decentralise Testing			Bright field In-Situ- Hybridization (SISH)	<ul> <li>"Newcard" (cardiology with lab performance)</li> <li>TGCa (entry into ICU that changes processes of care)</li> </ul>
Apply content For new Uses	Septifast method for mold testing (Asthma)	<ul> <li>CYP P450 (tamoxifen)</li> <li>HCV for Pegasys short-course therapy selection</li> </ul>	Her 2 for gastric cancer	<ul> <li>NT-proBNP (monitoring claim)</li> <li>P1NP (bone marker)</li> <li>Oncology (prostate cancer)</li> </ul>
Develop New Content	<ul> <li>Sequencing for DX (Oncology, Cardiac, CF, HLA, HIV, Blood grouping)</li> <li>Arrays for CGH</li> </ul>	<ul> <li>HPV</li> <li>SeptiFast (sepsis)</li> <li>Oncology: p53, EGFR, KRAS, B-RAF V600E</li> </ul>	<ul><li>EGFR, TOP 2A, cMET</li><li>TMPRSS/ Q-Dots</li></ul>	<ul> <li>PLGF/SFLT (pregnancy, cancer, cardiac)</li> <li>CRC Screen (colorectal cancer detection with serum panel test, e.g. on IMPACT)</li> </ul>



**Patient** 

### Medical Value - decentralise testing

# Time-critical testing closer to the patient



- Warfarin treatment for many serious diseases
- Dosing needs tight control
- Over- or underdosing can have serious consequences



Care

**Hospital** 

Patients who self-test achieve **superior** anticoagulation control compared to those receiving routine medical care



# Medical Value – finding and validating biomarkers Significant hurdles in discovery and development

#### **Research assay**

Generation of biomarker hypothesis

Identification of candidate markers

Develop prototype assay

# Technically validated assay

Clinical validation of candidate markers

Assay refinement & development IVD test

Regulatory test approval

# Clinically validated IVD assay

Distribution to laboratories

Auditing for result consistency

Clinician/ Lab education



### **Medical Value – Roche Personalised Healthcare**

# Leveraging Pharma & Diagnostics from discovery to commercialisation

Research	Development	Commercialisation	
Research assay	Technically validated assay	Clinically validated IVD assay	
Generation of biomarker sypothesis	Clinical validation of candidate markers	Distribution to laboratories	
dentification of candidate narkers	Assay refinement & development IVD test	Auditing for result consistency	
Develop prototype assay	Regulatory test approval	Clinician/ Lab educatio	
Jnrestricted exchange of knowhow and IP	Seamless platform transition	Faster adoption of new assays	

of new assays



### **Medical Value – Roche Personalised Healthcare**

# A comprehensive portfolio of novel companion tests

			3 programs in CNS
			7 programs in metabolism
		P53 gene mutation	3 programs in RA/inflam.
		MDM2 various markers	16 programs in oncology
		EGFR gene copy number	3 programs in virology
		EGFR protein expression (IHC)	
	CYP450	BRAF gene mutation	
	anti-CCP antibodies	IGF-1R various markers	
	Rheumatoid Factor	HER2/HER3 RNA expression	
	KRAS mutation		
Bone markers (e.g. tP1NP)	EGFR mutation		
HER2 gene copy number (SISH)	Quantitative HBV sAG		Disease Biology areas:
HER2 protein expression (IHC)			CNS
HPV HR detection/typing			Metabolism/CV
HCV viral load/genotyping			RA/Inflammation Oncology
HBV viral load			Virology
CMV viral load			
HIV viral load			
On Hand	Late Stage Clinical Validation	Early Stage Clinical Validation	Exploratory Stage

Selection of key tests on the market and in clinical validation



# Our strategy going forward Changing the practice of medicine



Where we focus

- Focus on Rx and Dx
- Fit the treatment to the patients



How we succeed

- Excel in science
- Use diversity of approaches
- Maintain long-term view
- Leverage global reach and scale



Why we succeed

- World class talent
- Unparalleled breadth/depth of knowledge
- Unique position (seamless Rx-Dx)



# We Innovate Healthcare