

Diagnostics:

Growth through innovation and Personalised Healthcare

Daniel O'Day, COO Roche Diagnostics

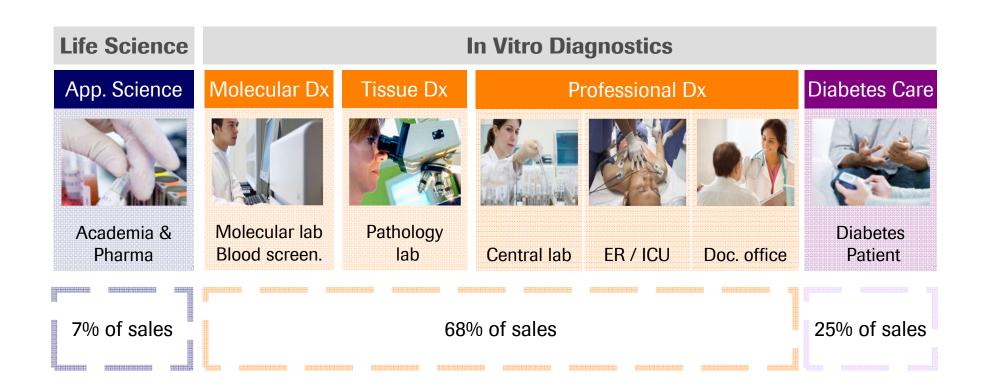
The future of medicine is personalised

Roche Investor Day 2012





### Roche Diagnostics portfolio overview Industry leading businesses covering the entire IVD spectrum





### **IVD** market

Our business model and strategy

**Personalised Healthcare** 



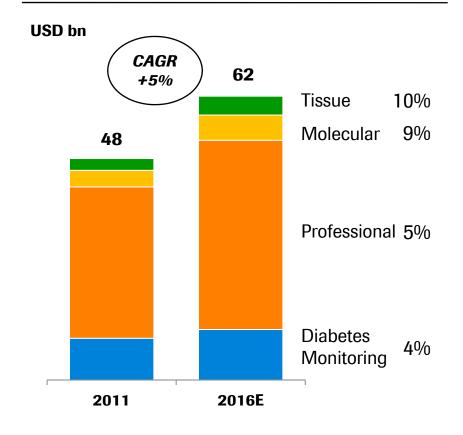


### IVD market overview Large and growing market; Roche is market leader

#### **Market share**

# Others 38% 12% Abbott 10% Siemens Danaher J&J

#### **Market size**

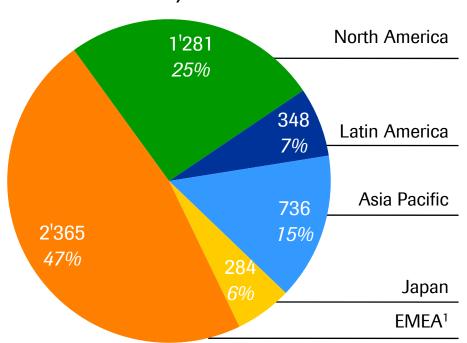




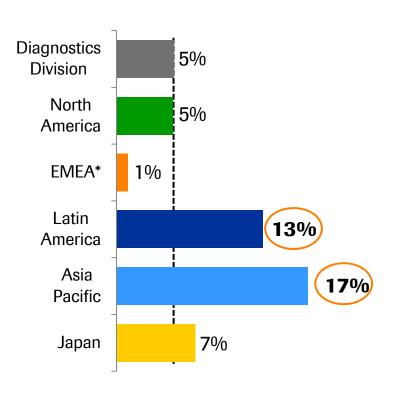
### Growth in all regions Strong double digit growth in emerging markets

#### **Roche Diagnostics HY 2012 sales**

#### CHF 5,014 m



#### **CER** sales growth



<sup>5</sup> 



### **IVD** market

### **Our business model and strategy**

**Personalised Healthcare** 





### Our business model Growing via differentiated business model and strong global presence

### Reagent pull-through model

Large worldwide installed base



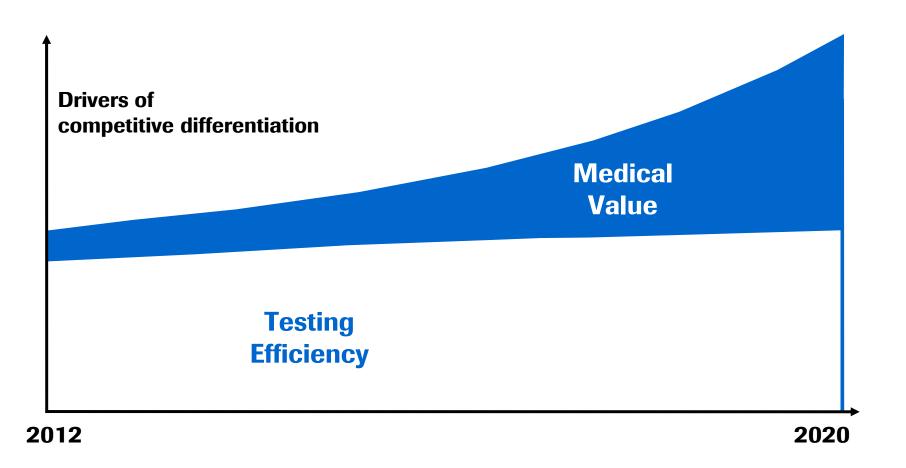






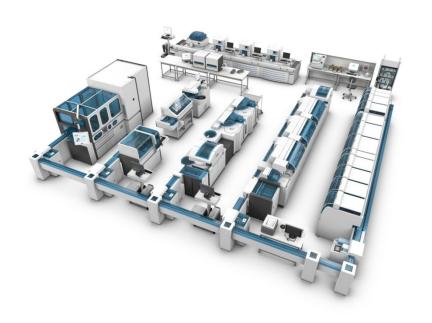


# Our strategy Differentiation through innovation in testing efficiency and medical value





### Testing efficiency Increasing productivity in labs



### **Testing efficiency value for customers**

- Saving costs via automation
- Fast turnaround times due to high throughput
- Efficient workflow from sample preparation to test results
- Modular and scalable solutions with flexibility for growth



### **Testing efficiency Examples of recent and upcoming innovations**

#### **Recent launches**

#### Ventana iScan HT



- Fully digitise pathology workflow
- High throughput and superior reliability
- Improve lab efficiency and productivity

### In development

#### cobas® 6800/8800

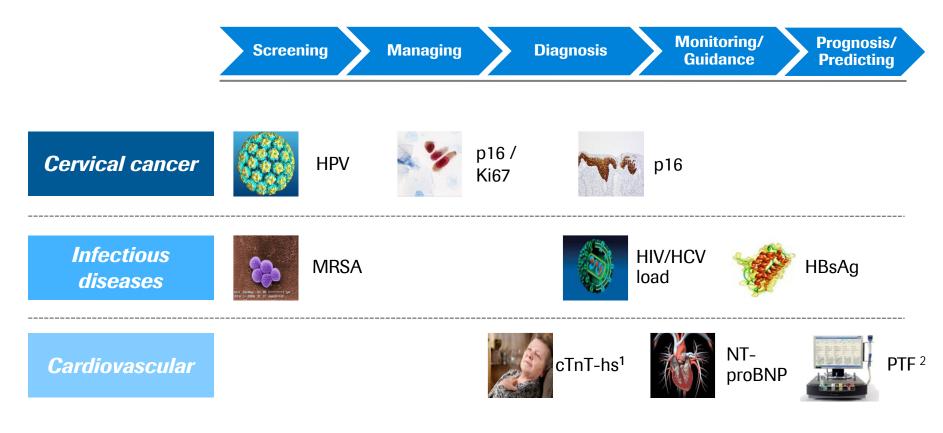


- The "One" molecular platform
- Broad test menu; random access capability
- Modular design to address laboratory throughput needs
- Designed to integrate pre & post analytics



### Medical value strategy Prioritise areas with unmet needs & growth potential

#### Selected Examples





### Medical value: Expanding intended uses of NT-proBNP for biomarker guided therapy

### **Heart Failure (HF)**



- Over 5% of US healthcare spending<sup>1</sup>
- Limited tools for treatment decision
- Unmet need for a biomarker to guide therapy titration

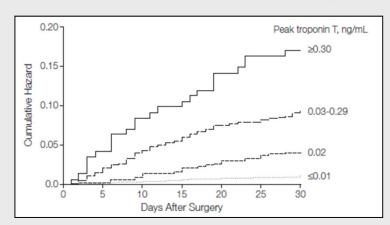
#### **NT-proBNP**

- Intended uses of NT-proBNP supported by clinical data
  - Rule in/out and early detection of HF;
     Risk stratification of ACS<sup>2</sup>; Therapy monitoring<sup>3</sup>
- GUIDE-IT: NT-proBNP target to guide medical therapy in HF
  - 1100 patient study in collaboration with Duke University and NIH
  - To repeat key results from PROTECT<sup>4</sup>
  - Targeting new intended use in the US in a large and growing market



### Medical value: Proving value for high sensitive troponin T in non-cardiac surgery patients

### **VISION study publication in JAMA**<sup>1</sup>



- Results from the first 15,133 <u>non-cardiac</u> surgery patients
- Peak post-operative troponin levels significantly associated with 30-day mortality
- Results will aid physicians assess individual patient risk and tailor therapy



### Roche Elecsys® Troponin T hs Assay

- Latest generation high sensitive troponin T test is a new tool to diagnose AMI<sup>2</sup> earlier
- Roche is the global troponin market leader with 30% share<sup>3</sup>



### Medical value: Improving the standard of care for women





**Vision:** Roche to lead the cervical cancer screening market by cost effectively **improving the standard of care** 

Extensive Clinical Data: ATHENA (cobas HPV test), PALMS (CINtec PLUS Cytology), Bergeron et al.\* (CINtec p16 Histology)

**Endorsement of the Roche Solution:** New guidelines (ASC, ASCCP, ASCCP-LAST) recommend use of HPV 16/18 genotyping and p16 in screening and diagnosis

### Screen Is my patient at high risk?

### **Manage**Does she need a colposcopy?

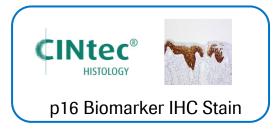
### **Diagnose**Should I initiate treatment?

### Monitor How closely do I need to monitor?

cobas<sup>®</sup> 14 hR HPV HPV Test

14HR HPV DNA with 16, 18



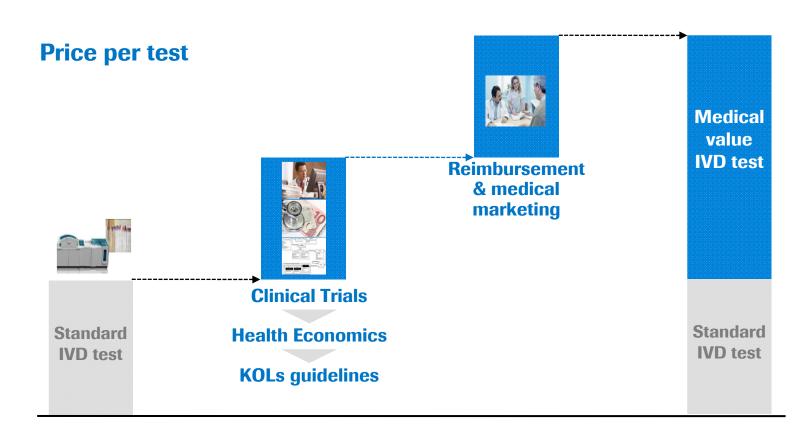


<sup>&</sup>lt;sup>1</sup> Bergeron, et al. Am J Clin Pathol 2010; 133:395-406

<sup>&</sup>lt;sup>2</sup> CAP/ASCCP Lower Anogenital Squamous Terminology for HPV-Associated Lesions: Summary of Consensus Recommendations June 28, 2012



## Medical value benefits Higher value through clinical utility and health economics





**IVD** market

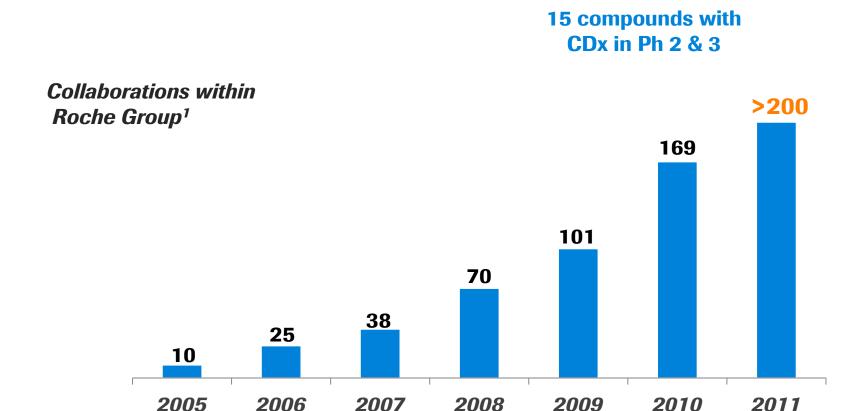
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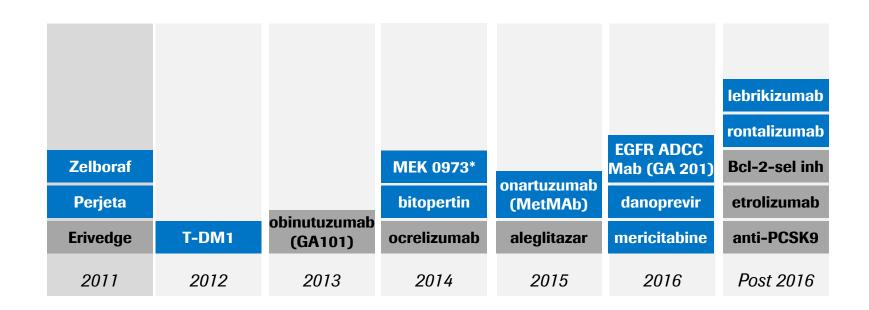


### Roche Diagnostics enables PHC Accelerating Companion Diagnostics (CDx) projects



<sup>17</sup> 





Late Stage Pipeline:
11 out of 18 compounds are targeted therapies for selected patients



### Breast & gastric cancer Herceptin, Perjeta & T-DM1

#### Ventana HER2 IHC & DISH

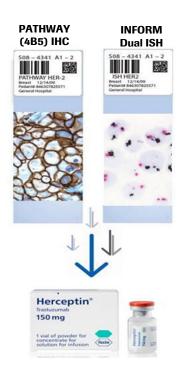
#### Key goal for Personalised Healthcare: Patients are accurately and quickly stratified



BenchMark automated slide staining platform



iScan Coreo



#### **Roche Solution:**

Integrated solution ensures:

- Clinical superiority <sup>1,2</sup>
- Analytical superiority
- Testing efficiency

The only fully automated, FDA approved HER2 diagnostics workflow

<sup>&</sup>lt;sup>1</sup> Mayr et al. Chromogenic in situ hybridization for HER-2/neu oncogene in breast cancer. Histopathology. 2009 Dec; 55(6):716-23.

<sup>&</sup>lt;sup>2</sup> Loftin IR, et al. Poster presented at ASCO Breast Cancer Symposium, September 2011

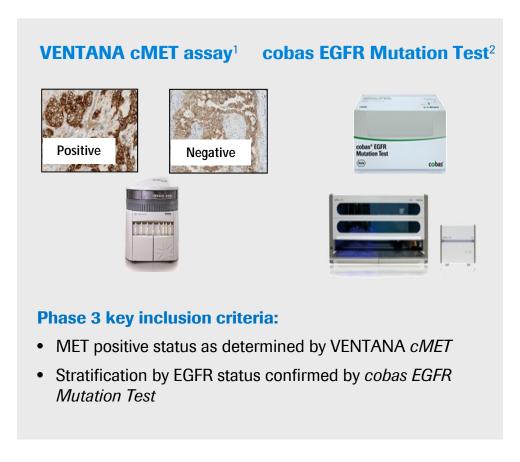


### Non small cell lung cancer (NSCLC) MetMab & Tarceva

#### Ventana cMET and cobas EGFR

### Providing the complete system for patient identification

- Detection of two key biomarkers in NSCLC
- High accuracy, broad mutation coverage
- Standardized workflow with fast and consistent results
- Worldwide distribution

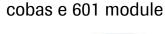




### Asthma *Lebrikizumab*

#### **Periostin**<sup>1</sup>

- Early collaboration and securing IP: UCSF-Genentech-RPD
- High quality and reliable in house IVD immunoassay based on ECL technology
- Delivered assay to meet tight Ph 2 & 3 timelines in consultation with FDA







Periostin assay

### Industry leading global reach

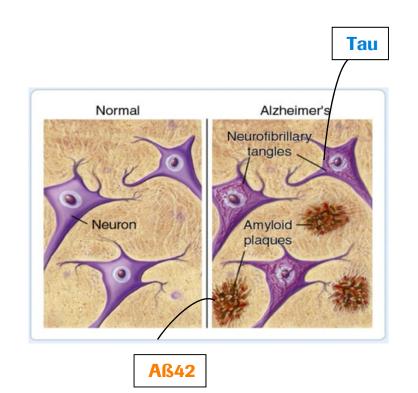
### Access to patients all over the world

 Over 40'000 SWA<sup>2</sup> instruments installed across 130 countries





### Alzheimer's Disease (AD) Gantenerumab



### Elecsys Aß42<sup>1</sup> and Tau<sup>1</sup>

- No current approved AD therapies with identified CDx biomarkers
- CSF<sup>2</sup> biomarker immunoassays to identify early (prodromal) AD eligible for Gantenerumab treatment
- Joint CDx development

Worldwide launch planned as fully automated IVD tests



### Roche Diagnostics enables PHC Preferred Partner for companion diagnostics (CDx)

#### Why partner with Roche



#### **Selected Partners**













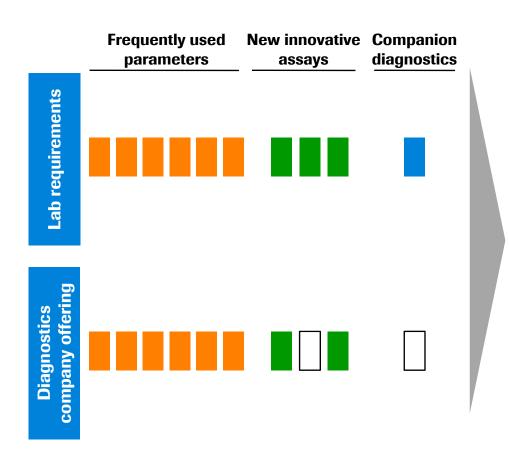








### Roche Diagnostics' commitment to PHC Value of CDx strategy to Roche Diagnostics



If the menu meets customer assay needs, customer uses fewer instruments in their lab:

Roche
"One-stop Shop"
Most relevant & complete offering



# Summary Roche Diagnostics well positioned to continue to outgrow the market

- Strengthen market leadership in growing IVD market
  Leveraging global installed base and delivering new key products
- Provide testing efficiency and demonstrate medical value Complete menu offering, high value assays, and building evidence
- Roche Diagnostics enabling Personalised Healthcare
  Large companion diagnostics pipeline driving value for the Group