



Diagnostics and Personalised Healthcare

Daniel O'Day | Chief Operating Officer
Roche Diagnostics

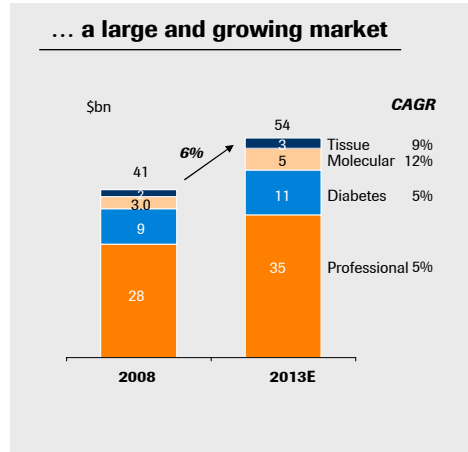
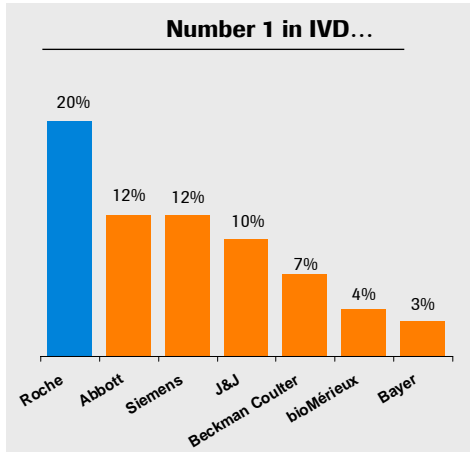


Roche Diagnostics: Uniquely Positioned

Revaluing in vitro Diagnostics

Driving Personalised Healthcare

Roche Diagnostics Leader in a growing market

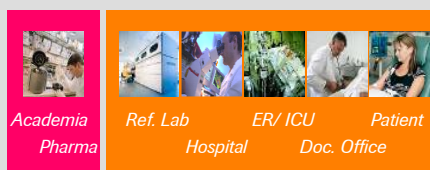


IVD = in vitro diagnostics
Source: Boston Biomedical Consultants, Company reports, Roche analysis

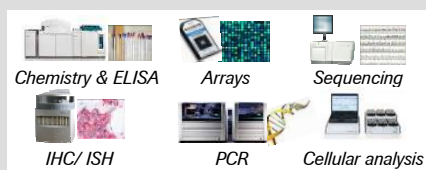
Strong presence and broad portfolio Solid basis for future growth



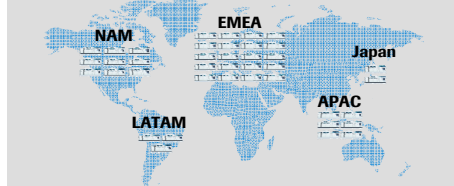
Present in all customer segments



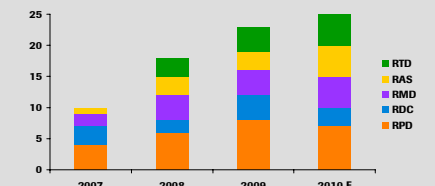
Broad array of technologies



Large installed base



Increasing # innovative products



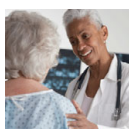
Roche Diagnostics: Uniquely Positioned

Revaluating in vitro Diagnostics

Driving Personalised Healthcare

Medical breakthroughs and market demographics

Increasing the importance of Diagnostics



Unmet medical need,
Market demographics

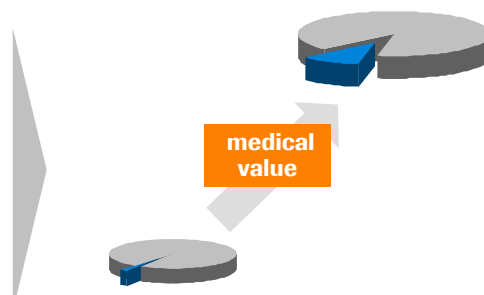


Advances in science
enabling new insights



Need for personalised
healthcare

Opportunity to revalue Diagnostics



IVD <2 % total worldwide healthcare spend
Influences >60 % of critical decision making

Creating medical value

Beyond diagnosis ... to Personalised Healthcare



Medical Value



Diagnostics



- Screening
- Diagnosis
- Prognosis
- Prediction
- Monitoring

Companion Diagnostics



- Treatment selection
- Response prediction
- Treatment monitoring

Medical value requires new capabilities

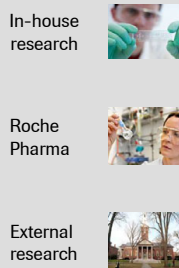
Roche uniquely positioned to capture the value



IVD System Development



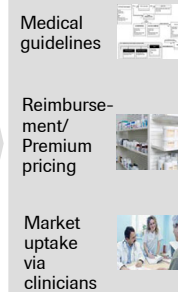
Content Development



Clinical Validation



Clinical Adoption

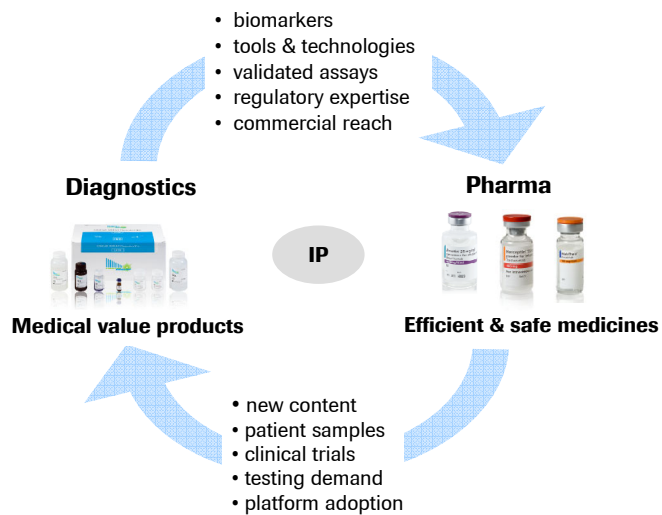


Increasing barriers to entry



Roche's distinctiveness

Significant advantages to both businesses



Roche Diagnostics: Uniquely Positioned

Revaluating in vitro Diagnostics

Driving Personalised Healthcare



Creating medical value Through new diagnostics tests...



Diagnostics



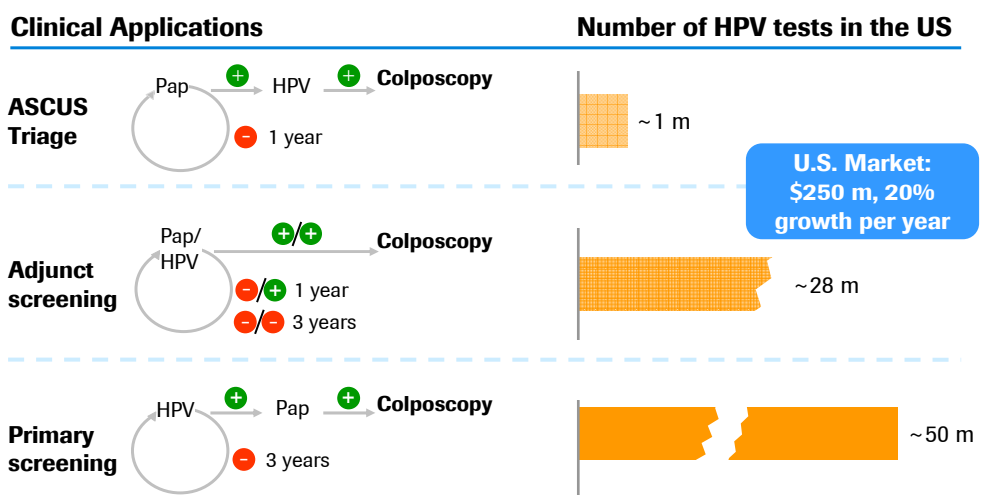
- Screening
- Diagnosis
- Prognosis
- Prediction
- Monitoring

Companion Diagnostics



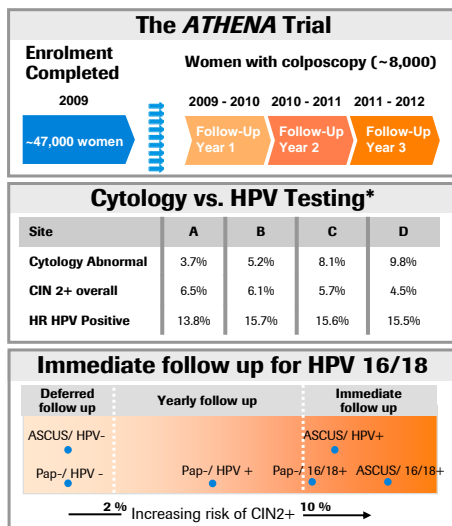
- Treatment selection
- Response prediction
- Treatment monitoring

Cervical Cancer: HPV screening algorithms Growth and market size driven by adoption of screening



Company reports, Roche analysis

ATHENA trial demonstrates medical value of HPV testing and Genotyping in Cervical Cancer screening



* Wright, TC., EUROGIN 2010

- Targets ASCUS triage, adjunct screening and HPV 16/18 claims
- Study results confirm variability of cytology and support improved consistency of HPV DNA based cervical cancer screening programs
- Data support HPV 16/18 genotyping as actionable information for intervention
- FDA submission mid 2010; data to be presented at IPV, Montreal 07/2010

ATHENA establishes the value of genotyping in cervical cancer screening programs

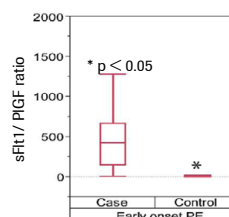
Preeclampsia: A significant unmet clinical need PlGF and sFlt1 - first IVD tests for Preeclampsia

Preeclampsia



- occurs in 3%-7% of pregnancies
- responsible for 18% of all maternal deaths in US¹
- costs more than \$7 bn in healthcare annually in US¹

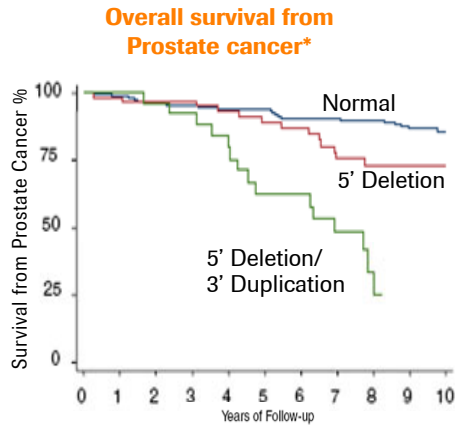
- Leading cause of fetal and maternal death
- Until recently, no specific tests available
- Roche developed first automated test to diagnose women with preeclampsia by measuring PlGF and sFlt1 levels²
- Early detection of patients at risk allows closer prenatal monitoring, early diagnosis and timely intervention



sFlt-1 = soluble fms-like tyrosine kinase; PlGF = placental growth factor
¹ World Health Organisation ² available ex-US

Verlohren et al., Am J of Obstetrics and Gynecology, 2010

Prostate Cancer: Rearrangements between TMPRSS2 and ERG genes found in ~50% of prostate cancer patients



Rearrangement status may determine clinical outcome

- How aggressive is my cancer?
- What should the course of my primary therapy be?
- What is my risk of metastasis?

* Oncogene (2008) 27, 253-263

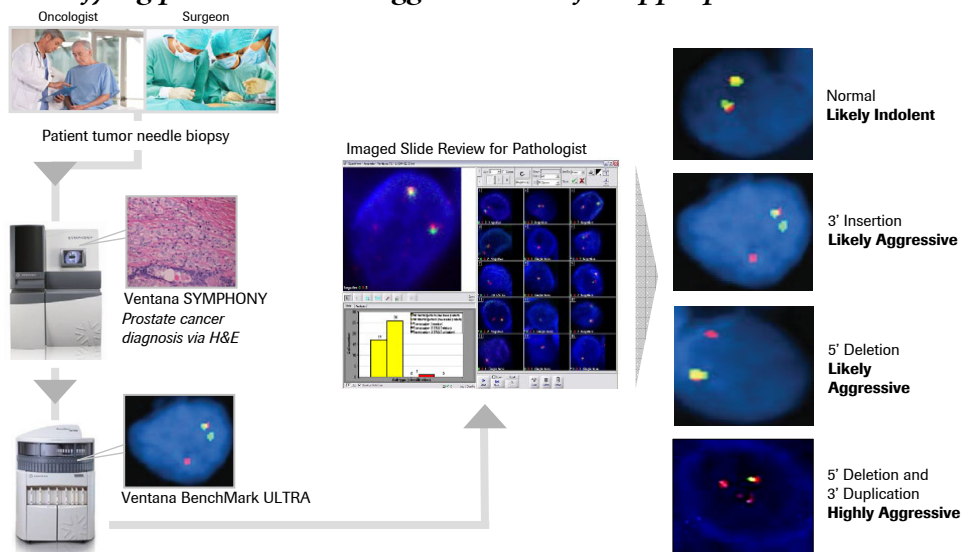
TMPRSS2= transmembrane protease, serine 2 (androgen responsive gene)

ERG=Ets Related Gene

Assay in development for ERG gene rearrangements



Identifying prostate cancer aggressiveness for appropriate treatment



Creating medical value Through Companion Diagnostics...



Diagnostics



- Screening
- Diagnosis
- Prognosis
- Prediction
- Monitoring

Companion Diagnostics

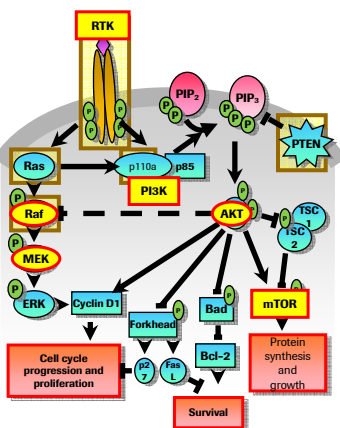


- Treatment selection
- Response prediction
- Treatment monitoring

Strong pipeline of companion diagnostics Joint Pharma and Diagnostics programs - Oncology



Roche Pharma targeting multiple pathways



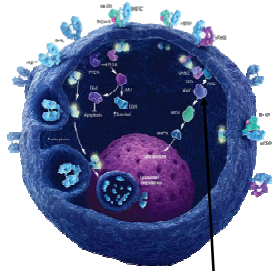
Molecular Tests for assessing presence of mutations offers opportunities to tailor treatment

Pipeline Drug	Biomarker	Pipeline Assay
RG7204 BRAF Inh/PLX4032 RG7167 MEK Inh/CIF	<i>BRAF</i>	cobas 4800 BRAF V600E test
RG7112 MDM2 Antagonist	<i>p53</i>	AmpliChip p53 array
RG7112 MDM2 Antagonist	<i>MDM2</i>	cobas MDM2 expression assay
Tarceva	<i>EGFR</i>	TheraScreen EGFR mutation test
RG7167 MEK Inh/CIF	<i>KRAS</i>	TheraScreen KRAS mutation test
RG1273 Pertuzumab RG3502 T-DM1	<i>Her1, 2, 3</i> <i>AREG, BTC</i>	cobas 4800 HER Family expression assay
RG7321 PI3K Inh RG7422 PI3K Inh	<i>PIK3CA</i>	PCR PIK3CA mutations FISH PIK3CA copy number assay

List not exhaustive

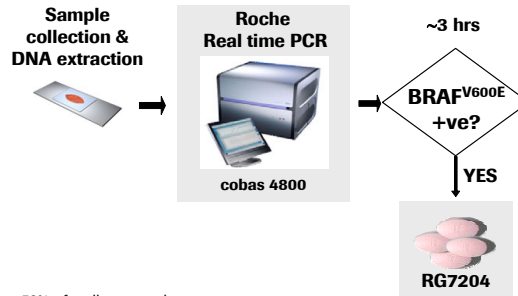
Mutation in BRAF Kinase

Co-development of test and drug in oncology



Single mutation in BRAF gene (BRAF^{V600E}) causes activation in absence of normal growth factor stimulation

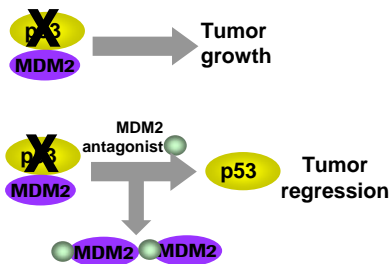
- Identifies patients whose tumor DNA carries BRAF^{V600E} mutation
- Increases feasibility of drug clinical development and probability of success
- IVD timelines aligned with RG7204 accelerated development plan → joint launch



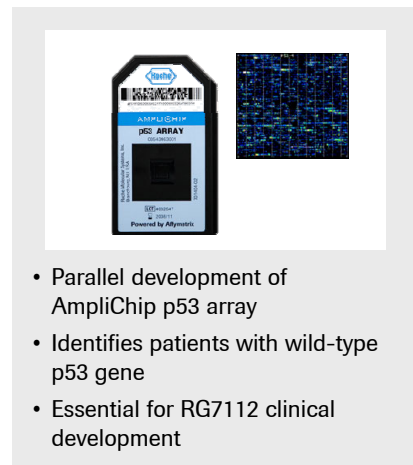
* BRAF gene mutations detected in ~8% of all cancers, over 50% of malignant melanomas

AmpliChip p53 and MDM2 Antagonist

Identifying patients with non-mutated tumor suppressor protein



- Blocking MDM2/ p53 binding enables p53 activity
- MDM2 antagonist (RG7112) may require wild-type p53*



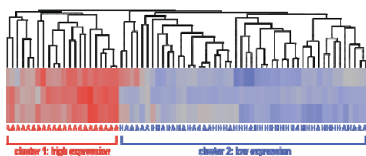
- Parallel development of AmpliChip p53 array
- Identifies patients with wild-type p53 gene
- Essential for RG7112 clinical development

* approx. 50% human tumors contain p53 mutants

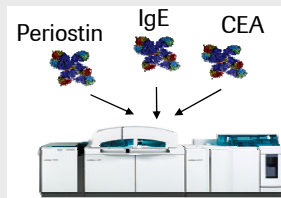
Serum markers and Lebrikizumab

May identify asthma patients most likely to respond

Two distinct Asthma sub-groups



- Need for non-invasive surrogate markers
- Serum Periostin, IgE and CEA - alone or combined - may predict drug response
- Potential to identify sub-population with improved clinical response to lebrikizumab (anti-IL-13)



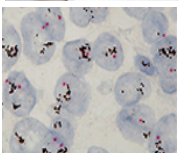
- Early Roche Diagnostics - gRED collaboration ensures timely availability of assays for trial program
- Enables patient stratification
- Combining multiple biomarkers may improve sensitivity & specificity

Roche Diagnostics

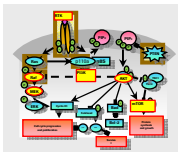
Driving future value for Roche



Uniquely positioned to revalue Diagnostics through delivery of medical value



Strong pipeline of innovative Diagnostics and Companion Dx tests



Combined strengths of Roche Pharma and Diagnostics to lead Personalised Healthcare



ROCHE: DELIVERING TODAY

DRIVING TOMORROW'S SUCCESS

18 March 2010 | New York