Roche Diagnostics
Innovating to improve healthcare

Dr. Michael Heuer, President EMEA-LATAM, Roche Diagnostics
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September 3, 2009
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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 Group Sales H1 ‘09

<table>
<thead>
<tr>
<th>Category</th>
<th>CHF 24 bn</th>
<th>4.9 bn</th>
<th>Total Dx</th>
<th>Est. Roche share</th>
<th>Roche position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharma</td>
<td></td>
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<tr>
<td>Diagnostics</td>
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<tr>
<td>Chugai</td>
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<tr>
<td>Molecular Dx</td>
<td></td>
<td>0.6</td>
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<td>35%</td>
<td>#1</td>
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<td>Diabetes Care</td>
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<td>1.4</td>
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<td>30%</td>
<td>#1</td>
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<tr>
<td>Professional Dx</td>
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<td>2.2</td>
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<td>15%</td>
<td>#2</td>
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<tr>
<td>Applied Science</td>
<td></td>
<td>0.4</td>
<td></td>
<td>21%</td>
<td>#1</td>
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<tr>
<td>Tissue Dx</td>
<td></td>
<td>0.2</td>
<td></td>
<td>n.a.</td>
<td>n.a.</td>
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</tbody>
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Source: Company Reports, Roche Analysis
Roche Diagnostics Strategy
Accessing novel content is a key driver of differentiation

Key Drivers of Differentiation

Increasing Testing Efficiency

Improving Medical Value

An opportunity to truly differentiate:
- Novel Markers
- PHC (including Companion Dx)

A prerequisite: “Blood, Sweat & Tears”
Innovating to improve Healthcare
In testing efficiency and in adding medical value

- Medical Value
  - Decentralise Testing
  - Apply Content for New Uses
  - Develop New Content
  - Solutions for testing outside the Central lab
  - Expand testing from Diagnosis to Monitoring
  - Novel assays / tests Personalised H’Care

- Testing Efficiency
  - Instrument Innovation
  - Menu Breadth
  - Workflow & IT
  - Instrument size, ease of use & throughput
  - Complete menu for all instruments
  - Data integration, connectivity

- Innovating to improve Healthcare
  - Testing Efficiency
  - Medical Value
  - Instrument Innovation
  - Menu Breadth
  - Workflow & IT
  - Decentralise Testing
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  - Instrument size, ease of use & throughput
  - Complete menu for all instruments
  - Data integration, connectivity
### Testing Efficiency – solutions across all business areas

**Projects and initiatives to increase testing efficiency**

<table>
<thead>
<tr>
<th>Instrument Innovation</th>
<th>Applied Science</th>
<th>Molecular Dx</th>
<th>Tissue Dx</th>
<th>Professional Dx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sequencing</td>
<td>New Gen</td>
<td>Benchmark Ultra (IHC/ISH)</td>
<td>cobas e801 (double channels &amp; throughput)</td>
</tr>
<tr>
<td></td>
<td>Array systems</td>
<td></td>
<td>Symphony (H&amp;E)</td>
<td>cobas b123 (blood gas analysis)</td>
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<tr>
<td></td>
<td>LC 1536 for high-throughput PCR</td>
<td></td>
<td>NexGen</td>
<td></td>
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<td></td>
<td>ACEA x-Celligence</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Menu Breadth</th>
<th>Applied Science</th>
<th>Molecular Dx</th>
<th>Tissue Dx</th>
<th>Professional Dx</th>
</tr>
</thead>
<tbody>
<tr>
<td>“PCR on demand”</td>
<td>Bioinformatic support for sequencing</td>
<td>Virology: CMV, EBV</td>
<td>Continuous expansion of antibody and molecular menu</td>
<td>Infectious Disease Menu Completion</td>
</tr>
<tr>
<td>Biomarker / Pathway</td>
<td></td>
<td>Microbiology: MRSA, C difficile, VRE</td>
<td></td>
<td>Cardiac Menu Expansion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Workflow &amp; IT</th>
<th>Applied Science</th>
<th>Molecular Dx</th>
<th>Tissue Dx</th>
<th>Professional Dx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioinformatic support for sequencing</td>
<td>Modular software cobas 4800</td>
<td>Vantage (Lab Workflow management solution)</td>
<td>Data manager c8000 (integrated IT middleware)</td>
<td></td>
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<td></td>
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<td></td>
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<td>Automated Storage &amp; Retrieval Module</td>
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## Testing Efficiency - cobas modular platforms

**Strengthening our portfolio to address all laboratory segments**

<table>
<thead>
<tr>
<th>cobas 8000 analyzer series*</th>
<th>Modular platform for all lab sizes</th>
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<tbody>
<tr>
<td><em>Large Volume</em></td>
<td></td>
</tr>
<tr>
<td>&lt;c 502&gt;</td>
<td></td>
</tr>
<tr>
<td>&lt;c 602&gt;</td>
<td></td>
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<tr>
<td>&lt;c 701&gt;</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>cobas 6000 analyzer series</th>
<th>Multiple configurations allowing easy expansion</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Mid Volume</em></td>
<td></td>
</tr>
<tr>
<td>&lt;c 501&gt;</td>
<td></td>
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<tr>
<td>&lt;c 601&gt;</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>cobas 4000 analyzer series</th>
<th>Improved efficiency and productivity</th>
</tr>
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<tbody>
<tr>
<td><em>Small Volume</em></td>
<td></td>
</tr>
<tr>
<td>&lt;c 311&gt;</td>
<td></td>
</tr>
<tr>
<td>&lt;c 411&gt;</td>
<td></td>
</tr>
</tbody>
</table>

* 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, T-Uptake, 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

**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

**Sepsis**
- IL 6, Procalcitonin

**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. Surveillance**
- Free ß hCG, PAPP-A
- PIGF/ SFIt1

* Not all assays approved in all markets

Blue indicates assays launched 2008/ plan to launch 2009
# Medical Value – innovative new products

## Projects and initiatives to improve medical value

### Applied Science
- **Decentralise Testing**
  - Septifast method for mold testing (Asthma)
- **Apply content For new Uses**
  - Septifast method for mold testing (Asthma)
  - CYP P450 (tamoxifen)
  - HCV for Pegasys short-course therapy selection
- **Develop New Content**
  - Sequencing for DX (Oncology, Cardiac, CF, HLA, HIV, Blood grouping)
  - Arrays for CGH

### Molecular Dx
- Bright field In-Situ-Hybridization (SISH)
- CYP P450 (tamoxifen)
- HCV for Pegasys short-course therapy selection

### Tissue Dx
- Her 2 for gastric cancer
- NT-proBNP (monitoring claim)
- P1NP (bone marker)
- Oncology (prostate cancer)

### Professional Dx
- “Newcard” (cardiology with lab performance)
- TGCa (entry into ICU that changes processes of care)
- EGFR, TOP 2A, cMET
- PLGF/SFLT (pregnancy, cancer, cardiac)
- CRC Screen (colorectal cancer detection with serum panel test, e.g. on IMPACT)
Medical Value - decentralise testing
*Time-critical testing closer to the patient*

**Coagulation Monitoring**

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

**Patient Self-testing**

- 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*

<table>
<thead>
<tr>
<th>Research assay</th>
<th>Technically validated assay</th>
<th>Clinically validated IVD assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generation of biomarker hypothesis</td>
<td>Clinical validation of candidate markers</td>
<td>Distribution to laboratories</td>
</tr>
<tr>
<td>Identification of candidate markers</td>
<td>Assay refinement &amp; development IVD test</td>
<td>Auditing for result consistency</td>
</tr>
<tr>
<td>Develop prototype assay</td>
<td>Regulatory test approval</td>
<td>Clinician/ Lab education</td>
</tr>
</tbody>
</table>
Medical Value – Roche Personalised Healthcare
Leveraging Pharma & Diagnostics from discovery to commercialisation

Research
- Generation of biomarker hypothesis
- Identification of candidate markers
- Develop prototype assay

Research assay
- Unrestricted exchange of knowhow and IP

Development
- Clinical validation of candidate markers
- Assay refinement & development IVD test
- Regulatory test approval

Technically validated assay
- Seamless platform transition

Commercialisation
- Distribution to laboratories
- Auditing for result consistency
- Clinician/ Lab education

Clinically validated IVD assay
- Faster adoption of new assays
Medical Value – Roche Personalised Healthcare
A comprehensive portfolio of novel companion tests

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