Leading the way in Integrated Diagnostics Solutions

Dr. Michael Heuer
CEO Roche Diagnostics

10 January 2019
Diagnostics

YTD Sep 2018 overview

Strategy
Newsflow & Innovation
Outlook
YTD Sep 2018: Diagnostics Division sales

*Strong growth driven by Centralised and Point of Care Solutions*

<table>
<thead>
<tr>
<th></th>
<th>2018 CHFm</th>
<th>2017 CHFm</th>
<th>Change in %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnostics Division</strong></td>
<td>9,378</td>
<td>8,798</td>
<td>7</td>
</tr>
<tr>
<td>Centralised and Point of Care Solutions</td>
<td>5,625</td>
<td>5,211</td>
<td>8</td>
</tr>
<tr>
<td>Diabetes Care</td>
<td>1,484</td>
<td>1,464</td>
<td>1</td>
</tr>
<tr>
<td>Molecular Diagnostics</td>
<td>1,468</td>
<td>1,388</td>
<td>6</td>
</tr>
<tr>
<td>Tissue Diagnostics</td>
<td>801</td>
<td>735</td>
<td>9</td>
</tr>
</tbody>
</table>

CER=Constant Exchange Rates
Underlying growth of Molecular Diagnostics excluding sequencing business: +6%
YTD Sep 2018: Diagnostics regional sales

Growth driven by Asia Pacific and North America

North America
+6%
~25% of divisional sales

Latin America
+8%
~7% of divisional sales

EMEA\(^1\)
+2%
~39% of divisional sales

Japan
+3%
~4% of divisional sales

Asia Pacific
+13%
~26% of divisional sales

+13% growth in E7 countries\(^2\)

\(^1\) Europe, Middle East and Africa; \(^2\) Brazil, China, India, Mexico, Russia, South Korea, Turkey
All growth rates at Constant Exchange Rates
YTD Sep 2018: Diagnostics Division highlights

Strong growth driven by Centralised and Point of Care Solutions

- Immunodiagnostics (+10%); clinical chemistry (+5%)
- Blood glucose measurement (+1%); insulin delivery systems (-4%)
- Virology (+4%), HIV (+6%); HPV (+17%); cobas® Liat® (+250%)
- Advanced staining portfolio (+10%); primary staining (+16%)

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*

<table>
<thead>
<tr>
<th></th>
<th>CHFm</th>
<th>% sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>6,264</td>
<td>100.0</td>
</tr>
<tr>
<td>Royalties &amp; other op. inc.</td>
<td>39</td>
<td>0.6</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>-2,846</td>
<td>-45.5</td>
</tr>
<tr>
<td>M &amp; D</td>
<td>-1,429</td>
<td>-22.8</td>
</tr>
<tr>
<td>R &amp; D</td>
<td>-715</td>
<td>-11.4</td>
</tr>
<tr>
<td>G &amp; A</td>
<td>-239</td>
<td>-3.8</td>
</tr>
<tr>
<td><strong>Core operating profit</strong></td>
<td><strong>1,074</strong></td>
<td><strong>17.1</strong></td>
</tr>
</tbody>
</table>

**HY 2018 vs. 2017**

<table>
<thead>
<tr>
<th>CER growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>6%</td>
</tr>
<tr>
<td>5%</td>
</tr>
<tr>
<td>5%</td>
</tr>
<tr>
<td>10%</td>
</tr>
<tr>
<td>4%</td>
</tr>
<tr>
<td>0%</td>
</tr>
</tbody>
</table>

**CER=Constant Exchange Rates**

+1% in CHF
Diagnostics

YTD Sep 2018 overview
Strategy
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Roche Clear Leader in Growing IVD Market

**Share of IVD sales 2017**

<table>
<thead>
<tr>
<th>Company</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche</td>
<td>19%</td>
</tr>
<tr>
<td>Abbott</td>
<td>13%</td>
</tr>
<tr>
<td>Danaher</td>
<td>9%</td>
</tr>
<tr>
<td>Siemens</td>
<td>8%</td>
</tr>
<tr>
<td>Sysmex</td>
<td>4%</td>
</tr>
<tr>
<td>bioMeriux</td>
<td>4%</td>
</tr>
<tr>
<td>OCD</td>
<td>3%</td>
</tr>
<tr>
<td>Becton Dickinson</td>
<td>3%</td>
</tr>
<tr>
<td>J&amp;J</td>
<td>3%</td>
</tr>
</tbody>
</table>

* includes acquisition of Alere by Abbott

**Expected IVD market growth**

**CHF 58bn**
- Blood Glucose Monitoring
- Tissue Diagnostics
- Molecular Diagnostics
- Centralized and Point of Care

**CHF 70bn**
- Blood Glucose Monitoring
- Tissue Diagnostics
- Molecular Diagnostics
- Centralized and Point of Care

IVD Market:
- +4% CAGR
- +6% CAGR
- +9% CAGR
- -3% CAGR
Roche continuously outgrowing the market
*Increasing market leadership*

Quarterly growth (% in CER)

- Strong commercial presence
- Broadest test menu

Source: 3rd party IVD consultancy
Integrated Core Lab
Expansion with integrated solutions and entering new disciplines

*cobas® pro, cobas® pure, cobas® Mass Spec have not been launched, yet.
Diagnostics

YTD Sep 2018 overview
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**Diagnostic innovation powerhouse: R&D budget > 11% of sales**

**BDDs reflecting the quality of our research**

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## Breakthrough Device Designations

<table>
<thead>
<tr>
<th>Year</th>
<th>Device</th>
<th>Intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td><em>Elecsys® β-Amyloid + p-Tau Cerebro Spinal Fluid assays</em></td>
<td>(AD: PET concordance)</td>
</tr>
<tr>
<td></td>
<td><em>(AD: Progression)</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>sFlt + PLGF</em></td>
<td><em>(Preeclampsia: rule-out within 1w)</em></td>
</tr>
<tr>
<td></td>
<td><em>FACT CDx (liquid biopsy assay)</em></td>
<td><em>(70 oncogenes + MSI + bTMB)</em></td>
</tr>
<tr>
<td></td>
<td><em>cobas® EBV</em></td>
<td><em>(EBV in transplant patients)</em></td>
</tr>
<tr>
<td></td>
<td><em>cobas® BKV</em></td>
<td><em>(BKV in transplant patients)</em></td>
</tr>
<tr>
<td></td>
<td><em>CoaguChek Direct-X</em></td>
<td><em>(patients on Factor Xa)</em></td>
</tr>
</tbody>
</table>
5,000 installations of cobas® 8000 modular analyzer series
Performing 15m tests/day
More than 14,000 installations of cobas® 6000 analyzer series
Performing 11m tests/day
Best in class manufacturing site with R&D center opened in China*
Roche investing in APAC region to meet growing healthcare needs

• Opened in 2018 and will build a workforce of >400 employees by 2021
• Ensure a sustainable supply for clinical chemistry and immunoassays in Asia Pacific
• Drive the development of innovative products for patients in collaboration with local industry and academic partners

*Roche's new manufacturing site with R&D center is located in Suzhou Industrial Park, in Suzhou, China
# Medical Value Assays

*Developing medical value assays that change patients’ lives*

<table>
<thead>
<tr>
<th>Disease Area</th>
<th>Oncology</th>
<th>Cardiovascular</th>
<th>Infectious Diseases</th>
<th>Neurology</th>
<th>Women's Health</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD-L1 marker as complementary diagnostics for CIT</td>
<td>Fastest time to diagnosis of acute myocardial infarction with high sensitive Troponin T</td>
<td>Plasma Separation Card added to Global Access Program</td>
<td>FDA breakthrough status for pTau/AB42 (Alzheimer)</td>
<td>NICE recommendation &amp; FDA breakthrough status for sFlt-1/PIGF (Preeclampsia)</td>
<td>Anemia, Bone, Coagulation, DAT, Endocrinology, Hematology, Hepatology, Inflammation, Renal, TDM, Urine</td>
<td></td>
</tr>
</tbody>
</table>

**Major achievements (examples)**

- PD-L1 marker as complementary diagnostics for CIT
- Fastest time to diagnosis of acute myocardial infarction with high sensitive Troponin T
- Plasma Separation Card added to Global Access Program
- FDA breakthrough status for pTau/AB42 (Alzheimer)
- NICE recommendation & FDA breakthrough status for sFlt-1/PIGF (Preeclampsia)

**Novel solutions (examples)**

- Sequencing, such as Avenio ctDNA and tissue panels
- Atrial fibrillation & heart failure indication programs
- Smarticles technology (for AST)
- Digital biomarker for Parkinson
- Gestation diabetes test

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
**Elecsys® B·R·A·H·M·S PCT™ receives FDA clearance for expanded use to aid in antibiotic therapy decision making**

Misuse and overuse of antibiotics (ABx) contribute to antibiotic resistance, which is a **growing threat to global health**.¹

**PCT expanded use:**
The kinetics of PCT provide insights in patient’s response to ABx, which helps clinicians determine **when to change or stop treatment**

Studies have shown that PCT-guided therapy results in
- Reduced **exposure to antibiotics**²,³,⁴
- Reduced **short-term and 1-year mortality**³,⁴

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PCT = procalcitonin
**cobas® 6800/8800 systems driving growth in molecular**

**Main menu completion in 2018**

<table>
<thead>
<tr>
<th>Blood Screening</th>
<th>Infectious Diseases</th>
<th>Women’s Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WNV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HEV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPX/DENV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zika</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Babesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Babesia</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Blood Screening (MPX)**
- Multiplex detection of HIV-1, HIV-2, HCV and HBV; WNV - West Nile virus; DPX - duplex detection of parvovirus B19 and HAV; HEV - Hepatitis E virus; CHIKV - chikungunya virus; DENV - Dengue virus; CMV - Cytomegalovirus; MTB - Mycobacterium tuberculosis; MAI - Mycobacterium avium-intracellulare infection; RIF - rifampicin; INH - isoniazid (detection of RIF/INH resistance in MTB positive samples); TV - Trichomonas vaginalis; MG - Mycoplasma genitalium; Babesia – detection of babesiosis caused by tick-born parasites; EBV - Epstein-Barr virus; BKV is a common post transplant opportunistic viral infection

**Infectious Diseases**
- HIV-1
- HBV, HCV
- CMV
- HIV-1/2 Qual
- MTB (Launch 2018)
- MAI (Launch 2018)
- RIF/INH (Launch 2019)
- EBV (Launch 2019)
- BKV (Launch 2019)

**Women’s Health**
- HPV (CE-IVO, US-IVO in 2019)
- CT/NG

**Installed instrument base: ~500**
Launch of cobas® Plasma Separation Card
*For testing and monitoring of HIV patients in resource limited settings*

- 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
Roche’s partnership with United Nations in Kenya helping to meet UNAIDS 90:90:90 goal¹

- More than 50% increase in testing of HIV/AIDS since the introduction of cobas 8800 in Kisumu County

¹ KEMRI/CDC laboratory was created through a public private partnership (PPP) with Roche Diagnostics, KEMRI (Kenya Medical Research Institute), CDC (Centers for Disease Control), CHAI (The Clinton Health Access Initiative) and USAID (United States Agency for International Development) where Roche Diagnostics installed the cobas® 8800; ²This means that by 2020, 90% of people in Kenya will know their HIV status, 90% of people who are HIV-positive will be receiving antiviral therapy, and 90% of people receiving this therapy will have viral suppression.
Strong flu season driving cobas® Liat® System sales

Pediatric and emergency room focus segments

Growing number of placements worldwide > 2500

Suitable for testing in a variety of settings

Menu of assays available

<table>
<thead>
<tr>
<th>Assay</th>
<th>CE</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td>cobas® Influenza A/B</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>cobas® Strep A</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>cobas® Influenza A/B &amp; RSV</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>cobas® Cdiff</td>
<td>✔️</td>
<td></td>
</tr>
</tbody>
</table>
Launch of NGS Avenio tumor tissue analysis kits

Comprehensive genomic profiling of solid tumors

**AVENIO tumor tissue targeted kit**
- Pan-cancer assay for tumor profiling
- 17 genes (81 kb)

**AVENIO tumor tissue expanded kit**
- Pan-cancer assay for expanded tumor profiling
- 77 genes (192 kb)

**AVENIO tumor tissue surveillance kit**
- Longitudinal tumor burden monitoring applications, focus on lung and colorectal cancer
- 197 genes (198 kb)

- Includes all reagents & informatics for a “sample in – result out” solution
- Each kit detects all four mutation classes including SNVs, CNVs, indels, and fusions
- Panel content matched with on-market AVENIO ctDNA assays expands clinical research opportunities

Research use only. Validated for use on Illumina NextSeq 500/550 instruments. NextSeq 500/550 instruments and associated sequencing reagents are manufactured and sold by Illumina and are not supplied by Roche; SNV=single nucleotide variant; CNV=copy number variant; indel=insertion or deletion
Launch of Ventana DP 200 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

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 NAVIFY Platform, A scalable, secure, and flexible platform enabling DIA teams to collaborate and deliver innovative and compliant cloud-based decision support products

2 Workflow Products, e.g. Tumor Board, OncoJourney, Mutation Profiler, Translational Research

3 Decision Support Apps, e.g. Publication Search, Clinical Trial Matching, IRIS Algorithms etc

4 Customer valued, data-enabled analytics services. Strong feedback loop to data aggregation and Decision Support Apps.

5 Ecosystem of 3rd party CDS App providers and Service providers forming around NAVIFY Platform and Workflows
Launch of NAVIFY clinical decision support apps
Facilitating access to relevant clinical trial information & publications

Product features

- **NAVIFY Clinical Trial Match app** identifies clinical trial options across multifold international registries based on patient attributes and tumor information.

- **NAVIFY Publication Search app** mines publication sources globally for most recent clinically and therapeutically-relevant literature.

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1 NAVIFY platform, a scalable, secure, and flexible platform enabling DIA teams to collaborate and deliver innovative and compliant cloud-based decision support products
2 NAVIFY workflow products, e.g. Tumor Board, Oncologist Workflow, Mutation Profiler, Translational Research
3 NAVIFY Clinical Decision Support apps, e.g. Publication Search, Clinical Trial Match (launched), Guidelines, IRIS Algorithms etc. (in development)
4 Change Management and Data-Enabled Analytics Services. Strong feedback loop to decision support apps.
Diagnostics

YTD Sep 2018 overview
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## Key launches 2018

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