Diagnostics Division

Thomas Schinecker
CEO Roche Diagnostics
YTD Sep 2019 overview

Strategy, Newsflow & Innovation

Outlook
YTD Sep 2019: Diagnostics Division sales

Growth driven by Centralised and Point of Care Solutions and Molecular Diagnostics

<table>
<thead>
<tr>
<th>Diagnostics Division</th>
<th>2019 CHFm</th>
<th>2018 CHFm</th>
<th>Change in %</th>
<th>CER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centralised and Point of Care Solutions</td>
<td>5,766</td>
<td>5,625</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Molecular Diagnostics</td>
<td>1,547</td>
<td>1,468</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Diabetes Care</td>
<td>1,395</td>
<td>1,484</td>
<td>-6</td>
<td>-2</td>
</tr>
<tr>
<td>Tissue Diagnostics</td>
<td>799</td>
<td>801</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

CER=Constant Exchange Rates; underlying growth of Molecular Diagnostics excluding sequencing business: +6%
YTD Sep 2019: Diagnostics Division regional sales

Growth driven by Asia Pacific and EMEA

**North America**
-1%
~25% of divisional sales

**Latin America**
+9%
~6% of divisional sales

**EMEA**
+3%
~38% of divisional sales

**Asia Pacific**
+9%
~27% of divisional sales

**Japan**
+3%
~4% of divisional sales

+10% growth in E7 countries

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1. Europe, Middle East and Africa; 2. Brazil, China, India, Mexico, Russia, South Korea and Turkey; all growth rates at Constant Exchange Rates (CER)
YTD Sep 2019: Diagnostics Division highlights

*Growth driven by Immunodiagnostics*

- **YoY CER growth**
  - **Centralised and Point of Care Solutions**: +5% (Immunodiagnostics +10%; Sales affected by decline in coagulation monitoring)
  - **Molecular Diagnostics**: +7% (Blood screening +9%; POC MDx +26%; Virology +1%)
  - **Diabetes Care**: -2% (Blood glucose monitoring -3%; Insulin delivery systems -2%)
  - **Tissue Diagnostics**: 0% (Primary staining +1%; Advanced staining +2%; Reagents +5%)

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1 Underlying growth of Molecular Diagnostics excluding sequencing business: +6%; 2 EMEA=Europe, Middle East and Africa; CER=Constant Exchange Rates
**HY 2019: Diagnostics Division**

*Core operating profit growing at +4%*

<table>
<thead>
<tr>
<th></th>
<th>HY 2019 CHFm</th>
<th>% sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>6,275</td>
<td>100.0</td>
</tr>
<tr>
<td>Royalties &amp; other op. inc.</td>
<td>33</td>
<td>0.5</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>-2,929</td>
<td>-46.6</td>
</tr>
<tr>
<td>M &amp; D</td>
<td>-1,405</td>
<td>-22.4</td>
</tr>
<tr>
<td>R &amp; D</td>
<td>-688</td>
<td>-11.0</td>
</tr>
<tr>
<td>G &amp; A</td>
<td>-222</td>
<td>-3.5</td>
</tr>
<tr>
<td><strong>Core operating profit</strong></td>
<td><strong>1,064</strong></td>
<td><strong>17.0</strong></td>
</tr>
</tbody>
</table>

**2019 vs. 2018 CER growth**

- **Diagnostics Division**
  - Core operating profit growing at +4%

**CER=Constant Exchange Rates**
YTD Sep 2019 overview

Strategy, Newsflow & Innovation

Outlook
Roche Clear Leader in Growing IVD Market

Share of IVD sales 2018

- Roche: 19%
- Abbott: 12%
- Danaher: 9%
- Siemens: 7%
- bioMerieux: 4%
- Sysmex: 4%
- Becton Dickinson Ortho Clinical Dia.: 3%
- Thermo Fisher: 2%
- Bio-Rad: 2%
Largest installed base worldwide

**Integrated Core Lab**
- cobas 6000/8000: +10%
- cobas 6800/8800: +22%
- cobas 4000: +7%

**Preanalytics**
- +10%

**Middleware**
- +10%

**Connectivity**
- +9%

Growth rates being from the period of January 1, 2019 to August 31, 2019
FDA clearance for cobas pro® integrated solutions

Key launch to further grow the medium/high volume segment

- Broadest Serum Work Area assay menu consolidated on a single platform
- Up to 2,200 tests per hour with 3 modules working in parallel and synchronized to improve efficiency
- Up to 3¼ hours less operating time
- Automated calibration in clinical chemistry significantly reducing operator hands on time
- Reduces turnaround times in delivering results to physicians and patients

1 for a daily routine workload, as compared to cobas 6000 <501|501|801>
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


PCT = procalcitonin
FDA clearance of cobas® TV/MG
Menu expansion of high volume STI testing on cobas 6800/8800

- Better diagnosis and screening of STIs and improved patient care
- Ability to test four STIs from a single patient sample
- Highest throughput testing solution on the market today for combination CT/NG and TV/MG testing

Installed instrument base: >729*

*August 2019

STI=sexually transmitted infections; CT=chlamydia trachomatis; NG=neisseria gonorrhoea; TV=trichomonas vaginalis; MG=mycoplasma genitalium
Launch of cobas® EBV and cobas® BKV

Transplant menu expansion on cobas® 6800/8800 Systems

- Perform critical transplant virus testing (CMV, EBV, BKV) from a single sample on cobas® 6800/8800 with full automation and proven performance
- Enables healthcare professionals to determine transplant patients at risk of further complications caused by reactivation of these viruses
- EBV and BKV tests received breakthrough device designation from the FDA
- Market size (molecular transplant diagnostics): USD 605m (CAGR +8%)

EBV=Epstein-Barr Virus, BKV=BK Virus, CMV=Cytomegalovirus
FDA approval of Babesia test on cobas® 6800/8800
Roche’s first whole blood donor screening assay

• Undetected Babesia infection can be fatal in patients receiving blood transfusions from infected donors
• Detection of 4 common species of Babesia parasites that live in red blood cells
• Simplified Babesia sample preparation through new whole blood collection tube, enabling more efficient laboratory processing and future menu expansion
**cobas® 6800/8800 systems driving growth in molecular**

*Continued menu expansion of our high medical value assays*

<table>
<thead>
<tr>
<th>Donor Screening</th>
<th>Infectious Disease</th>
<th>Sexual Health</th>
<th>Transplant</th>
<th>Respiratory</th>
<th>Antimicrobial Stewardship</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPX</td>
<td>HIV-1</td>
<td>HPV</td>
<td>CMV</td>
<td>MTB</td>
<td>MTB-RIF/INH</td>
</tr>
<tr>
<td>WNV</td>
<td>HBV</td>
<td>CT/NG</td>
<td>EBV</td>
<td>MAI</td>
<td></td>
</tr>
<tr>
<td>DPX</td>
<td>HCV</td>
<td>TV/MG</td>
<td>BKV</td>
<td>MPLX Respiratory</td>
<td></td>
</tr>
<tr>
<td>CHIKV/DENV (Not available in the US)</td>
<td></td>
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<tr>
<td>Zika (US-IVD, CE-IVD in 2019)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Babesia</td>
<td>Launch 2019</td>
<td></td>
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</tr>
</tbody>
</table>

**Installed instrument base: 729***

*August 2019*

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**Notes:**
- 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 post-transplant monitoring; BKV=BK virus post-transplant monitoring; ADV=Adenovirus post-transplant monitoring; HSV-1/2/VZV=multiplex detection of Herpes simplex virus 1 and 2 and Varicella-zoster virus; MPLX=detect and discriminate multiple (up to 14) pathogens associated with a clinical syndrome.
Expansion of Global Access Program beyond HIV

Delivering detection to enable treatment of hepatitis, tuberculosis and cervical cancer in lower access regions

- Focus on the UN Sustainable Development Goals (SDGs) which aim to “end the global tuberculosis (TB) epidemic” 95:90:00\(^1\)
- Contribute to Hepatitis Elimination Goals 90:65:80\(^2\)
- Focus on global call for action to prevent cervical cancer 90:70:90 goals\(^3\)

\(^1\) Targets to reduce TB deaths by 85%, cut new cases by 90% btw 2015 and 2035, and ensure that no family is burdened with catastrophic expenses due to TB; \(^2\) Targets to reduce new hepatitis infections by 90%, deaths by 65%, and treat 80% of HBV and HCV patients by 2030; \(^3\) Targets to have 90% of girls vaccinated with HPV vaccine by 15 years of age, 70% of women HPV screened at 35 and 45 years of age, and 90% of women identified with cervical disease receive treatment.
Launch of cobas vivoDx System for antibiotic resistance testing

Delivers fast phenotypic results in an automated workflow

- Results in <6 hours (vs 5 days for culture testing)
- 96 tests per 8 hours shift
- Single and multi sampling processing possible
- First launched with MRSA test
VENTANA HER2 dual ISH DNA probe cocktail

Brightfield microscopy as an alternative to FISH testing

- **Increased performance**, with oligo probes and new detection kits; highly concordant with FISH
- **Brightfield** assay that allows for interpretation within the context of tissue morphology
- **CE IVD** assay, indicated for patients for whom Herceptin treatment is considered

HER2+ receptor
Deliver **PRECISION DIAGNOSTICS** by combining best-in-class advanced staining assays with a high quality digital pathology portfolio.
NAVIFY Tumor Board 2.0 in collaboration with GE Healthcare

Clinical decision support with medical imaging capabilities

NAVIFY Tumor Board 2.0:
- Integration of GE Healthcare’s medical image viewer* into NAVIFY Tumor Board 2.0
- Enables radiologists to upload patient records to same dashboard as patient files from other disciplines

*Not yet commercially available in all countries; NAVIFY is a trademark of Roche. All other product names and trademarks are the property of their respective owners.
Launch of NAVIFY mutation profiler and therapy matcher\textsuperscript{1}

\textit{Clinical decision support solution for next generation sequencing labs}

\textbf{NAVIFY mutation profiler:}
- Provides annotation, interpretation and clinical reporting of NGS\textsuperscript{2} tests

\textbf{NAVIFY therapy matcher:}
- Helps clinicians to link clinically actionable mutations to relevant therapy options

\textsuperscript{1} CE-IVD marked software for comprehensive genomic profiling as a medical device; \textsuperscript{2} NGS: next generation sequencing
Accu-Chek® Solo micropump successfully launched
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

• Has **received** CE **Mark** in July 2018

Market

• Insulin pump market worldwide growing at +8% (FY 2018)
• Patch pump segment showing strong growth with +26% (FY 2018)
YTD Sep 2019 overview

Strategy, Newsflow & Innovation

Outlook
# Key launches 2019

<table>
<thead>
<tr>
<th>Area</th>
<th>Product</th>
<th>Description</th>
<th>Market</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instruments/Devices</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Workflow</strong></td>
<td>cobas prime</td>
<td>Pre-analytical platform to support cobas 6800/8800</td>
<td>CE/US</td>
</tr>
<tr>
<td><strong>Coagulation</strong></td>
<td>Protein C Chrom</td>
<td>Quantitative determination of protein C in citrated plasma on cobas t 511 / t 711 analyzers</td>
<td>CE</td>
</tr>
<tr>
<td><strong>Microbiology</strong></td>
<td>cobas TV/MG</td>
<td>High volume solution for TV/MG testing; dual-target test with ability to test with CT/NG from the same specimen during the same run</td>
<td>US</td>
</tr>
<tr>
<td></td>
<td>cobas vivoDx MRSA</td>
<td>Live cell assay for prevention and control of MRSA infections</td>
<td>US</td>
</tr>
<tr>
<td><strong>Tissue Dx</strong></td>
<td>VENTANA HER2 Dual ISH</td>
<td>Fully automated, brightfield ISH assay to determine eligibility for HER2 targeted therapy</td>
<td>CE</td>
</tr>
<tr>
<td><strong>Central Laboratory</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Software</strong></td>
<td>cobas Infinity Central Lab 3.0</td>
<td>One global laboratory middleware solution realizing a very high degree of integration in the laboratory</td>
<td>WW</td>
</tr>
<tr>
<td><strong>Tissue Dx</strong></td>
<td>Algorithm - Breast Panel</td>
<td>Whole slide analysis image analysis algorithm (HER2, ER, PR, Ki-67)</td>
<td>CE</td>
</tr>
<tr>
<td></td>
<td>Algorithm - PD-L1 Lung</td>
<td>Whole slide analysis image analysis algorithm (SP263)</td>
<td>CE</td>
</tr>
<tr>
<td><strong>Sequencing</strong></td>
<td>NAVIFY Mutation Profiler</td>
<td>Software as a medical device for annotating, variant classification, clinical interpretation and reporting from comprehensive genomic profile testing</td>
<td>CE</td>
</tr>
<tr>
<td></td>
<td>NAVIFY Therapy Matcher</td>
<td>Informing on treatment options based on local drug labels, medical guidelines and clinical trial outcomes</td>
<td>US</td>
</tr>
<tr>
<td><strong>Decision Support</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes Care</strong></td>
<td>Accu-Chek Sugar View 2.0</td>
<td>For non-insulin dependent T2 PwDs, allowing for meter-free blood glucose monitoring using Accu-Chek Active test strips and a smartphone camera</td>
<td>CE</td>
</tr>
</tbody>
</table>

1 CE: European Conformity, US: FDA approval, WW: Worldwide; GEHC DICOM: GE Healthcare Digital Imaging and Communications in Medicine; T2: Type II Diabetes; PwDs: People with Diabetes

2 NAVIFY Mutation Profiler and Therapy Matcher received CE mark; US approval expected by end of 2019.
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