Roche Diagnostics

Introduction and Business Overview
About Roche Diagnostics

Diagnostics Strategy and Business Model

Financials

Organization and Core Technologies

Personalized Healthcare and Data Management
Roche Clear Leader in Growing IVD Market

**Share of IVD sales 2017**

- **Roche**: 19%
- **Abbott**: 12%
- **Danaher**: 10%
- **Siemens**: 8%
- **Sysmex**: 4%
- **bioMeriux**: 4%
- **OCD**: 3%
- **Becton Dickinson**: 3%
- **J&J**: 3%

* includes acquisition of Alere by Abbott, and Cepheid by Danaher

**Expected IVD market growth**

- **IVD Market**: +5% CAGR
- **CHF 58bn**: -4% CAGR
- **CHF 72bn**: +6% CAGR

**2017**
- Blood Glucose Monitoring
- Tissue Diagnostics
- Molecular Diagnostics
- Centralized and Point of Care

**2022**
- Blood Glucose Monitoring
- Tissue Diagnostics
- Molecular Diagnostics
- Centralized and Point of Care

**IVD Market Growth**

- +5% CAGR
- -4% CAGR
- +6% CAGR
- +9% CAGR

**IVD Market Size**

- CHF 58bn
- CHF 72bn

*Includes forecasted market growth and market size projections.*
Diagnostics in a Glance

Diagnostics Division as Part of Roche Group

23% of 2018 Revenue

- % of Group Sales growth: 23%
- % of Group Core Operating Profit: 10%
- % of Group R&D spend: 13%
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Roche Diagnostics
Our competitive advantage

Total solution offering

Breadth of technologies
- DNA/RNA-based
- Protein-based
- Cell-based

Comprehensive menu
- Inflammation/Autoimmune
- Cardiology
- Virology/Microbiology
- Oncology
- Women’s health
- Metabolic diseases
- Hematology

IT and workflow connectivity

End-to-end workflow

Platforms (25+)

Software (50+)

Tests (500+)

Calibrators (1000+)
Servicing Clinical Diagnostics Customers
Managing complex product offering and business processes

Roche Diagnostics Customers
- Central lab
- Pathology
- Patients (Self Testing)
- Molecular Lab
- Point of Care

Roche Diagnostics Business Model
- Closed Systems
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## 2018: Diagnostics Division sales

*Strong sales growth with all business units contributing*

<table>
<thead>
<tr>
<th>Diagnostics Division</th>
<th>2018 CHFm</th>
<th>2017 CHFm</th>
<th>Change in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostics Division</td>
<td>12,879</td>
<td>12,079</td>
<td>7</td>
</tr>
<tr>
<td>Centralised and Point of Care Solutions</td>
<td>7,768</td>
<td>7,179</td>
<td>8</td>
</tr>
<tr>
<td>Molecular Diagnostics</td>
<td>2,019</td>
<td>1,920</td>
<td>5</td>
</tr>
<tr>
<td>Diabetes Care</td>
<td>1,980</td>
<td>1,965</td>
<td>1</td>
</tr>
<tr>
<td>Tissue Diagnostics</td>
<td>1,112</td>
<td>1,015</td>
<td>10</td>
</tr>
</tbody>
</table>

CER=Constant Exchange Rates; Underlying growth of Molecular Diagnostics excluding sequencing business: +6%
2018: Diagnostics regional sales
Growth driven by Asia Pacific and North America

North America
+7%
~25% of divisional sales

Latin America
+9%
~7% of divisional sales

EMEA\(^1\)
+3%
~39% of divisional sales

Japan
+6%
~4% of divisional sales

Asia Pacific
+13%
~26% of divisional sales

+14% growth in E7 countries\(^2\)

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

Strong growth driven by Centralised and Point of Care Solutions

<table>
<thead>
<tr>
<th>CHFbn</th>
<th>Centralised and Point of Care Solutions</th>
<th>Molecular Diagnostics</th>
<th>Diabetes Care</th>
<th>Tissue Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YoY CER growth</td>
<td>YoY CER growth</td>
<td>YoY CER growth</td>
<td>YoY CER growth</td>
</tr>
<tr>
<td></td>
<td>+8%</td>
<td>+5%</td>
<td>+2%</td>
<td>+10%</td>
</tr>
</tbody>
</table>

- **Centralised and Point of Care Solutions**: +8%
  - Immunodiagnostics (+11%); Clinical chemistry (+7%)
  - POC MDx² (+162%); Blood screening (+9%); Virology (+4%); HPV (+8%)
  - Blood glucose monitoring (+2%); insulin delivery systems (-6%)
  - Advanced staining (+10%); Companion diagnostics (+9%); Primary staining (+13%)

1 Underlying growth of Molecular Diagnostics excluding sequencing business: +6%; CER=Constant Exchange Rates; EMEA=Europe, Middle East and Africa; ² Point of Care Molecular Diagnostics
# Our Business Area/Unit structure

## Centralized and POC Solutions

- Serum work area/immuno-assays and clinical chemistry
- Point-of-care testing
- Specialty testing (hemostasis, hematology, urinalysis)
- Lab IT and workflow management
- Custom Biotech (applications for manufacturing)

## Molecular Solutions

### Molecular Diagnostics
- Virology
- Blood screening
- Genomics/oncology
- Microbiology
- Nucleic acid DNA purification and real-time PCR

### Tissue Diagnostics
- Primary staining
- Advanced staining
- Workflow management
- Digital pathology
- Companion Diagnostics

### Sequencing Unit
- Sample preparation
- Sequencing for clinical and life science applications
- Analytics
- Harmony prenatal test

## Diabetes Care

- Blood glucose monitoring
- Insulin delivery
- Continuous glucose monitoring
- Diabetes Management Solutions
Integrated Core Lab
Expansion with additional solutions and entering new disciplines

*cobas pure and cobas Mass Spec have not been launched, yet.
About Roche Diagnostics

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- Centralized and Point of Care Solutions

Personalized Healthcare and Data Management
Centralized and Point of Care Solutions

#1 in clinical chemistry and immunoassays

<table>
<thead>
<tr>
<th>New launches of Immunoassays</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>GDF-15</td>
<td>IGFBP-3</td>
</tr>
<tr>
<td>Active B-12*</td>
<td>Androstenedione</td>
</tr>
<tr>
<td>HIV Duo</td>
<td>17-OH-Progesteron</td>
</tr>
<tr>
<td>IGF-1*</td>
<td></td>
</tr>
<tr>
<td>Chagas</td>
<td></td>
</tr>
<tr>
<td>PIVKA</td>
<td></td>
</tr>
<tr>
<td>HCV Duo</td>
<td></td>
</tr>
</tbody>
</table>

- Installed base of ~900 cobas e 801 since launch
- Part of the cobas 8000 family
- Double throughput on same footprint

GDF 15 = growth-differentiation factor 15; Active B-12 = Vitamin B12; HIV Duo = HIV-1 and HIV-2 (HIV Antigen and HIV Antibody); IGF-1 = Insulin like growth factor; Pivka = Protein Induced by Vitamin K Absence or Antagonist II; HCV Duo (HCV Antigen and HCV antibody) IGFBP-3 = Insulin-like growth factor-binding protein 3; B2MG urine = Human β2 Microglobulin; AMH CDx = Anti-Müllerian hormone companion diagnostic; AB-42 = A beta Alzheimer marker; t-Tau p-Tau = Tau protein Alzheimer marker

* Assays will be available on the cobas e 801 by 2018-2019
Other lab instruments

Portfolio Overview

- **cobas c 513**
  - Diabetes Testing
  - HbA1c (Glycated hemoglobin) analyzer

- **cobas m 511**
  - Hematology
  - Digital morphology analyzer, cell counter and classifier

- **cobas t 411**
  - Coagulation Monitoring
  - Blood coagulation management

- **cobas 6500 analyzer**
  - Urine Testing
  - Fully automated urine work area solution
CPS: POC Solutions

Portfolio Overview

Blood Gas & Electrolytes
- Critical Care
- Diabetes
- Cardiovascular Diseases

Metabolic Disease Testing
- Acute Cardiovascular Diseases

Cardiac Testing
- Blood coagulation management

Coagulation Monitoring
- Diabetes
- Cardiovascular Diseases
- Kidney Injury

Kidney/Liver Diseases
- Diabetes
- Kidney/Liver Diseases
- Urinary Tract Infections

Urine Testing
About Roche Diagnostics

Diagnostics Strategy and Business Model

Financials

Organization and Core Technologies

- Molecular Diagnostics

Personalized Healthcare and Data Management
Roche Molecular Solutions
Connecting complementary disciplines

PATHOLOGY WORKFLOW

MOLECULAR WORKFLOW

H&E Staining

IHC/ISH Staining

Digital Slide Scanning & Advanced Image Analysis

AVENIO Millisect*

PCR

MagNA Pure 24

NGS

AVENIO ctDNA Analysis Kits*

Roche Molecular Solutions
Connecting complementary disciplines

*Research Use Only. Not for diagnostic use.
# Molecular Diagnostic: Centralized and PoC Solutions

<table>
<thead>
<tr>
<th>Blood Screening</th>
<th>Virology</th>
<th>HPV &amp; CT/NG</th>
<th>Microbiology</th>
<th>Genomics &amp; Oncology</th>
<th>PoC</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Multiplex HIV, HCV, HBV</td>
<td>• HIV</td>
<td>• Human Papillomavirus</td>
<td>• MTBMAI</td>
<td>• BRAF</td>
<td>• Influenza A/B</td>
</tr>
<tr>
<td>• West Nile Virus</td>
<td>• Hepatitis B, C</td>
<td>• Chlamydia &amp; Gonorrhea</td>
<td>• MRSA</td>
<td>• K-RAS</td>
<td>• Influenza A/B &amp; RSV</td>
</tr>
<tr>
<td>• B19 and HAV</td>
<td>• HSV</td>
<td>• C. Difficile</td>
<td>• HSV</td>
<td>• EGFR</td>
<td>• Strep A</td>
</tr>
<tr>
<td></td>
<td>• CMV</td>
<td></td>
<td>• CMV</td>
<td>• PIK3CA</td>
<td>• C. Diff</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RMD Assays</th>
<th>cobas 6800/8800 Systems</th>
<th>cobas 4800 System</th>
<th>cobas Liat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced PCR automation</td>
<td>Highest throughput (3x above closest competitor)</td>
<td>Broadest menu</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RMD Platform Strategy</th>
<th>cobas 6800/8800 Systems</th>
<th>cobas 4800 System</th>
<th>cobas Liat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low to middle volume throughput</td>
<td>Broadest menu</td>
<td>Point of care lab quality PCR results in ~20 min</td>
<td></td>
</tr>
</tbody>
</table>
**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>HIV-1</td>
<td>HPV</td>
</tr>
<tr>
<td>WNV</td>
<td>HBV, HCV</td>
<td>CT/NG</td>
</tr>
<tr>
<td>DPX</td>
<td>CMV</td>
<td>TV/MG</td>
</tr>
<tr>
<td>HEV</td>
<td>HIV-1/2 Qual</td>
<td></td>
</tr>
<tr>
<td>CHIKV/DENV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Not available in the US)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zika</td>
<td>MTB</td>
<td></td>
</tr>
<tr>
<td>(US-IVD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Babesia</td>
<td>MAI</td>
<td></td>
</tr>
<tr>
<td>(US-IVD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Babesia</td>
<td>RIF/INH</td>
<td></td>
</tr>
<tr>
<td>(US-IVD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EBV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BKV</td>
<td></td>
</tr>
</tbody>
</table>

**Installed instrument base: ~500**

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
Strong flu season driving cobas® Liat® System sales

Pediatric and emergency room focus segments

Growing number of placements worldwide > 2500

Menu of assays available

<table>
<thead>
<tr>
<th></th>
<th>CE</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>cobas® Influenza A/B</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>cobas® Strep A</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>cobas® Influenza A/B &amp; RSV</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>cobas® Cdiff</strong></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

Easy to use with less than one minute hands-on time
Lab quality performance in 20 minutes or less

Suitable for testing in a variety of settings

Hospital Emergency Room Physician Office Health Clinic Retail Pharmarcy
About Roche Diagnostics

Diagnostics Strategy and Business Model

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Organization and Core Technologies

- Tissue Diagnostics

Personalized Healthcare and Data Management
# Tissue Diagnostics: Product Portfolio

Comprehensive offering across the pathology workflow

<table>
<thead>
<tr>
<th>Work processes</th>
<th>Pre-Analytical</th>
<th>Primary Staining</th>
<th>Advanced Staining</th>
<th>Imaging/Reporting</th>
</tr>
</thead>
</table>
| Tissue Preparation | - Tracking  
- Grossing  
- Fixation  
- Processing | H&E Stain | - Binary Diagnosis  
- Tissue  
- Morphology | SS  
IHC  
ISH | Image Analysis |
| Vantage | VENTANA HE 600 | Benchmark Special Strainer | Benchmark ULTRA | iScan HT |

- SS = Special Stains; IHC = immunohistochemistry; ISH = in situ hybridization

VANTAGE Workflow and Connectivity
Launch of Ventana DP 200\(^1\) slide scanner for digital pathology

*Provides a foundation in offering a comprehensive, high quality digital pathology portfolio*

**VENTANA DP 200**
- **slide scanner**
  - Launch\(^1\) in Q1 2018

**uPATH Workflow Software**
- Launch\(^2\) planned Q4 2018

**Enabler of** high medical value assays

**Deliver a fully digitised pathology lab**

- Breast Panel
- HER2 DISH
- PD-L1

**Image Analysis Algorithms**

**Multiplex Algorithms\(^3\)**

---

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
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- Sequencing

Personalized Healthcare and Data Management
Roche Sequencing Vision

- AUTO IMMUNITY
- IMMUNOLOGY
- HEART DISEASE
- INFECTION DISEASE
- IMMUNOLOGY
- IMMUNOLOGY
- INFECTIOUS DISEASE
- ONCOLOGY
- OTHER
- MICROBIOME
- HIV
- HCV
- MRD
- Transplantation
- Field Testing
- TILS
- Immunosequencing
- Postnatal screening
- Early Diagnosis
- Trisomy
- Personalization
- Monitoring
- Resistance
- Recurrence
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Financials

Organization and Core Technologies

- Diabetes Care

Personalized Healthcare and Data Management
Roche Diabetes Care Portfolio

Continuous Glucose Monitoring

Accu-Chek Insight CGM

Blood Glucose Monitoring

Accu-Chek Guide
Accu-Chek Instant
Accu-Chek Mobile

Insulin Delivery Systems

Accu-Chek Solo Micropump
Accu-Chek Insight
Accu-Chek Combo
Accu-Chek Infusion Sets
Accu-Chek DiaPort

Digital Diabetes Management Solutions

emminens
Accu-Chek Connect
Accu-Chek SmartPix

Lancing Devices

Accu-Chek Lancing Systems
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Roche Diagnostics
Leader in Personalised Healthcare (PHC)

- 60% of late stage Pharma development products have an accompanying companion diagnostics test
- Combined strengths of Pharmaceuticals and Diagnostics: 300 internal collaboration, 50 external collaborations
- Synergies in research, development and marketing
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
### Expanding CDx Menu

**Market leading portfolio**

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Indication(s)</th>
<th>Biomarker</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herceptin</td>
<td>Breast, Gastric, Breast, Breast</td>
<td>HER2</td>
<td>IHC/ISH</td>
</tr>
<tr>
<td>Perjeta</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kadcyla</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>XALKORI</td>
<td>NSCLC</td>
<td>ALK</td>
<td>IHC</td>
</tr>
<tr>
<td>ZYKADIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TECENTRIQ</td>
<td>Bladder, NSCLC, Bladder, NSCLC</td>
<td>PD-L1</td>
<td>IHC</td>
</tr>
<tr>
<td>IMFINZI™, KEYTRUDA, OPDIVO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLEEVEC</td>
<td>GIST</td>
<td>C-KIT</td>
<td>IHC</td>
</tr>
<tr>
<td>Tarceva</td>
<td>NSCLC</td>
<td>EGFR</td>
<td>PCR (Tissue/Plasma)</td>
</tr>
<tr>
<td>TAGRISSO™</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zelboraf &amp; COTELLIC</td>
<td>Melanoma</td>
<td>BRAF</td>
<td>PCR</td>
</tr>
<tr>
<td>ERBITUX</td>
<td>CRC</td>
<td>KRAS</td>
<td>PCR</td>
</tr>
<tr>
<td>Vectibix</td>
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<td></td>
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</tbody>
</table>
First liquid biopsy test approved by FDA

cobas EGFR v2 CDx for Tarceva and Tagrisso

- Test can utilize plasma and tissue sample
- Leverages cobas 4800 platform
Doing now what patients need next