Ventana Companion Diagnostics

Building the future of pathology through partnership
Mission & Vision Overview

Companion Diagnostics & the Value of Personalized Healthcare

Current State & the Future of Companion Diagnostics

Sources and Uses of Information for CDx
Pathologist founded, patient focused
Maintaining a focus on the mission we share with you

Our mission
To improve the lives of all patients afflicted with cancer

Our vision
To empower our customers by providing the highest quality, most innovative cancer diagnostic solutions
Tools to deliver on our mission
*A vision to support you in an ever changing environment*

The market challenges you face today...bring opportunities to differentiate.

- **Demand for health economic evidence** → **Medical value assays with published clinical data**
- **Labs doing more with less** → **Advanced automation to improve quality and reduce labor costs**
- **Increasing competition and price pressure** → **Integrated AP lab solutions to improve efficiency**
Healthcare today is in crisis, as it is expensive, reactive, inefficient & focused largely on one-size-fits-all treatments for events of late stage disease. An answer is personalized, predictive, preventive & participatory medicine.¹
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Companion diagnostics & bio-targeted therapy

Standard therapy means: same disease, same therapy

Personalized healthcare means: the right therapy for the right group of patients at the right time

One-size-fits-all approach

Targeted strategy
Why are companions important?

*Treatment efficacy historically elusive for oncology*

For every 10 cancer patients treated, an average of only half will benefit.

*Source: Roche Personalized Healthcare brochure, 2011*
Value of Personalized Healthcare

High value diagnostics benefit physicians, patients & payers

Physicians: easier prescription decisions & better prediction of treatment outcome

Payers: optimized use of resources & the potential reduction of co-treatments for side effects

Patients: better efficacy builds confidence through proven outcomes
Companion diagnostics deliver real value
Help to reduce costs & improve outcomes

$160B
of drug spend is ineffective

$15B
Savings CDx can deliver to healthcare

$604M
Annual savings if patients with metastatic colorectal cancer receive a genetic test prior to treatment

34%
Decrease in chemo if women with breast cancer receive a genetic test prior to treatment
ALK positive gene mutation status in non-small cell lung cancer qualifies patients for Crizotinib.

- Crizotinib increases progression free survival in comparison to standard chemotherapy\(^4\)

Lives are impacted, by knowing biomarker status to qualify patients for potential life saving therapy.

The VENTANA ALK (D5F3) Rabbit Monoclonal Primary Antibody is not available for this use in the United States. Check with your local Roche representative for the availability of products in your region and the applicable intended use.
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The need for companions will continue to grow

*FDA approvals flat overall but 600% more likely with bio-target*

The last ten years in NSCLC

Number of compounds being investigated
+62%

R&D funding has **doubled**

FDA approvals – **flat without a companion**

Biomarker targeted therapies **six-fold increase in clinical trial success**

### Roche diagnostics market leading CDx portfolio

Our diagnostic offerings cover several therapies & technologies.

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<th>Biomarker</th>
<th>Technology</th>
<th>Therapy Application</th>
<th>Roche Solution</th>
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<tr>
<td>HER2 *</td>
<td>IHC/ISH</td>
<td>Herceptin, Perjeta, Kadcyla Breast, Gastric</td>
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<td>ALK**</td>
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<tr>
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<td>C-KIT</td>
<td>IHC</td>
<td>Gleevec GIST</td>
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*Biomarkers include only those required per FDA approved therapeutic label. **Not all CDx Assays are available in all markets for all indications.
What is our strategy?
Offer pharma a premiere end to end solution

**Antibody Development**
Rabbit Monoclonal Antibody manufacturer of first-in-class clones for RUO/IVD.

**Assay Prototyping**
Biomarker evaluation, efficient & robust LDT development

**CAP/CLIA Lab**
In-house lab for first in-human clinical trials and rapid “go/no-go” project determination

**Pathology Expertise**
Dedicated to Pharma clinical trials, assay algorithm development, CDx Assay training

**Regulatory Experience**
Clinical Trial Support

**Commercial Support**
Education, pre-launch, training product marketing & commercialization

- Industry’s #1 Commercial and Technical Support Network
- Largest Global Installed Base
- #1 in IHC Market Share in all Regions
Delivering on our vision

Building a robust pipeline of innovative diagnostics
New CDx products on the horizon
The future is clear for key diseases and targets.
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**Information Tsunami**

1,000,000,000 CHF Investment*
7,000,874 Working hours
6,587 Experiments
423 Scientists
1 Drug

19,155,303 PubMed Articles+
94,941 Research institutes
43,048 Gene sequences
4,946 Journals
1 Fact

**Driving question:**
How can we efficiently process the huge amount of information for our scientists such that they can focus on innovation?
Scientific & Business Information Services

Scientific Information Services

- Individual Searches
- Continuous Searches (Alerts)
- Structure & Substructure Search
- Gene & Protein Sequence Search

Get information to innovate!

Scientific Information Services

Business Information

- Business News
- Market & Company Reports
- Cooperations & Licences, M&A

Patent Information

- Freedom to operate (FTO)
- State of the Art
- Infringement/Validity Search
- Patent Landscaping/Mining

Analytics Services

- Data & Text Mining
- Patent Landscaping
- Application Development

Enduser Services

- Training
- Support
- Helpdesk

SciFinder®

embase®

Orbit®

GenomeQuest®

STN®
Companion Dx Information Resources

**Databases**
- Citeline Trial Trove/ Pharma projects - Clinical Trials, drug profiles
- Cortellis (Thomson Reuters)
- Adis R&D Insight (Springer)

**Associations**
- American Society of Clinical Oncology Meeting Library (ASCO)
- American Association for Cancer Research Meeting Abstracts (AACR)
- College of American Pathologists (CAP)
- National Comprehensive Cancer Network (NCCN)
- European Society for Medical Oncology (ESMO)

**Regulatory and News**
- [FDA Companion Diagnostics](#)
- [List of Cleared or Approved CDx Diagnostic Devices](#)
- Pharma & MedTech Business Intelligence
- Genome Web
- BioCentury
- Bio Pharma Dive
References

1) **The Case for Personalized Medicine**, 3rd Edition  The Personalized Medicine Coalition (Oct 2011)


4) **Crizotinib versus Chemotherapy in Advanced ALK-Positive Lung Cancer**
Doing now what patients need next