PUTTING A FACE ON PERSONALIZED MEDICINE
BECAUSE SHE DESERVES MANY MORE DAYS IN THE SUNSHINE

You have a vision: to take a promising therapeutic candidate from clinical trials to successful commercialization. The stakes are high. And the decisions you make today may transform people's lives tomorrow.

Fortunately, you're not alone; the Abbott Molecular team stands behind you. Our knowledge, passion and commitment come together to create companion diagnostic solutions that help translate your vision into reality…and help ensure plenty of sunshine for the people who matter.

Abbott's Approach to Personalized CDx Partnerships

- 25-year history of success
- Commitment to quality
- Broad technology portfolio
- Established global communication channels

FLEXIBILITY WHEN YOU NEED IT...

...guidance when you want it.

READY TO TAKE YOUR PROGRAM TO THE NEXT LEVEL?

To schedule a meeting to review your needs or discuss our biomarker pipeline, contact Abbott Molecular today.

LEARN MORE

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**BUILDING ON BIOMARKERS**

**INSPIRED TO CHART NEW COURSES**

See how we leverage biomarkers for discovery and development

See how we incorporate quality into your project from Day One

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SIMPLIFYING SOLUTIONS FOR THE LAB

HE HAS EVERY REASON IN THE WORLD TO SMILE

At Abbott Molecular, we embrace the next generation of innovative solutions that have the potential to bring testing closer to the patient. Our goal is to deliver streamlined, standardized molecular diagnostics that can be run routinely, reproducibly and accurately in any lab around the world.

By combining the power of emerging technology with our scientific expertise, we are working to redefine the standards of patient care tomorrow. And that makes everyone smile.

See how next generation testing can accelerate access to patient results: BioView
See how simplified, standardized multiplex testing can improve global access to diagnostics: Idylla

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INCREASING THE VELOCITY OF THERAPEUTIC UPTAKE

POISED ON THE BRINK OF SOMETHING BIG

Changing established medical practice doesn’t happen overnight. It requires connecting a complex network of stakeholders, each with unique needs and demanding expectations.

Abbott Molecular delivers the resources to get the job done: dedicated reimbursement and market access expertise...350+ global commercial team members...and the knowledge and experience to help drive commercial success.

TOGETHER... we will CHANGE medical PRACTICE.

TOGETHER... we can CHANGE people’s LIVES.

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ABBOTT’S INSTRUMENT SYSTEMS AND ASSAYS
ENABLE GLOBAL PATIENT ACCESS TO TESTING, FROM COMMUNITY HOSPITALS TO CONSOLIDATED REFERENCE LABS

1. FLUORESCENCE IN SITU HYBRIDIZATION (FISH)
   - DNA copy number changes, deletions, translocations
   - Quantitative RNA FISH
   - Multiplex FISH (7+ colors)
   - Automated enumeration and imaging

2. PCR-BASED TECHNOLOGY
   - Mutation detection
   - Gene expression
   - Multiplex panels
   - Gene rearrangements

3. SEQUENCING
4. NUCLEIC ACID EXTRACTION
5. CIRCULATING FREE DNA (cfDNA)
6. CIRCULATING TUMOR CELLS

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BIOMARKERS
ABBOTT MOLECULAR OFFERS A COMPREHENSIVE ROSTER OF BIOMARKERS

Browse by Names:
A–H I–P Q–Z

Browse by Disease States:
A–B C–K L–Me Mu–Z
### BIOMARKERS

#### NAMES A–H

<p>| | |</p>
<table>
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| A | ACTN4  
AKT  
ALK  
Androgen Receptor (AR)  
AR  
ATM 11q22.3  
AURKA  
AXL |
| B | BCL2  
BCL6 (3q27) Rearrangements  
BCR/ABL  
BCR/ABL t(9;22)  
BRAF  
BRCA1  
BRCA2 |
| C | 13q14.3  
CBFB Break Apart  
CCND1  
CCND1 (11q13) Rearrangements  
CDK6  
CEBPE  
cKIT  
CKS1B  
cMET  
c-MYC 8q24  
c-Myc Rearrangements t(8;14), t(2;8), t(8;22)  
COT  
CRAF  
CRLF2 |
| D | D5S23/D5S721 CEP 9  
D5S721  
D7S486  
D13S319/CEP12  
DCC |
| D cont. | DDR2  
DEK/NUP214  
del(5q)  
del(7q)  
del(9q)  
del(13q)  
deletion 7q31 (D7S552) |
| E | E2A/PBX1 (TCF/PBX1)  
EGFR  
EGFRvIII  
EGR-1 5q31 del  
EGR1/D5S23  
EML4  
ERG  
ETV1  
ETV6/RUNX1 (TEL/AML1) |
| F | FGFR1  
FGFR2  
FGFR3  
FGFR3-TACC3 |
| G | GNA11  
GNAQ |
| H | HER2  
HER3  
Heregulin  
Hyperdiploidy |
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BIOMARKERS

NAMES I–P

I

i(17q) or t(17p)
ider(22)(q10)t(14;22)(q34;q11)
IDH1
IDH2
idic(X)(q13)
IGFIR
IGFR-1
IGH/CCND1 t(11;14)
IGH/CCND3
IGH/FGFR3 t(4;14)
IGH/MAF t(14;16)
IGH/MAFB
IGH/MALT1 t(14;18)
IKZF1
inv(3)(3q21q26.2)
inv(16)
isochromosome 17

K

KEAP1
KIF5B
KIT
KRAS

L

LKB1

M

MAGEA3
MAP3K1
MCL1
MDM2/CEP12
MEK
MEK1
MGMT
MLL
MLL Rearrangements 11q23
Monosomy 7
Monosomy 7 or 7q del
MUC1
MYB
MYB 6q23
MYC
MYF11/CBFB inv(16) or t(16;16)

N

NF1
NFE2L2
NKX3.1
NRAS
NTRK

P

p53
p53 17p13.1
PD-1/PDL-1
PDGFRA
PDGFRB
PDGFRB Rearrangements
PIK3CA
PML/RARA t(15;17)
PRAME
PTEN
### BIOMARKERS

#### NAMES Q-Z

<table>
<thead>
<tr>
<th>R</th>
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<tbody>
<tr>
<td>RET</td>
<td>t(3;v)</td>
<td>ZNF217</td>
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<tr>
<td>ROS1</td>
<td>t(8;14) IGH/MYC</td>
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<td>RPN1/MECOM inv(3) or t(3;3)</td>
<td>t(8;21)</td>
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<td>RREB1</td>
<td>t(8;v) Myc Rearrangements</td>
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<td>RUNX1/RUNX1T1 t(8;21)</td>
<td>t(9;11)(p22;q23)</td>
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# BIOMARKERS

**DISEASE STATES A–B**

## ACUTE LYMPHOCYTIC LEUKEMIA
- BCR/ABL t(9;22)
- c-Myc Rearrangements t(8;14), t(2;8), t(8;22)
- CRLF2
- E2A/PBX1 (TCF/PBX1)
- ETV6/RUNX1 (TEL/AML1)
- IKZF1
- MLL Rearrangements 11q23
- PDGFRB Rearrangements
- Trisomy of 4, 7, or 17

## ACUTE MYELOID LEUKEMIA
- BCR/ABL t(9;22)
- CBFB Break Apart
- D5S721
- D7S486
- DEK/NUP214
- deletion 7q31 (D7S552)
- EGR1/D5S23
- EGR-1 5q31 del
- Monosomy 7
- MLL Rearrangements 11q23
- MYF11/CBFB inv(16) or t(16;16)
- PML/RARA t(15;17)
- RPN1/MECOM inv(3) or t(3;3)
- RUNX1/RUNX1T1 t(8;21)
- t(9;11)(p22;q23)
- t(10;11)(p12;q23)
- Trisomy 8

## BILIARY
- MCL1

## BLADDER
- AURKA
- FGFR3
- FGFR3-TACC3
- HER2
- TSC1

## BRAIN
- cMET
- EGFR
- PIK3CA

## BREAST
- AKT
- Androgen Receptor (AR)
- CCND1
- CKS1B
- cMET
- FGFR1
- FGFR2
- HER2
- IGFIR
- MAP3K1
- PIK3CA
- PTEN
- TOP2A
- TP53
- ZNF217
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BIOMARKERS
DISEASE STATES C–K

CERVICAL
- TERT

CHRONIC LYMPHOCYTIC LEUKEMIA
- 13q14.3
- ATM 11q22.3
- c-MYC 8q24
- D13S319/CEP12
- IGH/CCND1 t(11;14)
- IGH/MALT1 t(14;18)
- MYB 6q23
- p53 17p13.1
- TP53/ATM
- Trisomy 12

COLORECTAL
- AKT
- ALK
- BRAF
- cMET
- DCC
- KRAS
- NRAS
- NTRK
- PIK3CA
- PTEN
- ROS1
- SMAD4

CHRONIC MYELOGENOUS LEUKEMIA
- BCR/ABL
- ider(22)(q10)t(9;22)(q34;q11)
- isochromosome 17
- Monosomy 7 or 7q del
- Trisomy 8

DIFFUSE LARGE B-CELL LYMPHOMA
- BCL6 (3q27) Rearrangements
- CCND1 (11q13) Rearrangements
- t(3;\gamma)
- t(8;14) IGH/MYC
- t(8;\gamma) Myc Rearrangements
- t(14;18) IGH/MALT

GASTRIC
- BRAF
- cKIT
- cMET
- HER2
- PDGFRA

GLIOBLASTOMA
- BRAF
- EGFR
- EGFRvIII
- IDH1
- IDH2
- KIT
- MGMT
- PDGFRA
- PTEN

KIDNEY
- cMET
- PIK3CA
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**LEUKEMIA**
- BCL2
- CDK6
- MCL1
- MLL
- TP53

**LUNG**
- ACTN4
- ALK
- AXL
- BRAF
- cMET
- DDR2
- EGFR
- EGFRvIII
- EML4
- FGFR1
- FGFR2
- FGFR3-TACC3
- HER2
- HER3
- Heregulin
- IGF1R
- KEAP1
- KIF5B
- KRAS

**LUNG cont.**
- LKB1
- MAGEA3
- MEK1
- NF1
- NFE2L2
- NRAS
- NTRK
- PD-1/PDL-1
- PIK3CA
- PRAME
- PTEN
- RET
- ROS1

**LYMPHOMA**
- TCR-B

**MELANOMA**
- BRAF
- CCND1
- cKIT
- COT
- CRAF
- GNA11
- GNAQ
- IGFR-1
- KRAS
- MAGEA3
- MEK
- MYB
- NF1
- NRAS
- p53
- PDGFRB
- PTEN
- RREB1

**DISEASE STATES L–Me**
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MULTIPLE MYELOMA
- c-MYC 8q24
- D5S23/D5S721 CEP 9
- IGH/CCND1 t(11;14)
- IGH/CCND3
- IGH/FGFR3 t(4;14)
- IGH/MAF t(14;16)
- IGH/MAFB
- Hyperdiploidy
- p53 17p13.1

MYELODYSPLASTIC SYNDROME
- CEBPE
- D7S486
- del(5q)
- del(7q)
- del(9q)
- del(13q)
- EGR1/D5S23
- t(17q) or t(17p)
- idic(X)(q13)
- inv(3)(3q21q26.2)
- inv(16)
- t(8;21)
- t(15;17)
- PDGRFB Rearrangements

OVARIAN
- BRAF
- BRCA1
- BRCA2
- cMET
- KRAS
- MUC1
- PIK3CA
- PTEN

PROSTATE
- AR
- ERG
- ETV1
- IGF1R
- MYC
- NNX3.1
- PTEN

SARCOMAS
- MDM2/CEP12

DISEASE STATES M–Z
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QUALITY

ABBOTT MOLECULAR INCORPORATES A TOTAL PRODUCT LIFE CYCLE (TPLC) APPROACH FOR IVD DEVICE DEVELOPMENT

Quality is Maintained and Monitored Throughout the Product Life Cycle

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

LEARN MORE

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

QUALITY

TPLC

01 DESIGN

02 ANALYTICAL EVALUATION

03 CLINICAL EVALUATION

04 QUALITY SYSTEMS 21CFR §820

05 POSTMARKET SURVEILLANCE

PREMARKET

POSTMARKET

COMPLIANCE

APPROVAL/CLEARANCE

DESIGN

ANALYTICAL EVALUATION

CLINICAL EVALUATION

QUALITY SYSTEMS 21CFR §820

POSTMARKET SURVEILLANCE

PREMARKET

COMPLIANCE

APPROVAL/CLEARANCE
SYNCHRONIZING DEVELOPMENT

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ACCELERATED APPROVAL

As Pfizer was developing XALKORI® (crizotinib) for the treatment of ALK-positive non-small cell lung cancer, Abbott was simultaneously developing the Vysis ALK Break Apart FISH Probe Kit. Through our coordinated efforts, we were able to achieve simultaneous PMA approval for the XALKORI® NDA and the Vysis ALK test on August 26, 2011—in only 4.9 months.

The drug and diagnostic test were made available on August 29, 2011. NCCN guideline inclusion occurred in 2011, with CAP/AMP/IASLC in 2011 and 2012.

See how a typical IVD development timeline can be consolidated if accelerated approval is possible.
Typical IVD Development Timeline Scenario
Changes Dramatically if Accelerated Approval is Possible

See how this consolidation translated into the timeline for the Vysis ALK test.
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Drug Accelerated Approval, if Granted, Requires a Similar Compressed IVD Development Timeline

1H YR1 2H YR1 1H YR2 2H YR2 1H YR3 2H YR3 1H YR4
- Start-Up - Start-Up - Technical Performance Verification Studies
- Start-Up - Start-Up - Software - System Validation
- Core System Platform
- Start-Up - Software - System Validation
- Core System Platform

Module 1 (Analytical)

Start-Up - Clinical Reproducibility Study

Module 2 (Clinical Repro.)

Clinical Accuracy Study

Research Lots - 3 Pilot Lots - 3 Standardized Lots - Process Validation

Uncontrolled Trial (Phase II)

3 Pilot Lots - Process Validation

Randomized, Controlled Trial (Phase III)

Module 3 (CMC)

Module 4 (Clinical Utility)

NDA Submission

PMA Submission Approval in ~18 mos.
ACCELERATING ACCESS TO PATIENT RESULTS

ABBOTT IS PARTNERED WITH BIOVIEW TO DEVELOP AND DELIVER AUTOMATED FISH SOLUTIONS TO THE GLOBAL MARKET

• Secure, web-based enumeration decreases physician review time
• Simplified physician review from any remote location
• Scalable systems support varying workloads from clinical trials to clinical practice

See how next generation testing can accelerate access to patient results: BioView
See how simplified, standardized multiplex testing can improve global access to diagnostics: Idylla

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To schedule a meeting to review your needs or discuss our biomarker pipeline, contact Abbott Molecular today.
At Abbott Molecular, we embrace the next generation of innovative solutions that have the potential to bring testing closer to the patient. Our goal is to deliver streamlined, standardized molecular diagnostics that can be run routinely, reproducibly and accurately in any lab around the world.

By combining the power of emerging technology with our scientific expertise, we are working to redefine the standards of patient care tomorrow. And that makes everyone smile.

MOST MOLECULAR ONCOLOGY BIOMARKER TESTS ARE SENT OUTSIDE OF HOSPITALS TO CENTRALIZED FACILITIES

80% of all oncology patients are treated locally

90% of molecular testing is sent to an external lab

See how next generation testing can accelerate access to patient results: BioView

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A Typical Sample-to-Result Workflow

**Turnaround time for results back to physicians can be longer than 2 weeks**

- **Tissue embedding**
- **Biopsy**
- **Administration of sample and entry into LIM system**
- **Transportation of sample to centralized lab**
- **WEEKEND**
- **Pathologist review and macrodissection (as required)**
- **WEEKEND**
- **PCR run of BRAF samples**
- **Pathologist review**
- **Report is emailed to oncologist**
- **Patient is informed about his/her eligibility for treatment**

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A Typical Sample-to-Result Workflow

Idylla™ can shorten turnaround time by 50% or more

- Tissue embedding
- Biopsy
- Administration of sample and entry into LIM system
- Pathologist review and macrodissection (as required)
- Pathologist review
- Administration of sample and entry into LIM system
- Pathologist review and macrodissection (as required)
- Report is emailed to oncologist
- PCR run of BRAF samples
- Pathologist review
- Report is emailed to oncologist
- Pathologist review
- Pathologist review and macrodissection (as required)
- Transportation of sample to centralized lab
- Day 0
- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15

WEEKEND

- Patient is informed about his/her eligibility for treatment
- Patient is informed about his/her eligibility for treatment
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ABBOTT-BIOCARTIS PARTNERSHIP

ABBOTT MOLECULAR AND BIOCARTIS HAVE JOINED FORCES TO DEVELOP BIOMARKER PANEL TESTING FOR COMPANION DIAGNOSTICS

- The streamlined, standardized workflow of Idylla™ enables local testing around the globe, bringing testing closer to the patient and decreasing time to results
- Abbott Molecular will co-develop with Biocartis and globally commercialize CDx products on Idylla

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IDYLLA™: STANDARIZING MDx TESTING
ONE SAMPLE—ALL REAGENTS ON BOARD—MULTIPLE MARKERS

SAMPLE IN
- Tissue (including FFPE)
- Feces
- Sputum/BAL
- Swabs
- Urine

RESULT OUT
- Multiplexed: up to 30 targets/test*
- Qualitative or quantitative results
- Rapid results
*In standard mode; more with HRM

SAMPLE LIQUEFACTION → CELL LYSIS → DNA/RNA EXTRACTION → AMPLIFICATION/DETECTION → DATA ANALYSIS

SAMPLE IN
- Tissue (including FFPE)
- Feces
- Sputum/BAL
- Swabs
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RESULT OUT
- Multiplexed: up to 30 targets/test*
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DATA ANALYSIS

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INCREASING THE VELOCITY OF THERAPEUTIC UPTAKE
POISED ON THE BRINK OF SOMETHING BIG

Changing established medical practice doesn’t happen overnight. It requires connecting a complex network of stakeholders, each with unique needs and demanding expectations.

Abbott Molecular delivers the resources to get the job done: dedicated reimbursement and market access expertise…350+ global commercial team members…and the knowledge and experience to help drive commercial success.

TOGETHER... we will CHANGE medical PRACTICE.
TOGETHER... we can CHANGE people’s LIVES.

PARTNERSHIPS
Abbott currently has active CDx programs with 12 pharmaceutical partners. This is what they are saying:

“Abbott Molecular has been very flexible, but I also like how they push back when needed—for instance, to ensure study design and the integrity of the filing is maintained.”

“We have frank and honest conversations between the team members. The group is very collaborative and solution oriented.”

See what commercial success looks like

See what partnership success looks like

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Increasing the Velocity of Therapeutic Uptake

Posed on the Brink of Something Big

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Together... we can change people’s lives.

LEARN MORE

See what partnership success looks like
See what commercial success looks like

Ready to take your program to the next level? To schedule a meeting to review your needs or discuss our biomarker pipeline, contact Abbott Molecular today.

COMMERCIALIZATION SUCCESSES

THE VYSIS ALK BREAK APART FISH PROBE KIT

• The first FDA-approved test for identification of ALK gene rearrangements
• Developed as the global clinical trial test used to identify patients for XALKORI® (crizotinib) lung cancer treatment in Phase II and Phase III clinical trials
• 2014 NCCN guidelines upgraded ALK testing to the highest recommendation; Vysis ALK listed in CAP/IASLC/AMP NSCLC guidelines
• The Vysis ALK test is now registered in 72 countries

MATT ELLEFSON:
Read about his journey on RichardsStory.com
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TOGETHER...
we can CHANGE people’s LIVES.

COMMERICALIZATION SUCCESSES

THE PATHVYSION HER-2 DNA PROBE KIT

• The first FDA-approved, gene-based companion diagnostic test (1998)
• Developed as the test of record in the pivotal HERCEPTIN® (trastuzumab) breast cancer trials
• Current guidelines recommend testing for HER2 using an FDA-approved assay
• PathVysion is an accurate, reproducible and precise predictor of HER2 expression in routine diagnostic laboratories

ROSEANN KOLB:
Read about her journey on RichardsStory.com

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See what commercial success looks like