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?

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LEARN MORE
See how Abbott's technologies can benefit your approach
ABBOTT MOLECULAR SUPPORTS YOUR VISION, EVERY STEP OF THE WAY.

The choice is clear. An Abbott Molecular partnership can help you deliver successful outcomes.
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SYNCHRONIZING DEVELOPMENT

FRESH PERSPECTIVES CAN OFFER A NEW OUTLOOK ON LIFE

As the paradigm of healthcare is evolving, companion diagnostics plays an increasingly important role in Rx development and eventual commercial success. The growing number of partnerships in this space is giving rise to new development models—each with its own potential…and potential implications.

Navigating this challenging environment requires experience, strategy and agility. And that’s where Abbott Molecular shines. Whether you need help with simultaneous global regulatory submissions or guidance with compressing timelines to meet accelerated project goals, we deliver the insights and trusted leadership you seek.

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See how Abbott worked with Pfizer to accelerate approval of ALK gene testing

SYNCHRONIZING
DEVELOPMENT

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ENABLING MEASURABLY BETTER HEALTHCARE PERFORMANCE

HE HAS EVERY REASON IN THE WORLD TO SMILE

At Abbott Molecular, we embrace the next generation of innovative solutions that enable the lab to deliver measurably better healthcare performance. 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 test turnaround time can impact patient care

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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. PCR-Based Technology
   - Mutation detection
   - Gene expression
   - Multiplex panels
   - Gene rearrangements

2. Fluorescence in Situ Hybridization (FISH)
   - DNA copy number changes, deletions, translocations
   - Quantitative RNA FISH
   - Multiplex FISH (7+ colors)
   - Automated enumeration and imaging

3. Nucleic Acid Extraction

4. Circulating Free DNA (cfDNA)

5. Circulating Tumor Cells
BUILDING ON BIOMARKERS

ABOTT MOLECULAR OFFERS ACCESS TO A COMPREHENSIVE ROSTER OF BIOMARKERS THAT MAY BE USED IN THE DEVELOPMENT OF COMPANION DIAGNOSTICS

Browse by Names:
- A–H
- I–P
- Q–Z

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

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BUILDING ON BIOMARKERS INSPIRED TO CHART NEW COURSES

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BIOMARKERS NAMES A–H

A

13q14.3
ACTN4
AKT
ALK
Androgen Receptor (AR)
AR
ATM 11q22.3
AURKA
AXL

B

BCL2
BCL6
BCL6 (3q27) Rearrangements
BCR/ABL
BCR/ABL t(9;22)
BRAF
BRCA1
BRCA2

C

c-MYC 8q24
CBFB Break Apart
CCND1
CCND1 (11q13) Rearrangements
CDK6
CDKN2A
CDKN2C
CEBPE
CEP9
Chromosome 3
Chromosome X
Ckit

D

D5S23
D5S23/D5S721 CEP 9
D5S721
D7S486

D cont.

D13S319/CEP12
DCC
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
ERBB3
ERG
ETV
ETV1
ETV6/RUNX1 (TEL/AML1)

F

FGFR1
FGFR2
FGFR3
FGFR3-TACC3

G

GNA11
GNAQ

H

H3F3A
HER2
HER3
Heregulin
HOX11L2/TLX3
Hyperdiploidy
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BIOMARKERS

NAMES I–N

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**BIOMARKERS**

**NAMES P-Z**

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### ACUTE LYMPHOBlastic LEUKEMIA
- iAMP21
- TAL1/STIL
- TLX3/BCL11B

### ACUTE LYMPHOCYTIC LEUKEMIA
- BCR/ABL t(9;22)
- CRLF2
- E2A/PBX1 (TCF/PBX1)
- ETV6/RUNX1 (TEL/AML1)
- HOX11L2/TLX3
- IKZF1
- MLL Rearrangements 11q23
- MYC Rearrangements t(8;14), t(2:8), t(8;22)
- NUP98/RAP1GDS1
- 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
- IDH1
- IDH2
- MLF1
- MLL Rearrangements 11q23
- Monosomy 7
- MYF11/CBFB inv(16) or t(16;16)
- MYST3/CREBBP
- NPM1
- NUP98
- 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)
- TERT
- Trisomy 8

### ALZHEIMER’S DISEASE
- PICALM

### BILIARY
- EGFR
- IDH1
- MCL1

### BLADDER
- AURKA
- CDKN2A
- ERBB3
- FGFR3
- FGFR3-TACC3
- HER2
- PIK3CA
- TSC1

### BRAIN
- cMET
- EGFR
- p53
- PIK3CA

### BREAST
- AKT
- Androgen Receptor (AR)
- CCND1
- CKS1B
- cMET
- FGFR1
- FGFR2
- HER2
- IGF1R
- IGFR-1
- JAK2
- MAP3K1
- MET
- p53
- PD-1/PD-L1
- PIK3CA
- PTEN
- TERT
- TOP2A
- TP53
- ZNF217
## BIOMARKERS
### DISEASE STATES C–K

### CERVICAL
- Chromosome 3
- Chromosome X
- DSS23
- DSS721
- TERC

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

### COLORECTAL
- AKT
- ALK
- BRAF
- MET
- DCC
- FGFR2
- IGFR-1
- KRAS
- NRAS
- NTRK1/2/3
- PIK3CA
- PTEN
- ROS1
- SMAD4

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

### GASTRIC
- BRAF
- cKIT
- HER2
- MET
- FGFR2
- PDGFRA

### GLIOBLASTOMA
- BRAF
- EGFR
- EGFRvIII
- H3F3A
- IDH1
- IDH2
- KIT
- MGMT
- PDGFRA
- PIK3RI
- PTEN

### CHRONIC MYELOGENOUS LEUKEMIA
- BCR/ABL
- 1dεr(22)(q10)t(9;22)(q34;q11)
- isochromosome 17
- Monosomy 7 or 7q del
- Trisomy 8

### KIDNEY
- cMET
- PIK3CA
**BIOMARKERS**

**DISEASE STATES L–Me**

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**BIOMARKERS**

**DISEASE STATES L–Me**

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<td>IGF1R</td>
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<td>MYB</td>
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<td>MET</td>
<td>TCR-B</td>
<td>MYB</td>
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<td>NFE2L2</td>
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<td>NTRK1/2/3</td>
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<td>RREB1</td>
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<td>PIK3CA</td>
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<td>PRAME</td>
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<td>TP53</td>
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<td>FGFR3-TACC3</td>
<td>PTEN</td>
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<td></td>
<td>RET</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>ROS1</td>
<td></td>
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</tbody>
</table>
## BIOMARKERS

**DISEASE STATES Mu–Z**

### MULTIPLE MYELOMA
- c-MYC 8q24
- CDKN2C
- CEP9
- CKS1B
- D5S23/D5S721 CEP 9
- IGH/CCND1 t(11;14)
- IGH/CCND3
- IGH/FGFR3 t(4;14)
- IGH/MAF t(14;16)
- IGH/MAFB
- IGFR-1
- Hyperdiploidy
- MYC
- TP53

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

### OVARIAN
- BRAF
- BRCA1
- BRCA2
- MET
- KRAS
- MUC1
- PIK3CA
- PTEN

### PROSTATE
- AR
- AURKA
- ERG
- ETV1
- FGFR1
- IGFIR
- IGFR-1
- MDM2
- MYC
- NKX3.1
- PTEN

### SARCOMAS
- ETV
- IDH1
- IDH2
- MDM2/CEP12
- p53
BUILDING ON BIOMARKERS

Every journey has a beginning, and yours starts here—with your early-stage clinical trials. Your therapy may hold the promise of exceptional outcomes, so long as you target the right patients.

At Abbott Molecular, we’re here to help set the path for remarkable change. We offer flexible partnership options appropriate for this stage of the game. Should positive data emerge, we can leverage the framework we’ve established in this early work to smoothly transition to the next stage, supporting your journey from beginning to end.

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.

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

QUALITY
01 DESIGN
02 ANALYTICAL EVALUATION
03 CLINICAL EVALUATION
04 QUALITY SYSTEMS 21CFR §820
05 POSTMARKET SURVEILLANCE

PREMARKET
APPROVAL/CLEARANCE
COMPLIANCE
POSTMARKET

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

See how we leverage biomarkers for discovery and development
See how we incorporate quality into your project from Day One

LEARN MORE

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SYNCHRONIZING DEVELOPMENT
FRESH PERSPECTIVES CAN OFFER A NEW OUTLOOK ON LIFE

As the paradigm of healthcare is evolving, companion diagnostics plays an increasingly important role in Rx development and eventual commercial success. The growing number of partnerships in this space is giving rise to new development models—each with its own potential…and potential implications.

Navigating this challenging environment requires experience, strategy and agility. And that's where Abbott Molecular shines. Whether you need help with simultaneous global regulatory submissions or guidance with compressing timelines to meet accelerated project goals, we deliver the insights and trusted leadership you seek.

READY TO TAKE YOUR PROGRAM TO THE NEXT LEVEL?
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LEARN MORE
See how Abbott worked with Pfizer to accelerate approval of ALK gene testing

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.
As the paradigm of healthcare is evolving, companion diagnostics plays an increasingly important role in Rx development and eventual commercial success. The growing number of partnerships in this space is giving rise to new development models—each with its own potential…and potential implications. Navigating this challenging environment requires experience, strategy and agility. And that's where Abbott Molecular shines. Whether you need help with simultaneous global regulatory submissions or guidance with compressing timelines to meet accelerated project goals, we deliver the insights and trusted leadership you seek.

See how Abbott worked with Pfizer to accelerate approval of ALK gene testing.

Typical IVD Development Timeline Scenario
Changes Dramatically if Accelerated Approval is Possible

<table>
<thead>
<tr>
<th>1H YR1</th>
<th>2H YR1</th>
<th>1H YR2</th>
<th>2H YR2</th>
<th>1H YR3</th>
<th>2H YR3</th>
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<td>System Validation</td>
<td>Core System Platform</td>
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<td>Start-Up</td>
<td>Clinical Trial</td>
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PMA Submission Approval in ~18 mos.

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

<table>
<thead>
<tr>
<th>1H YR1</th>
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<th>1H YR2</th>
<th>2H YR2</th>
<th>1H YR3</th>
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<td>Module 2 (Clinical Repro.)</td>
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<td>Module 3 (CMC)</td>
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<td>3 Pilot Lots</td>
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<td>Module 3 (CMC)</td>
<td>Module 4 (Clinical Utility)</td>
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<tr>
<td>1H YR1</td>
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<td>2H YR3</td>
<td>1H YR4</td>
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</table>

PMA Submission Approval in ~18 mos.
At Abbott Molecular, we embrace the next generation of innovative solutions that enable the lab to deliver measurably better healthcare performance. 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.

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 test turnaround time can impact patient care

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.
CANCER DIAGNOSIS IS BASED ON CELL STRUCTURE: MULTIPLE TECHNOLOGIES AVAILABLE FOR ASSESSMENT OF LUNG CANCER

- Hematoxylin and Eosin (H&E)
- In Situ Hybridization FISH (Fluorescence In Situ Hybridization)
- Immunohistochemistry (IHC)
- Quantitative (Real-Time) PCR
- Next Generation Sequencing (NGS)

Source: Cancer Treatment Centers of America; American Lung Association; Lung Cancer Mutation Consortium
**TURNAROUND TIME FOR TEST RESULTS IS OFTEN SUB-OPTIMAL, EXTENDING TIME TO TREATMENT DECISIONS**

<table>
<thead>
<tr>
<th>Working Days</th>
<th>Actual Days</th>
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</tbody>
</table>

- **Sample acquisition and test results**
- **Histological diagnosis determined**
- **Samples sent for biomarker testing (within three working days)**
- **Result received**
  - PD-L1
  - ROS1
  - ALK
- **Result received**
- **Physician reviews results**
- **MDT discuss results and treatment strategy**
- **EGFR result received**

**Source:** Ruggiero 2017 ASCO Quality Care Symposium abstract #212
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ENABLING 
MEASURABLY BETTER

HOW DO LABS BALANCE THE NEEDS OF THE PATIENT WITH TESTING REQUIREMENTS, TAT, AND COSTS?

- Guidelines recommend lung MDx testing be completed in two weeks
- Reflex testing is acceptable to a point but may increase TAT
- Some labs run EGFR PCR and ALK FISH five days a week to meet TAT requirements
- Labs may have issues/concerns about reimbursement of NGS or reimbursement for multiple tests per patient


LEARN MORE
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See how test turnaround time can impact patient care

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ENABLING MEASURABLY BETTER HEALTHCARE PERFORMANCE

HE HAS EVERY REASON IN THE WORLD TO SMILE

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AN INCREASING NUMBER OF LABS REPORT PARALLEL MDx TESTING FOR LUNG CANCER TO ENABLE PHYSICIANS TO BEST GUIDE CARE DECISIONS

Abbott Molecular proposed model, NGS Ad Board July 2018
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 MULTIPLE 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.”

PAST AND PRESENT PARTNERS

abbvie agios
AstraZeneca Celgene NOVARTIS
Pfizer Xcovery
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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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COMMERCIALIZATION 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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