Ordering an ALK test to identify patients for Xalkori® (crizotinib)

FISH testing alone for ALK has been found to be more cost-effective than IHC-testing alone.

The Vysis ALK Break Apart FISH Probe Kit is designed to ensure that the correct locus is identified.

Ordering Information

<table>
<thead>
<tr>
<th>Product</th>
<th>List number</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vysis ALK Break Apart FISH Probe Kit</td>
<td>06N38-020</td>
<td>20 assays</td>
</tr>
<tr>
<td>Vysis Paraffin Pretreatment IV &amp; Post-hybridization Wash Buffer Kit</td>
<td>01N31-005</td>
<td>1 kit</td>
</tr>
<tr>
<td>Vysis ProbeCheck ALK Negative Control Slides</td>
<td>06N38-005</td>
<td>5 slides</td>
</tr>
<tr>
<td>Vysis ProbeCheck ALK Positive Control Slides</td>
<td>06N38-010</td>
<td>5 slides</td>
</tr>
</tbody>
</table>

Abbott Molecular is committed to providing comprehensive training and support

- Training in specimen preparation, assay procedure, and interpretation of FISH testing of ALK gene rearrangements is available for inexperienced users
- Training in interpretation of the Vysis ALK FISH test is recommended for all laboratories
- Visit [AbbottMolecular.com](http://AbbottMolecular.com) and select Scientific Innovative Resources in the Support section of the website to watch “Evaluation of ALK Rearrangements by FISH in FFPE NSCLC Specimens” and learn more from leading experts.

If you have questions or would like to order an enumeration guide, call Abbott Molecular Customer Support at 1-855-TEST-ALK or visit our websites, at AbbottALK.com and AbbottMolecular.com.

ALK Enumeration Guide

For use with Vysis ALK FISH Probe Kit.

Let the patient’s signal guide the need for therapy

- Companion diagnostic for XALKORI® (crizotinib)
- NEW NSCLC Guidelines include ALK testing at diagnosis
- NEW health economics outcomes research available


The Vysis ALK Break Apart FISH Probe Kit and other multiple direct label DNA FISH probe products are covered by U.S. Patents 5,663,319 and 5,491,224 assigned to Abbott Molecular. Vysis LSI direct label fluorescence probe are covered by U.S. Patents RE40,494, 6,596,479, 7,115,709, 5,756,696 and 6,607,877, 6,280,929 exclusively licensed to Abbott Molecular Inc. by The Regents of the University of California. Methods of detecting multiple hybridization signals simultaneously is covered by U.S. Patent 6,203,977, exclusively licensed to Abbott Molecular Inc., by Yale University.

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ALK gene rearrangements define unique NSCLC tumor biology

- ALK gene rearrangements involve a gene fusion between ALK and the promoter region of another gene.
- ALK can partner with several genes, including EML4, TFG, KIF5B, and KCL1.
- Breakpoints in EML4 can vary, while the breakpoint in ALK is consistent.

Early FISH testing at diagnosis can determine appropriate ALK-directed therapy

- Optimal performance of this test requires appropriate specimen handling, preparation, and storage, as described in the instructions for use.

Major guidelines recognize FISH as the current standard for detecting ALK rearrangements

Non-small-cell lung cancer (NSCLC) Guidelines

- NCCN Guidelines™ for NSCLC†
  - Include ALK testing concurrently with EGFR mutation testing for diagnosing the following NSCLC historical subtypes: adenocarcinomas, large cell carcinomas, and NOS.
  - State that a new molecular diagnostic test that uses fluorescence in situ hybridization (FISH) has been approved by the FDA to determine which patients with NSCLC are positive for ALK rearrangements.

- CAP/JASCL/AMP Guidelines§
  - Recommend that ALK testing be ordered at the time of diagnosis for advanced-stage patients.
  - Recommend ALK testing for initial therapy selection.
  - State that laboratories should use an ALK-FISH assay using dual-labeled break-apart probes for selecting patients for ALK tyrosine kinase inhibitor (TKi) therapy.

- Efficacy Results

  - The Vysis ALK Break Apart FISH Probe Kit has been optimized only for identifying and quantifying rearrangements of the ALK gene from formalin-fixed, paraffin-embedded human NSCLC tissue specimens. The assay should be performed only on 10% neutral buffered FFPE human lung cancer tissue. Other types of specimens or fixatives should not be used.
  - The performance of the Vysis ALK Break Apart FISH Probe Kit was established using the procedures provided in the assay package insert only. Modifications to the procedures may alter the performance of the assay.
  - FISH assay results may not be informative if the specimen quality and/or specimen skills preparation is inadequate.

Caution

- United States federal law restricts this device to sale and distribution to or on the order of a physician or to a clinical laboratory, and use is restricted to, by, or on the order of a physician.

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