# Consumer Information on: Vysis ALK Break Apart FISH Probe Kit, with the Vysis Paraffin Pretreatment IV and Post Hybridization Wash Buffer Kit, ProbeChek ALK Negative Control S...

U.S. Food & Drug Administration

**Product Name:** Vysis ALK Break Apart FISH Probe Kit, with the Vysis Paraffin Pretreatment IV & Post Hybridization Wash Buffer Kit, ProbeChek ALK Negative Control Slides, and ProbeChek ALK Positive Control Slides
**PMA Applicant:** Abbott Molecular, Inc.
**Address:** 1300 E. Touhy Ave., Des Plaines, IL 60018
**Approval Date:** August 26, 2011
**Approval Letter:** http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110012a.pdf [1]

**What is it?** Vysis ALK Break Apart FISH [2] Probe Kit is a laboratory test that uses DNA probes with attached fluorescent dyes to detect the presence of chromosomal rearrangements of the ALK gene [3], located on chromosome 2, in a non-small cell lung cancer (NSCLC) [4] tissue sample. If the test result indicates the presence of rearrangements [5] (such as translocation [6]) involving the ALK gene in the cancer cell, then a patient with NSCLC may be eligible for treatment with the cancer drug Xalkori® (crizotinib).

The Vysis Paraffin Pretreatment IV & Post Hybridization Wash Buffer Kit, ProbeChek ALK Negative Control Slides, and ProbeChek ALK Positive Control Slides are additional products that need to be used with the Vysis ALK Break Apart FISH Probe Kit.

Xalkori® is a drug used to treat patients with advanced (locally or metastatic) NSCLC who have a tumor with a specific molecular abnormality. Xalkori® selectively interferes with the ALK gene.  If the test result indicates that the patient's tumor is positive for ALK gene rearrangements, then the patient may benefit treatment with Xalkori®.

**How does it work?**

- The doctor takes a small sample from the patient’s lung cancer (biopsy).
- The sample is embedded in paraffin wax and a thin slice is cut and attached to a glass microscope slide.
- With special chemicals and heat treatment, an orange fluorescent-tagged DNA probe and green-fluorescent-tagged DNA probe bind to matching DNA adjacent to each other on the ALK gene. If no chromosome rearrangement has occurred, the probe signal will appear as adjacent orange and green

signals or a single yellow signal. If a chromosome rearrangement has occurred, the signal will break apart or appear as separate orange and green signals . If part of the gene has been removed, a single orange or green signal may be seen.
- A trained medical professional uses a fluorescence microscope to check the quality of the slide and to count the number of yellow, orange and green signals.
- The pathologist reviews the results and reports the findings to the ordering doctor.

**When is it used?** For NSCLC patients whose tumor characteristics suggest they might be candidates for Xalkori® therapy.

**What will it accomplish?** When used with other clinical information and laboratory tests, this test helps to determine if a patient with previously treated NSCLC is eligible for Xalkori® treatment which may prolong their life.

**When should it not be used?** No known contraindications.

**Additional information**: Summary of Safety and Effectiveness and labeling [7] are available online.

**Other Resources:**

- American Society for Pathology - Pathologist [8]

SOURCE [9]

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**Links:**
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110012a.pdf
[2] http://www.genome.gov/Glossary/index.cfm?id=65
[3] http://ghr.nlm.nih.gov/gene/ALK
[4] http://www.nlm.nih.gov/medlineplus/ency/article/007194.htm
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