

NEW TEST

NOTIFICATION DATE: February 27, 2017

EFFECTIVE DATE: April 4, 2017

ALK ON CYTOLOGY SPECIMENS, FISH
Test ID: FALKC

USEFUL FOR: Detection of rearrangements involving the *ALK* gene region at 2p23 in patients with non-small cell lung carcinoma who may benefit from treatment with the *ALK* inhibitor drugs, like Xalkori (Crizotinib), on previously stained routine cytology slides.

METHOD: Fluorescence In Situ Hybridization (FISH) using DNA Probes

REFERENCE VALUES: An interpretative report will be provided.

SPECIMEN REQUIREMENTS:

Submit a previously stained and cover slipped cytology slide from a cytology specimen that was fixed in ethanol- or methanol-based fixatives.

Slides: 1 slide

Additional Information: Processed slides will be retained by Mayo Medical Laboratories and will not be returned to the client.

Note: A quality specimen is essential for evaluation. A cytology slide less than 10 years in age and containing > or =100 non-overlapping tumor cells within an 18-mm area should meet quality standards.

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time	Special Container
Slide	Ambient (preferred)		SLIDE
	Refrigerated		SLIDE

CAUTIONS: This test is intended to be used for therapeutic purposes in pulmonary carcinoma. This FISH assay does not rule out other chromosome abnormalities.

While results may indicate the likely response to *ALK* inhibitor therapy, selection of treatment remains a clinical decision.

CPT CODE: 88377

DAY(S) SET UP: Monday through Friday; 8 a.m. - 5 p.m.

ANALYTIC TIME: 5 days

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Kristin Hickey, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710