

LAB ALERT – NEW TEST**NOTIFICATION DATE: 10/11/2013**
EFFECTIVE DATE: 11/14/2013**NSCLC GENOTYPING PANEL WITH REFLEX TO ALK BY FISH AND ROS1 BY FISH****TEST CODE:** MDFCPNSCLCREF**INTERFACE CODE:** 1004137**METHODOLOGY:** NSCLC Genotyping Panel (SNaPshot® and Triplex Sizing); ALK gene rearrangement (Fluorescence in situ hybridization); ROS1 gene rearrangement (Fluorescence in situ hybridization).**CLINICAL UTILITY:** This test is intended to be used for the mutational profiling of tumors from patients with Non-Small-Cell Lung Cancer in order to help prioritize and direct treatment. It may be useful for patients who have become refractory to prior therapies and are searching for investigational targeted therapies offered in clinical trials or for newly diagnosed patients who would like to know their mutational profile to inform treatment options with approved targeted therapies or for the identification of potential future clinical trials or future approvals of targeted therapies.**NOTES:** If NSCLC Genotyping Panel is reported as "Negative, no mutation detected," then ALK by FISH will be added. Additional charges apply. If ALK by FISH is reported as "Negative for ALK gene rearrangement," then ROS1 by FISH will be added. Additional charges apply.

ALK gene rearrangement by FISH is an FDA approved test.

NSCLC Genotyping Panel Components: AKT1 (p.E17K); BRAF (p.G466V, p.G469A, p.L597V, p.V600E); EGFR (p.G719C/S/A, p.T790M, p.L858R, p.L861Q, exon 19 deletions, exon 20 insertions); ERBB2/HER2 (exon 20 insertions); KRAS (all mutations in codons 12, 13, and 61); MEK (p.Q56P, p.K57N, p.D67N); NRAS (all mutations in codon 61); PIK3CA (p.E542K, p.E545K/Q, p.H1047R); PTEN (p.R233X).

PERFORMED:	NSCLC Genotyping Panel (Thursday); ALK gene rearrangement (Thursday); ROS1 gene rearrangement (Mon-Sat).
COLLECTION:	Tissue (see specimen preparation).
SPECIMEN PREPARATION:	Formalin-fixed paraffin-embedded tumor block or 6-10 FFPE slides accompanied by a circled H & E slide indicating area to be examined and most recent pathology report. Specimen to be tested must contain a minimum of 10 percent tumor.
STABILITY (FROM COLLECTION TO INITIATION OF TESTING)	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable.
TRANSPORT:	Formalin-fixed paraffin-embedded tissue block: Ambient or on ice pack in summer. Slides: Ambient.
REFERENCE RANGE:	An interpretive report will be provided.
RESULTS REPORTED:	NSCLC Genotyping Panel (8-15 days); ALK gene rearrangement (3-10 days); ROS1 gene rearrangement (3-7 days).
CPT CODE(S):	81235, 81210, 81403, 81275, 81479X6, if reflexed add 88365, 88291, if further reflexed add 88368.
PERFORMING LAB:	NSCLC Genotyping Panel (med fusion); ALK gene rearrangement (med fusion); ROS1 gene rearrangement (Knight Diagnostic Laboratories).

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