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Laboratory Bulletin

DATE:	2022 January 24
TO:	North Sector Clinicians, Pathologists and Technical Staff
FROM:	Cheryl Mather, Medical Lead, Molecular Pathology North
RE:	**New Molecular Test for Lung Adenocarcinoma Patients**

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Comprehensive NGS Testing of Lung Adenocarcinoma Patients in North Sector

Key Message

- As of January 31, 2022, all lung adenocarcinoma cases with requested molecular testing will undergo comprehensive next generation sequencing (NGS) using the Oncomine Focus Assay (Thermo Fisher Scientific). ALK and ROS1 immunohistochemistry will be discontinued as reflexive testing.

Background

- The number of actionable biomarkers in lung adenocarcinoma has exceeded the capacity of the clinical laboratory to test all markers in a sequential, single-gene fashion. The Oncomine Focus Assay is an NGS-based test that analyzes 52 cancer-relevant genes from patient DNA and RNA in a single workflow. The test has been validated for use for the testing of actionable mutations, copy number alterations and fusions in EGFR, BRAF, KRAS, ERBB2, ALK, ROS1, RET, MET, NTRK, and other genes in lung cancer with an overall sensitivity of more than 98%. When operational, this panel will replace current testing by Massarray and ALK and ROS1 immunohistochemistry.

  Genes evaluated for single nucleotide variants (SNVs) and small insertions/deletions (indels) in hotspot regions: AKT1, ALK, AR, BRAF, CDK4, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR2, FGFR3, GNA11, GNAQ, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, PDGFRA, PIK3CA, RAF1, RET, ROS1 and SMO.
  Genes evaluated for copy number alterations (CNA): ALK, AR, BRAF, CCND1, CDK4, CDK6, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, FGFR4, KIT, KRAS, MET, MYC, MYCN, PDGFRA, and PIK3CA.
  Genes evaluated for fusions: ABL1, AKT3, ALK, AXL, BRAF, EGFR, ERBB2, ERG, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, MET, NTRK1, NTRK2, NTRK3, PDGFRA, PPARG, RAF1, RET and ROS1.

How this will impact you

- As of January 31, 2022, orders for Lung Mutational Analysis will be performed using the Oncomine Focus Assay. The reflexive ordering of immunohistochemistry for ALK and ROS1 will be discontinued. Immunohistochemical testing for PD-L1 will continue to be offered.

Action Required

- Order lung mutational analysis testing as is currently done. The molecular pathology team will perform the assay and send slides for PD-L1 immunohistochemistry. Look for results in EPIC under the Lung Carcinoma Massarray template for now until an NGS reporting template is built.

Effective **January 31, 2022**

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Questions/Concerns

- Cheryl Mather, Medical Lead, Molecular Pathology North, 780-407-2717 / 2758 Cheryl.Mather@aplabs.ca
- Soufiane El Hallani, Scientific Lead, Molecular Pathology North, 780-613-5393 Soufiane.ElHallani@aplabs.ca

Approved by

- Imran Mirza, Provinical Medical Lead, Molecular Pathology Program