NOTICE DATE: August 28, 2017

EFFECTIVE DATE: August 30, 2017

NEW TESTS

Colorectal Cancer NGS Panel
Order Code: NGCRC
Fee Code: NA085, NA037
CPT Code: 81445, G0452-26, 88381-TC, 88381-26

Effective August 30, 2017 the MLabs Molecular Diagnostics Laboratory will transition to a new panel for colorectal cancer testing. The Colorectal Cancer NGS Panel test will replace the Comprehensive CRC Mutation Panel and contains additional content which now includes assessment of gene amplification, gene fusions, and an expanded number of gene mutations.

Molecular testing of colorectal cancer (CRC) is currently the standard of care for guiding the use FDA-approved targeted therapies such as anti-EGFR and anti-PDL1 antibodies. In addition, more investigational clinical actions are often employed for patients with advanced stage CRC including the use of FDA-approved drugs for an off-label indication and enrollment in clinical trials. This assay is designed to provide comprehensive molecular results relevant for both standard of care and emerging/investigational clinical actions. This DNA and RNA based, next-generation sequencing test targets 50 genes to detect substitution and insertion/deletion mutations (35 genes), gene amplifications (19 genes), and gene fusions (21 genes). Detectable variants relevant for CRC include, but are not limited to, mutations of KRAS, NRAS, BRAF, PIK3CA, and AKT1; amplification of ERBB2, FGFR1, KRAS, and MYC; and rearrangements of ALK. A complete list of sequenced regions, genes assessed for amplification, and detectable fusion transcripts will be available in MLabs online Clinical Test Catalog at https://www.pathology.med.umich.edu/handbook. Please note: Microsatellite instability testing is NOT included in this assay and must be ordered separately if clinically indicated.

Lung Cancer NGS Panel
Order Code: NGMEL
Fee Code: NA085, NA037
CPT Code: 81445, G0452-26, 88381-TC, 88381-26

Effective August 30, 2017 the MLabs Molecular Diagnostics Laboratory will transition to a new panel for lung cancer testing. The Lung Cancer NGS Panel test will replace the Comprehensive NSCLC Mutation Panel and contains additional content which now includes assessment of gene amplification, gene fusions, and an expanded number of gene mutations.

Molecular testing of non-small cell lung cancer (NSCLC) is currently the standard of care for guiding the use FDA-approved targeted therapies such as inhibitors of EGFR, ALK and ROS1. In addition, there is growing clinical evidence supporting the efficacy of other treatments such as BRAF and MEK inhibitors for BRAF V600E-mutated NSCLC, crizotinib for NSCLC with MET exon 14 skipping mutations or high level MET amplification, various tyrosine kinase inhibitors (TKI) for NSCLC with RET rearrangements and ERBB2 antibodies and TKI for NSCLC with ERBB2 mutations. The use FDA-approved drugs for an off-label indication, such as these, and enrollment in clinical trials based on molecular findings is an important aspect of the care of patients with advanced stage NSCLC. This assay is designed to provide
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comprehensive molecular results relevant for both standard of care and emerging/investigational clinical actions. This DNA and RNA based, next-generation sequencing test targets 50 genes to detect substitution and insertion/deletion mutations (35 genes), gene amplifications (19 genes), and gene fusions (21 genes). Detectable variants relevant for NSCLC include, but are not limited to, mutations of EGFR, KRAS, NRAS, BRAF, ERBB2, MET (including exon 14 skipping), MAP2K1, PIK3CA, AKT1, FGFR2, FGFR3, DDR2, ALK, ROS1 and RET; amplification of EGFR, FGFR1, ERBB2, KRAS, PIK3CA, and MYC; and rearrangements of ALK, ROS1, RET, NTRK1/2/3, BRAF, and FGFR3. A complete list of sequenced regions, genes assessed for amplification, and detectable fusion transcripts will be available in the MLabs online Clinical Test Catalog at https://www.pathology.med.umich.edu/handbook.

Melanoma NGS Panel
Order Code: NGMEL
Fee Code: NA085, NA037
CPT Code: 81445, G0452-26, 88381-TC, 88381-26

Effective August 30, 2017 the MLabs Molecular Diagnostics Laboratory will transition to a new panel for melanoma testing. The Melanoma NGS Panel test will replace the Comprehensive Melanoma Mutation Panel and contains additional content which now includes assessment of gene amplification, gene fusions, and an expanded number of gene mutations.

Molecular testing of metastatic melanoma is currently the standard of care for guiding the use FDA-approved targeted therapies such as BRAF, MEK and KIT inhibitors. In addition, more investigational clinical actions are often employed for patients with metastatic melanoma including the use FDA-approved drugs for an off-label indication and enrollment in clinical trials. This assay is designed to provide comprehensive molecular results relevant for both standard of care and emerging/investigational clinical actions. This DNA and RNA based, next-generation sequencing test targets 50 genes to detect substitution and insertion/deletion mutations (35 genes), gene amplifications (19 genes), and gene fusions (21 genes). Detectable variants relevant for melanoma include, but are not limited to, mutations of BRAF, NRAS, KIT, MAP2K1, CTNNB1, GNAQ and GNA11; amplification of CCND1 and KIT; and rearrangements of BRAF, NTRK1, ROS1, ALK and RET. A complete list of sequenced regions, genes assessed for amplification, and detectable fusion transcripts will be available in the MLabs online Clinical Test Catalog at https://www.pathology.med.umich.edu/handbook.

Solid Tumor NGS Panel
Order Code: NGSST
Fee Code: NA085, NA037
CPT Code: 81445, G0452-26, 88381-TC, 88381-26

The MLabs Molecular Diagnostics Laboratory will begin performing Solid Tumor NGS Panel testing effective Wednesday August 30, 2017.

Molecular testing of solid tumor neoplasms – particularly advanced-stage cancer – is currently the standard of care for indications such as guiding the use FDA-approved targeted therapies. In addition, more investigational clinical actions are often employed for patients with solid tumors including the use of FDA-approved drugs for an off-label indication and enrollment in clinical trials. This assay is designed to provide molecular results relevant for both standard of care and emerging/investigational clinical actions for solid tumor neoplasms. This DNA and RNA based, next-generation sequencing test targets 50 genes to detect substitution and insertion/deletion mutations (35 genes), gene amplifications (19 genes), and gene fusions (21 genes). A complete list of sequenced regions, genes assessed for amplification, and detectable fusion
transcripts will be available in the MLabs online Clinical Test Catalog at [https://www.pathology.med.umich.edu/handbook](https://www.pathology.med.umich.edu/handbook).

Collection Instructions for all new NGS Panels: For formalin-fixed, paraffin-embedded tissue, a block containing an area with a high percentage of neoplastic cells (for micro-/macro-dissection) is preferred. Unstained, UNBAKED slides (5-8, 10-micron slides; 10-15 if few neoplastic cells are present) with associated H&E stained slide are also acceptable. Decalcified tissue or other fixatives will be accepted and the assay attempted, however these may result in failed testing due to degraded nucleic acid. Both blocks and slides should be stored at room temperature. A Diff-Quik or Papanicolaou stained aspirate smear (preferable containing a high percentage and overall amount of neoplastic cells) is also acceptable. Store at room temperature.

**EFFECTIVE DATE:** August 24, 2017

**TEST DOWN**

**Fluoxetine, Serum**
Order Code: FLX  
Fee Code: 20064  
Reference Laboratory: Mayo FLUOX (80228)

Due to assay performance issues Mayo Medical Laboratories Fluoxetine assay is down effective August 24, 2017. Requests for this test will be forwarded to MedTox Laboratories test 225 (Mayo test FLUPR) until further notice.

Collection Instructions: Collect specimen in a red top tube; do not use SST tube. Centrifuge, aliquot 2 mL (minimum 0.5 mL) of serum into a plastic vial and refrigerate.

Reference Range: 120 - 500 ng/mL (Fluoxetine + Norfluoxetine)

**EFFECTIVE DATE:** August 24, 2017

**REFERENCE RANGE CHANGES**

Please note the following revised reference ranges effective August 24, 2017:

**Thallium, Blood**
Order Code: TL-B  
Fee Code: 32112  
Reference Laboratory: Mayo TLB (8149)

Reference Range: Age 0-17 years: not established; age >or= 18 years: <2 ng/mL.
Thallium, Urine
Order Code: TL-U
Fee Code: 32113
Reference Laboratory: Mayo TLU (8603)

Reference Range: Age 0-17 years: not established; age ≥ 18 years: <2 mcg/24 hour.

EFFECTIVE DATE: September 5, 2017

REFERENCE LABORATORY CHANGE

Adalimumab and Adalimumab Antibodies
Order Code: FAAAB
Reference Laboratory: Mayo FAAAB (Esoterix 803890)

New Order Code: ADALX
New Reference Lab: Mayo ADALX

Effective September 5, 2017, Mayo Medical Laboratories will begin performing Adalimumab with reflex to Antibody. If the result of adalimumab quantitation is less than or equal to 5 mcg/mL the adalimumab antibody test (order code ADLAB) will be performed at an additional charge. This test will replace the Adalimumab and Antilimumab Antibodies assay currently sent to Esoterix Laboratory.

Collection Instructions: Collect trough specimen in a red top or SST tube. Centrifuge and aliquot serum into a plastic vial and refrigerate (preferred) for up to 7 days or freeze for longer storage.

Reference Range: Adalimumab: limit of quantitation is 0.8 mcg/mL. Optimal therapeutic ranges are disease specific. Adalimumab Antibody: <14.0 AU/mL.