MLabs
Expertise Delivered Personally

MLABS – DEPARTMENT OF PATHOLOGY
ATTN: IMPORTANT TEST INFORMATION
TEST UPDATE 609

NOTICE DATE: February 16, 2017

EFFECTIVE DATE: February 22, 2017

TEST METHODOLOGY CHANGE

KRAS Mutation in Malignancy
Order Code: KRAS

The MLabs Molecular Diagnostics Laboratory will transition to a new test methodology for KRAS mutation testing effective February 22, 2017.

The new KRAS mutation test will be performed by Next-Generation Sequencing (NGS) in place of Sanger Sequencing. The NGS test interrogates KRAS exons 2, 3, and 4 to provide comprehensive evaluation of KRAS mutations in formalin-fixed paraffin-embedded tumor specimens and Diff-Quik stained aspirate smears**. Importantly, this new method offers improved analytic sensitivity (5% mutation) which offers the ability to test challenging cases with a low percentage of neoplastic cells.** This method also requires a much lower DNA input, enabling comprehensive evaluation of specimens with very few neoplastic cells. The analytic time will increase slightly from 3-10 days to 5-12 days.

Specimen collection and handling requirements and billing will not change.

EFFECTIVE DATE: February 22, 2017

TEST METHODOLOGY CHANGE

NRAS Mutation in Malignancy
Order Code: NRAS

The MLabs Molecular Diagnostics Laboratory will transition to a new test methodology for NRAS mutation testing effective February 22, 2017.

The new NRAS mutation test will be performed by Next-Generation Sequencing (NGS) in place of Sanger Sequencing. The NGS test interrogates NRAS exons 2, 3, and 4 to provide comprehensive evaluation of NRAS mutations in formalin-fixed paraffin-embedded tumor specimens and Diff-Quik stained aspirate smears**. Importantly, this new method offers improved analytic sensitivity (5% mutation) which offers the ability to test challenging cases with a low percentage of neoplastic cells.** This method also requires a much lower DNA input, enabling comprehensive evaluation of specimens with very few neoplastic cells. The analytic time will increase slightly from 3-10 days to 5-12 days.

Specimen collection and handling requirements and billing will not change.

University of Michigan Health System Department of Pathology – MLabs Traverwood 4 2900 Huron Parkway Ann Arbor MI 48105-3454
800.862.7284 toll-free 734.936.2598 phone 734.936.0755 fax www.mlabs.umich.edu

MLabs
Expertise Delivered Personally

MLABS – DEPARTMENT OF PATHOLOGY
ATTN: IMPORTANT TEST INFORMATION
TEST UPDATE 609

EFFECTIVE DATE: January 16, 2017

NEW GERMLINE NGS PANELS

Hereditary Breast and Ovarian Cancer (HBOC) High-Moderate Risk Germline NGS Panel

Order Code:	MIBOC
CPT:	81408, 81211, 81406 x4, 81321, 81404, G0452-26
Genes in panel:	ATM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, PALB2, PTEN, TP53

Hereditary Breast and Ovarian Cancer (HBOC) Comprehensive Germline NGS Panel

Order Code:	MIBCC
CPT:	81432, G0452-26
Genes in panel:	ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, STK11, CHEK2, EPCAM, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, TP53, FANCC, XRCC2

The MMGL Molecular Genetics Laboratory is pleased to announce the launch of two germline Next Generation Sequencing (NGS) panels for hereditary breast and ovarian cancer effective January 16, 2017.

NGS is the most cost effective and rapid way to perform comprehensive clinical genetic testing. These two germline panels were developed in collaboration with the Michigan Center for Translational Pathology (MCTP). The entire coding sequence (exons plus 20 bp upstream and 20 bp downstream of each coding exon) of the targeted genes are captured, sequenced using NGS, and aligned to the human reference genome. A minimum NGS coverage of 20X for all coding exons is achieved. Copy number variation is assessed by coverage depth within the targeted regions compared to a normalized set of controls. Copy number variants within the targeted regions that are of potential clinical significance will also be reported. In addition to NGS, Sanger sequencing is used to amplify and sequence CHEK2 and PMS2 to avoid known pseudogene regions. All reported variants of potential clinical significance will be confirmed by a different technology or platform. Only the targeted genes requested by the ordering provider will be analyzed. The Analytic Time is 28 days for each test. Note that there will be no change in other test offerings currently available from MMGL.

University of Michigan Health System Department of Pathology – MLabs Traverwood 4 2900 Huron Parkway Ann Arbor MI 48105-3454
800.862.7284 toll-free 734.936.2598 phone 734.936.0755 fax www.mlabs.umich.edu