NOTICE DATE: February 21, 2018

EFFECTIVE DATE: February 20, 2018

NEW TEST DELAY

HIGH SENSITIVITY TROPONIN ASSAY

Troponin T, High Sensitive
Order Code: HTRPT
CPT Code: 84484
Fee Code: 23368

Troponin T, High Sensitive, Rule Out Acute Coronary Syndrome (ACS)
Order Code: RTNT
CPT Code: 84484 x2
Fee Code: 23368 x2

Please note that implementation of the High Sensitivity Troponin assay was delayed until February 20, 2018.

EFFECTIVE DATE: February 14, 2018

NEW TEST

BRACA1 and BRACA2 Sequencing and Del/Dup (NGS)
Order Code: BOPND
CPT Code: 81162, G0452-26
Fee Code: DA139

Effective February 14, 2018, the MLabs Michigan Medical Genetics Laboratory (MMGL) began offering new testing for BRCA1 and BRCA2 Sequencing and Deletion/Duplication.

Collection Instructions: Collect 5-10 mL of whole blood in a lavender top tube. Store and ship intact specimen at room temperature within 24 hours of collection or if stored refrigerated up to 5 days. Please include patient's family history, pedigree and ethnicity on the test requisition. An informed consent is strongly recommended prior to genetic testing. If desired, Michigan Medicine request and Consent for Genetic Testing form can be obtained by contacting MLabs Client Services Center at 1-800-862-7284 or online at http://mlabs.umich.edu/files/pdfs/PCI-MMGL_InformedConsent.pdf.

Test Usage: Targeted NGS BRCA1 and BRCA2 sequencing and deletion/duplication analysis is used for the detection of germline pathogenic variants in patients at increased risk for breast, ovarian, prostate, or pancreatic cancer. Not all individuals with pathogenic BRCA1 or BRCA2 variants will have breast or ovarian cancer. Women with BRCA1 or BRCA2 pathogenic variants face an estimated 40-80% lifetime risk for breast cancer and 11-40% for ovarian cancer. In addition, men with BRCA1 or BRCA2 pathogenic variants face an estimated 1-10% lifetime risk for breast cancer (Ford et al. Am J Hum Genet 62:676-689, 1998; Antoniou et al. J Med Genet 42:602-603, 2002; Antoniou et al. Am J Hum Genet 72:1117-1130, 2003; http://www.ncbi.nlm.nih.gov/books/NBK1247/). Other types of cancers have also been reported in individuals with pathogenic BRCA1 and BRCA2 variants (http://www.ncbi.nlm.nih.gov/books/NBK1247/).
Additional Information: Prior authorizations are required by most insurance carriers and BRCA testing will not begin until prior authorization is received or it has been confirmed that it is not required. It is the obligation of the ordering health care provider to obtain prior authorization before testing can begin. To obtain BCN prior authorization call Joint Venture Hospital Laboratories (JVHL) at 800-445-4979; for all others insurances, contact the plan directly. By ordering this test the clinician acknowledges that informed consent has been obtained from the patient as required by applicable state or federal laws and the ordering clinician has authorization from the patient permitting MLabs to report the test results to the ordering clinician. Test includes medical geneticist interpretation of results billed as a separate additional charge. This test is not available without interpretation.

**EFFECTIVE DATE:** February 14, 2018

**NEW TEST**

**BRACA1 and BRACA2 Sequencing (NGS)**

Order Code: BOPN  
CPT Code: 81211, G0452-26  
Fee Code: DA141

Effective February 14, 2018, the MLabs Michigan Medical Genetics Laboratory (MMGL) began offering new testing for BRCA1 and BRCA2 Sequencing.

Collection Instructions: Collect 5-10 mL of whole blood in a lavender top tube. Store and ship intact specimen at room temperature within 24 hours of collection or if stored refrigerated up to 5 days. Please include patient's family history, pedigree and ethnicity on the test requisition. An informed consent is strongly recommended prior to genetic testing. If desired, Michigan Medicine request and Consent for Genetic Testing form can be obtained by contacting MLabs Client Services Center at 1-800-862-7284 or online at [http://mlabs.umich.edu/files/pdfs/PCI-MMGL_InformedConsent.pdf](http://mlabs.umich.edu/files/pdfs/PCI-MMGL_InformedConsent.pdf).

Test Usage: Targeted NGS BRCA1 and BRCA2 sequencing analysis is used for the detection of germline pathogenic variants in patients at increased risk for breast, ovarian, prostate, or pancreatic cancer. Not all individuals with pathogenic BRCA1 or BRCA2 variants will have breast or ovarian cancer. Women with BRCA1 or BRCA2 pathogenic variants face an estimated 40-80% lifetime risk for breast cancer and 11-40% for ovarian cancer. In addition, men with BRCA1 or BRCA2 pathogenic variants face an estimated 1-10% lifetime risk for breast cancer (Ford et al. Am J Hum Genet 62:676-689, 1998; Antoniou et al. J Med Genet 42:602-603, 2002; Antoniou et al. Am J Hum Genet 72:1117-1130, 2003; http://www.ncbi.nlm.nih.gov/books/NBK1247/). Other types of cancers have also been reported in individuals with pathogenic BRCA1 and BRCA2 variants (http://www.ncbi.nlm.nih.gov/books/NBK1247/).

Additional Information: Prior authorizations are required by most insurance carriers and BRCA testing will not begin until prior authorization is received or it has been confirmed that it is not required. It is the obligation of the ordering health care provider to obtain prior authorization before testing can begin. To obtain BCN prior authorization call Joint Venture Hospital Laboratories (JVHL) at 800-445-4979; for all others insurances, contact the plan directly. By ordering this test the clinician acknowledges that informed consent has been obtained from the patient as required by applicable state or federal laws and the ordering clinician has authorization from the patient permitting MLabs to report the test results to the ordering clinician. Test includes medical geneticist interpretation of results billed as a separate additional charge. This test is not available without interpretation.
EFFECTIVE DATE: February 14, 2018

NEW TEST

MLH1, MSH2, MSH6, PMS2 Sequencing and Del/Dup (NGS)
Order Code: CCND
CPT Code: 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, G0452-26
Fee Code: DA143, DA144, DA145, DA146, DA147, DA148, DA149, DA150

Effective February 14, 2018, the MLabs Michigan Medical Genetics Laboratory (MMGL) began offering new testing for MLH1, MSH2, MSH6, PMS2 Sequencing and Deletion/Duplication.

Collection Instructions: Collect 5-10 mL of whole blood in a lavender top tube. Store and ship intact specimen at room temperature within 24 hours of collection or if stored refrigerated up to 5 days. Please include patient’s family history, pedigree and ethnicity on the test requisition. An informed consent is strongly recommended prior to genetic testing. If desired, Michigan Medicine request and Consent for Genetic Testing form can be obtained by contacting MLabs Client Services Center at 1-800-862-7284 or online at http://mlabs.umich.edu/files/pdfs/PCI-MMGL_InformedConsent.pdf.

Test Usage: Targeted NGS MLH1, MSH2, MSH6, and PMS2 sequencing and deletion/duplication analysis is used for the detection of germline pathogenic variants in patients at increased risk for hereditary colorectal cancer and cancers of the endometrium, stomach, ovary, small bowel, hepatobiliary tract, urinary tract, brain, and skin. Not all individuals with pathogenic MLH1, MSH2, MSH6, or PMS2 variants will have hereditary colorectal cancer. Patients with such pathogenic variants face an estimated 52-82% for colorectal cancer; 25-60% for endometrial cancer in women; 6-13% for gastric cancer; and 4-12% for ovarian cancer. Other types of cancers have also been reported in individuals with pathogenic MLH1, MSH2, MSH6, or PMS2 variants (https://www.ncbi.nlm.nih.gov/books/NBK1211/).

Additional Information: Prior authorizations are required by most insurance carriers and testing will not begin until prior authorization is received or it has been confirmed that is it not required. It is the obligation of the ordering health care provider to obtain prior authorization before testing can begin. To obtain BCN prior authorization call Joint Venture Hospital Laboratories (JVHL) at 800-445-4979; for all others insurances, contact the plan directly. By ordering this test the clinician acknowledges that informed consent has been obtained from the patient as required by applicable state or federal laws and the ordering clinician has authorization from the patient permitting MLabs to report the test results to the ordering clinician. Test includes medical geneticist interpretation of results billed as a separate additional charge. This test is not available without interpretation.

EFFECTIVE DATE: February 14, 2018

NEW TEST

Reanalysis of NGS Data
Order Code: RND
CPT Code: 81479
Fee Code: DA140

Effective February 14, 2018, the MLabs Michigan Medical Genetics Laboratory (MMGL) began offering a new test for reanalysis for previously ordered germline next gene sequencing data.
NEW TEST

Cytogenetics, FISH Panel for Multiple Myeloma
Order Code: CGMMP
CPT Code: 88271x1 for each DNA probe set (maximum x10), 88275x1 Interphase in situ hybridization, 100 to 300 cells, each probe set (maximum x10)
Fee Code: EA023 (maximum x10), EA024 (maximum x10)

The MLabs Cytogenetics Laboratory began offering the Multiple Myeloma FISH panel effective February 19, 2018. This test replaces Chromosome Analysis, FISH for Plasma Cell Proliferative Disorder (order code PCPDF) sent to Mayo Medical Laboratories.

This test is used to detect common abnormalities associated with plasma cell neoplasms. Plasma cells (CD138) are enriched from peripheral blood or bone marrow aspirates. For diagnostic samples, the test will be run in a tiered approach. The first tier tests include 17p/cen (TP53/CEP17), t(4;14) (IGH/FGFR3), 14q (IGH), and 1p/1q (CKS1B/CDKN2C). Second tier probes are, +5 (D5S23, D5S721), +9 (CEP9), +15 (CEP15), 8q24 (MYC), and del(13q)/-13 (D13S319/13q34). When an IGH rearrangement is identified and the partner is not FGFR3, reflex testing is performed to identify the translocation partner. Probes include identification of t(11;14) CCND1/IGH, t(14;16) IGH/MAF, and t(14;20) IGH/MAFB. For follow-up samples, probes that were abnormal in a previous study will be tested along with 1p/1q, TP53/cen17 and MYC probes if sufficient plasma cells are obtained. If previous FISH results are unknown, the sample will be evaluated as a diagnostic sample.

Collection Instructions: Specimen transport should be arranged so that the specimen is received by MLabs the same day it is collected. The sample must be in the Cytogenetics lab Monday - Friday by 4pm. Call for a STAT courier if necessary. Collect specimen in a green top (sodium heparin) tube. Invert the tube several times to prevent clotting. Send at room temperature as soon as possible. Do not allow specimen to overheat or freeze. Clotted samples or those that are greater than 24 hours old are suboptimal. Multiple Myeloma FISH panel testing may be performed as a "stand alone" test or included with Chromosome Analysis.