ACL Laboratories
Every Sample is a Life™

Test Bulletin

October 2017

ACL Laboratories Releases First In-House Assay Utilizing Next Generation Sequencing (NGS)

Effective Wednesday, October 18, 2017, ACL Laboratories will release its first in-house assay utilizing Next Generation Sequencing (NGS) for solid tumors (Test Order Code STMP15). See article below.

NGS is the latest "generation" of state-of-the–art genetic testing methodology. Next Generation Sequencing is necessary to fully realize the potential of personalized medicine because this medical tool uses **the specific genetic makeup of each individual patient** to determine if a given patient should receive a given therapy, called "companion therapy." The corresponding laboratory test is known as the "companion diagnostic test."

Examples of companion diagnostic tests/therapies include:

- HER2 testing in breast cancer to qualify for Herceptin therapy
- EGFR testing in lung cancer to qualify for Tarceva therapy
- BCR-abl testing in leukemia to qualify for Gleevec therapy
- BRAF testing in melanoma to qualify for Zelboraf therapy
- Extended RAS testing in colon cancer to qualify for Erbitux therapy

All of these, and many others, are currently performed by ACL Laboratories as separate genetic tests which are expensive and very labor intensive. NGS, on the other hand, will allow ACL to run an entire PANEL of genetic tests **at one time.**

The goal in NGS is to determine the actual sequence of a patient's tumor DNA to find a very specific change in the makeup which the therapy can then target to destroy the tumor. To accomplish this, tiny samples of the tumor are taken off a glass microscopic slide, DNA is removed, and amplified a million fold. This produces short DNA fragments that are like puzzle pieces. These samples can then be reconstructed back into the completed puzzle picture—if one piece doesn't fit, then you know that the "targeted" change (mutation) is present.

The computer analysis tool is so powerful that DNA from several patients, for numerous targets, can be analyzed in a **single reaction**—producing results which are equally precise, take less "hands-on" time and are less expensive than running each test separately.

ACL Laboratories Offers New Test Solid Tumor Mutation Panel 15 By Next Gen Sequencing (Test Order Code STMP15)

Effective Wednesday, October 18, 2017, ACL Laboratories will offer a new multiplex assay Solid Tumor Mutation Panel 15 (Test Order Code STMP15) based on NGS TruSight Tumor 15 gene panel from Illumina. The Solid Tumor Mutation Panel will encompass 15 genes with variable full exon, partial region, or hot spot coverage. It is very focused on gene mutations with targeted therapies available. KRAS, BRAF, and NRAS are three of the genes in this panel—see chart below. The panel will target tumor originations in Lung, Colon, Breast, Ovarian, Melanoma, Thyroid, and GIST (Gastointestinal Stromal Tumors). This is a very targeted test and should meet most of the genetic testing needs of our clinicians. This assay can be useful for diagnosis, prognosis and/or treatment of individuals with solid tumor cancers at initial diagnosis or in the presence of refractory disease.

AKT1 – Exon 3 (partial)
BRAF – Exon 15 (partial)
EGFR – Exon 12 (partial), 18, 19, 20, 21 (partial) + Focal Amplification
ERBB2 – Exons 14 (partial), 17, 18, 19, 20 (partial), 21 (partial), 24, 26
FOXL2 – Exon 1 (partial)
GNA11 – Exon 5 (partial)
GNAQ – Exon 5 (partial)
KIT – Exons 8, 9, 10, 11, 13, 14, 17, 18
KRAS – Exon 2 (partial), 3 (partial), 4 (partial)
MET – Focal Amplification
NRAS – Exon 2 (partial), 3 (partial), 4 (partial)
PDGFRA – Exon 12, 14, 18
PIK3CA – Exon 10, 21
RET – Exon 16
TP53 – Full Gene

For additional information regarding this test, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit ACL's website at www.acllaboratories.com/test-catalog/.

ACL Laboratories Offers New Reflex Urine Electrophoresis Tests (Test Order Codes UPERRX and UPETRX 24)

Effective Wednesday, October 18, 2017, ACL Laboratories will offer two new test order codes – UPERRX (Protein Electrophoresis with Reflex to Immunofixation, Urine Random) and UPETRX (Protein Electrophoresis with Reflex to Immunofixation, Urine – 24 Hour). These tests will automatically reflex to immunofixation testing if any abnormal urine electrophoresis result is obtained and a recent prior immunofixation has not been performed. This new option for automatic reflex is intended to expedite the diagnostic process and provide more timely results by not requiring an additional order from the physician.

The current urine protein electrophoresis tests will remain active:
Test Order Code UPETMX – Protein Electrophoresis, 24 hr Urine
Test Order Code UPERMX – Protein Electrophoresis, Random Urine
Test Order Code UMETMX – Protein Electrophoresis Monoclonal, 24 hr Urine
Test Order Code UMERMX – Protein Electrophoresis Monoclonal, Random Urine

Specimen Requirements:
Collect: One urine – random or 24 hour urine (no preservative)
Transport: 5.0 mL (Min 2.5 mL) aliquot, refrigerated
Stability: Refrigerated: 7 Days / Frozen: 14 Days

For additional information regarding these tests, as well as specimen collection requirements, contact ACL Client Services at 1.800.877.7016 or visit ACL's website at www.acllaboratories.com/test-catalog/.

ACL Laboratories Offers New Test for HIV Genotyping and Drug Resistance (Test Order Code HIVGEN)

Effective Wednesday, October 18, 2017, ACL Laboratories will offer a new HIV genotyping and drug resistance test (Test Order Code HIVGEN). This test is based on the FDA-approved, in-vitro diagnostic "ViroSeq" reagents from Abbott.

This new test will improve result reporting and provide additional drug resistance reports from the Stanford HIV data base to physicians. This also allows ACL to provide electronic transmission of assay data to the Illinois Department of Public Health (IDPH) and the Wisconsin State Laboratory of Hygiene (WSLH).

The current HIV genotyping test (Test Order Code TXHIVG) will be de-activated on **Wednesday, October 18, 2017.**

For additional information regarding this test, as well as specimen collection requirements, contact ACL Client Services at 1.800.877.7016 or visit ACL's website at www.acllaboratories.com/test-catalog/.

Changes to the QuantiFERON TB Gold Collection Kit

The current QuantiFERON TB Gold (Test Code QUANTB) kit supplied ACL Laboratories storerooms is undergoing changes as noted below:

Current Kit Components
Specimen Bag (ambient/special handling)
Kit Expiration Label
Tubes (gray, red, lavender)
Drawing Instructions
22G Eclipse Needle
Vacutainer Holder

New Kit Components
Specimen Bag
Kit Expiration Label
Tubes (gray, red, lavender)
NEW Drawing Instructions
Special Handling/Room Temperature Label

- The vacutainer holder and needle have been **removed** from the kit for several reasons:
  - Common supply items that sites already have in their inventory
  - Most sites discard the needles and holders from the kits
  - Reduced waste
- **NEW** Special Handling/Ship at Room Temperature Label on specimen bag.

- Updated collection instructions will assist in standardizing the proper collection process for the specialized QuantiFERON tubes.
- The ordering process for the kits will remain the same.
- **Current kits** that are supplied from ACL Laboratories supply **are still valid** and can be utilized until old stock has been depleted.
- The Directory of Services (https://www.acllaboratories.com/test-catalog/) reflects the updated collection and transportation instructions, as of 8/30/17.
- ACL supply began making updated versions of the kit, starting 9/4/17.
- Please contact ACL Laboratories Client Services at 1.800.877.7016 if you have any questions or need additional information.

ACL Laboratories Discontinues Obsolete Test MTHFR Genotype (Test Order Code TXMTHF)

Effective Wednesday, October 18, 2017, MTHFR Genotype (Test Order Code TXMTHF) has been deemed obsolete by Advocate's Clinical Effectiveness Laboratory Steering committee, Aurora's Hospital Inpatient Efficiency and Patient Safety Steering committee and ACL's Clinical Effectiveness Implementation team.

The American College of Obstetricians and Gynecologists, the American Heart Association, and American College of Medical Genetics and Genomics and the National Society of Genetic Counselors do not recommend MTHFR polymorphism or homocysteine testing in any patient group for the purpose of determining risk for cardiovascular disease, DVT or PE, or pregnancy complications, such as pregnancy loss, preeclampsia, and placental abruption.

Hologic Renames Vaginal Swab Product – Aptima Multitest Swab

Effective immediately, Hologic has renamed their vaginal swab product. The former name – Aptima Vaginal Swab has been renamed Aptima Multitest Swab.

As a result of this product name change, ACL Laboratories has renamed the collection kits, as well. The former name – Aptima Vaginal Swab Collection Kit has been renamed Aptima Multitest Swab Specimen Collection Kit.

The multitest swab will be replacing the vaginal swab. During this transition period between phasing out the "Vaginal" labeled swabs, both kits will be available until the "Vaginal" labeled swabs inventory is depleted.

There are no other changes to the swab, other than the renaming of the product. In addition, there are no changes in how the product is ordered. The swabs will continue to be orderable as "each" or as "boxes of 50."

Please contact ACL Laboratories Client Services at 1.800.877.7016 if you have any questions or need additional information.

Ordering Information	
Current Product Info	**New Product Info**
Description: Vaginal Swab	**Description: Multitest Swab**
Lawson: 418556	**Lawson: 553185**
IREQ: 464217	**IREQ: 518846**
Catalogue: 301162	**Catalogue: PRD-03546**