the DLO LAB NEWSLETTER

Fall 2013

Empowering Better Health with Diagnostic Insights

dlolab.com

Health Trends: Preemptive tests help identify risk

NEW Cardio IQ™ Provides Deeper Insights into Cardiovascular Risk

DLO announced in August a new advanced, preemptive cardiovascular test that provides clinicians with the tools needed to enhance cardiovascular patient care through deeper insights into cardiovascular risk and a personalized approach to disease management.

Advanced cardiovascular tests, as an adjunct to major risk factors, help provide a more accurate and individualized patient risk characterization. Through the use of ion mobility fractionation, the latest technological evolution in advanced lipid subclass measurement, these advanced tests move beyond the past compromises between full spectrum lipoprotein characterization, high resolution lipid particle sizing, and particle quantification.

Overall, clinicians can now better risk stratify their patients; determine which patients would benefit from a more aggressive treatment strategy; and help motivate patients to adhere to drug therapies or make lifestyle changes to reduce their risk

The fully integrated menu of advanced cardiovascular testing may be ordered using DLO's Cardio IQ Requisition or through Care360®.

The 4myheart program, offered to patients who take the Cardio IQ test, is a personalized approach to disease management by providing trained clinical educators to help patients achieve their healthcare goals based on their clinicians' treatment plans.

ROS1 Mutation Testing for Lung Cancer Patients Now Available

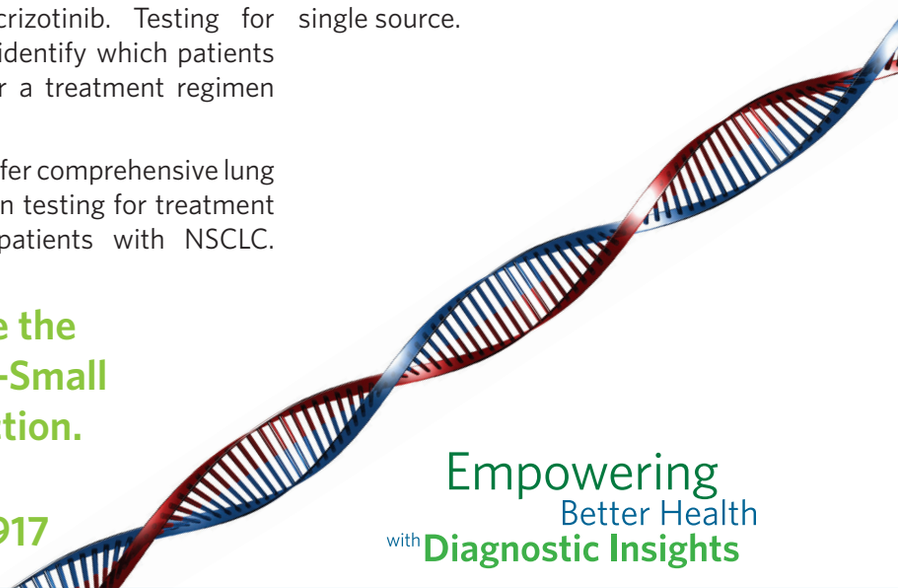
Lung cancer is one of the most prevalent cancers in the United States, with an estimated 228,000 new cases each year. Approximately 160,000 patients die from this disease annually. Lung cancer is by far the leading cause of cancer death among both men and women. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined.

DLO is pleased to announce the availability of ROS1 mutation testing for lung cancer patients. ROS1 is a Receptor Tyrosine Kinase of the insulin receptor family. ROS1 mutation occurs in 2% of Non-Small Cell Lung Cancer patients. Studies show that NSCLC patients whose tumor has an ROS1 rearrangement often have clinical response to crizotinib. Testing for ROS1 helps to identify which patients are suitable for a treatment regimen with crizotinib.

We currently offer comprehensive lung cancer mutation testing for treatment selection for patients with NSCLC. This important addition to the DLO menu complements the continuum of care for a patient's diagnostic portfolio. DLO offers the added benefit of making it easier for clinicians to manage a patient's health – all from a single source.

Current NCCN Guidelines include the use of ROS1 testing to aid in Non-Small Cell Lung Cancer treatment selection.

For more information, call 800.891.2917



Empowering Better Health with Diagnostic Insights

Test Spotlight

New Tests Highlight DLO's Commitment to Women's Health

Over the past several months, DLO has launched several new offerings that highlight our commitment to, and leadership, in Women's Health.

BRCAvantage™

DLO announced on Oct. 15, the availability of BRCAvantage™, a suite of four new lab-developed genetic tests (LDT) that identify mutations in BRCA1 and BRCA2 genes, which are associated with increased risk of breast and ovarian cancers. BRCAvantage is offered by DLO through Quest Diagnostics, a joint venture partner of DLO. Film actress Angelina Jolie has brought recent national attention to BRCA after a positive test convinced her to undergo a double mastectomy.

As part of the BRCAvantage offering, DLO will provide to physicians and patients access to third-party genetic counselors and a free, concierge-level pre-authorization service that helps expedite access to insurance-covered BRCA testing through any of the health plans in the DLO network. Patients can submit blood specimen for testing at DLO's more than 42 patient service centers located across the state, for geographic convenience unmatched by any other BRCA test provider.

BRCA1 and BRCA2 are genes with known mutations responsible for increasing the risk of hereditary breast and ovarian cancer and associated cancers in women, and for prostate and breast cancer among men. Genetic testing is recommended for people with an immediate family member diagnosed with breast cancer at age 45 or younger; a personal history of breast cancer at age 45 or younger; a family member diagnosed with ovarian cancer at any age; a personal or family history of both breast and ovarian cancers on the same side of the family; a personal or family history of male breast cancer; Ashkenazi Jewish heritage; or a personal or family history of bilateral breast cancer (both breasts).

The BRCAvantage test is performed using next-generation sequencing and multiplex ligation dependent probe amplification (MLPA) to detect all published deleterious mutations in BRCA1 and BRCA2. If a gene variant is identified, it is cross referenced with mutational databases to promote reliable clinical interpretation. Quest also plans to support open access to patient-consented de-identified BRCA data to promote research and innovation in the field.

Angelina Jolie chose to have a preventive double mastectomy after learning that she carried the BRCA1 gene.

Learn more by visiting BRCAvantage.com

Three New Women's Health Panels Now Available

DLO is now offering three new panels, which are subsets of the TemPCR™ Women's Health Panel. These three panels, exclusive to DLO, can now be requested as individual panels or as one panel that identifies all 15 pathogens.

Bacterial Vaginosis Panel (test code **95176**) detects molecular targets that identify

- Atopobium vaginae
- Garnerella vaginalis
- Mycoplama genitalium
- Mycoplasma hominis
- Ureaplama urealyticum

Candidiasis Panel (test code **95621**) detects molecular targets that identify

- Candida albicans
- Candida flabrata
- Candida Krusei
- Candida parapsilosis
- Candida tropicalis

STD 5 Panel (test code **95848)** detects molecular targets that identify

- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Trichomonas vaginalis
- Herpes Simplex Virus 1
- Herpes Simplex Virus 2

For more information call 800.891.2917, Option 5

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APTIMA® HPV mRNA

The FDA-approved APTIMA® HPV Assay, utilizing mRNA, offers comparable sensitivity and increased specificity compared to DNA-based tests. Studies have shown the APTIMA HPV test to report up to 40% fewer false-positive test results than HC2 HPV DNA. The reduction in false positives means fewer difficult patient conversations and reduces the potential for over-treatment.

In addition, the HPV RNA, High Risk E6/E7, TMA assay has shown to have 24% fewer false-positives than an FDA-approved DNA test. Many transient HPV infections detected by DNA methods resolve over time. The HPV RNA, High Risk, E6/E7 TMA assay detects the expression of oncogenes that foster persistent infections that lead to cervical cancer.

APTIMA Combo 2®

Through its new partnership with Hologic, DLO now offers the APTIMA Combo 2® assay to replace our Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) testing. The new testing was transitioned on Oct. 7. After Nov. 30 BD ProbeTec™ tests for CT/NG will no longer be processed.

The benefits of APTIMA to clinicians include a high sensitivity and specificity due to its ability to target and amplify ribosomal RNA and enable the detection of even trace amounts of CT/NG infection. In addition, APTIMA provides the ability for a wide spectrum of specimen types to be tested for CT/NG, with statistically similar rates of accuracy.

Visit the *new* DLO Website:

- Learn about our new tests
- Easily access important physician tools
- Access free continuing education Webinars

DLOlab.com

NEW!

QuestConnect

- Request results
- Add or cancel tests
- Order supplies
- Update account information

Access QuestConnect at **DLOlab.com**

CMS Issues Advisory Opinion on Free Cervical Biopsy Brushes

In September the Centers for Medicare & Medicaid Services (CMS) issued Advisory Opinion (AO) 2013-02, addressing whether a physician can receive biopsy brushes from a laboratory for free. The AO supports the position that DLO and Quest Diagnostics have long taken regarding the provision of biopsy brushes collection devices, and advises that providing such supplies to a physician implicates the physician self-referral law and therefore is not permissible. An Advisory Opinion issued by CMS provides guidance about whether a physician's referrals for services payable by Medicare to an entity with which he or she has a financial relationship are prohibited under the Medicare program. For more information on AO 2013-02, please visit CMS.gov.

Education Center

Online Education Presentations Now Available

Noninvasive Prenatal Testing: Separate But NOT Equal

Buck Strom, MD, PhD discusses indications and society recommends for noninvasive prenatal testing (NIPT) and current NIPT methodologies, including the clinical utility of free floating fetal DNA testing.

http://www.education.questdiagnostics.com/

Free CME Webinar

14-3-3 eta Protein: A New Direction in the Early Diagnosis of Rheumatoid Arthritis

Walter Maksymowych, MD, a scientist at Alberta Heritage Foundation for Medical Research and consultant rheumatologist and professor of medicine at the University of Alberta, discusses the diagnostic and prognostic value of the 14-3-3 eta protein in rheumatoid arthritis and the clinical relevance of a new assay that measures this biomarker.

http://education.questdiagnostics.com/presentations

Free CME Webinar

Vitamin D: Where is the Evidence?

Vin Tangpricha, MD, PhD discusses the currently accepted vitamin D levels for optimal vitamin D status, describes chronic diseases associated with vitamin D deficiency, risk factors as well as treatment regimens. http://www.education.questdiagnostics.com/

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