FDA clears test for CHD events, 3/15

March 2014—The Food and Drug Administration cleared a screening test that predicts a patient's risk of future coronary heart disease events, such as heart attacks.

The test is cleared for use in all adults with no history of heart disease, but studies submitted by the company and reviewed by the FDA show that the test is better at discerning this risk in women, particularly black women.

The PLAC Test for Lp-PLA2 Activity measures the activity of lipoprotein-associated phospholipase A2 in a patient's blood. Patients with test results that show Lp-PLA2 activity greater than 225 nmol/min/mL are at increased risk for a CHD event while patients with results below this level are at decreased risk.

In the PLAC Test for Lp-PLA2 Activity validation study, a substudy from the National Institutes of Health's national Reasons for Geographic and Racial Differences in Stroke study that targeted a balanced enrollment of gender and race, researchers performed the test on 4,598 participants aged 45 to 92 with no history of CHD. The participants included 41.7 percent men and 58.3 percent women, and 41.5 percent blacks and 58.5 percent whites.

Researchers followed the participants for several years and recorded who experienced a CHD-related event. The median follow-up time was 5.3 years. The study showed that participants with test results higher than 225 nmol/min/mL had a CHD event rate of 7 percent, while patients with test results below that level had a CHD event rate of 3.3 percent.

The FDA requested data analyses of additional subgroups, including black women, which showed that black women experienced a higher jump in the rate of CHD events compared with other participants when Lp-PLA2 levels were higher than 225 nmol/min/mL. As a result, the test's labeling contains separate performance data for black women, black men, white women, and white men.

The PLAC Test for Lp-PLA2 Activity is manufactured by diaDexus, based in South San Francisco, Calif.
NGS solution for forensic genomics

Illumina launched the MiSeq FGx Forensic Genomics System, a fully validated forensic next-generation sequencing system that simultaneously interrogates short tandem repeats and other valuable genetic markers, including single nucleotide polymorphisms, to provide informative DNA profiles. The system enables robust analysis of a range of genetic markers in a single workflow.

Designed in collaboration with leading forensic genomics and human identification experts, the MiSeq FGx system leverages Illumina's sequencing by synthesis chemistry. Compatible with existing DNA databases, including the Combined DNA Index System, the system can be used for criminal casework and in other situations such as mass disasters, missing persons, and unidentified human remains. Dense data sets, with powerful population statistics, can be generated for highly compromised samples, such as DNA degraded to less than 100 base pairs. The technology can also provide SNP-based physical information about biogeographical ancestry and visible, physical traits, including hair and eye color.

In addition to the MiSeq FGx DNA sequencer, the system includes the ForenSeq DNA Signature Prep Kit and ForenSeq Universal Analysis Software. This sample-to-answer solution aims to enable labs to maximize the information derived from a sample, eliminating the need for multiple rounds of partial, iterative testing. Using low quantities of DNA (< 1 ng), the prep kit amplifies forensic targets via a streamlined workflow that maximizes the genetic information recovered from challenging samples and minimizes the potential for errors. Intuitive ForenSeq software facilitates the complete run setup, sample management, and analysis, and delivers reports on a standalone, dedicated server.

***Illumina**, 858-202-4500*