



Omega Laboratories Receives FDA 510(k) Clearance for Marijuana Metabolite (THCA) Drugs of Abuse Test Utilizing Hair and Publishes Lowest Limit of Detection

MOGADORE, Ohio, Dec. 11, 2012 /PRNewswire/ -- Omega Laboratories, Inc. announced that it has received 510(k) clearance from the Food and Drug Administration (FDA) for its Marijuana Metabolite Test, which detects the use of marijuana through human hair analysis. Omega Laboratories is one of the largest laboratories in the world performing hair testing for drugs of abuse and one of only three hair testing laboratories to have proven their capability to obtain FDA 510(k) clearances for the technology.

Omega has collaborated with Agilent Technologies to develop a highly-precise marijuana metabolite confirmation assay for the Agilent Technologies GC/MS/MS. This has enabled Omega to test at a Limit of Detection (LOD) level of 0.005 picograms per milligram of hair for the FDA submission. Additional research conducted by Omega Laboratories and Agilent Technologies has been presented at the Society of Forensic Toxicology (SOFT). This data confirms Omega's ability to reach an LOD as low as 0.002 picograms per milligram of hair for testing marijuana metabolite. "Over the last few years this collaboration with Omega has tested our GC/MS/MS product line in their production environment and we are very happy to report that the equipment maintained and continues to maintain the required precision," remarked Thomas Gluodenis, Forensics & Toxicology Business Manager for Agilent Technologies.

The ability to test for Marijuana Metabolite has become increasingly important to organizations as drug abuse continues to increase and concerns grow about this serious and growing health problem. A recent report by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) identified marijuana as the most commonly abused form of illicit drug in the United States.

As stated at a meeting of the U.S. Department of Health and Human Service's Drug Testing Advisory Board (DTAB) in January 2011, the DTAB views this type of FDA clearance as a key component in the future adoption of hair testing for Federal Workplace Drug Testing Programs. In addition, many companies regulated by Federal Guidelines (such as the U.S. Department of Transportation's 49 CFR Part 40) have come to rely on hair testing for drugs of abuse because drug abuse has become a critical workplace safety issue. Regulated companies in industries such as trucking, oil and gas, nuclear power, and railroads, are now able to conduct expanded drug testing programs for safety-sensitive positions under "company authority." These companies often do so because of the inherent flaws in the current urine-based Federal testing program.

"Omega prides itself on challenging the boundaries of what a hair testing laboratory can accomplish," said Bill Corl, CEO of Omega Laboratories. "Rather than confuse the market by patenting portions of these procedures, Omega has chosen to work with companies like Agilent Technologies to promote higher standards for the detection of drugs of abuse."

The Omega 510(k) submissions were evaluated by the FDA at a much more stringent level than those submissions cleared over a decade ago. Omega's 510(k) submissions averaged over 7,000 pages in length, and included extensive studies involving precision, agreement, stability, recovery, and possible effects of contamination. Omega also researched the possible effects of different hair cosmetic treatments including multiple coloring products, straighteners/relaxers, and shampoos specifically marketed to evade a drug test. Hair color, curvature, body location (head or body), and ethnic origin of the samples were analyzed to ensure that a diverse population was represented in the studies.

In addition to having clearance for Marijuana Metabolite testing, Omega has FDA clearance for Cocaine, Methamphetamine, PCP, Opiates and is currently the *only* hair testing laboratory to have FDA clearance for Codeine, Oxycodone, and Hydrocodone testing.

About Omega Laboratories - Omega Laboratories, Inc. is a state-of-the-art facility providing laboratory-based hair and oral fluid testing for drugs of abuse to over 6,000 clients worldwide. Omega's reputation for performing accurate, timely and cost effective testing, coupled with an unmatched reputation for client service, has positioned Omega as the leader in the alternative specimen drug testing industry.

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