



## Omega Laboratories becomes the First Laboratory to Receive 510(k) Clearance for Oxycodone and Hydrocodone Drugs of Abuse Test for Hair

Mogadore, Ohio, December 20, 2011 / PRNewswire/ -- Omega Laboratories, Inc. announced that it has become the first and only laboratory to receive 510(k) clearance from the Food and Drug Administration (FDA) for its Extended Opiates Test that detects the use of Oxycodone and Hydrocodone through human hair analysis. The clearance also included the test for Codeine, Morphine and Heroin.

The ability to test for Oxycodone (eg. OxyContin® and Percocet®)\* and Hydrocodone (eg. Vicodin® and Lortab®)\* has become increasingly important to organizations as prescription drug abuse continues to rise, and has been recognized as a serious and growing health problem. A recent report by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) found that use of prescription pain relievers without a doctor's prescription, or for nonmedical use, is the second most common form of illicit drug use 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 of this year, the DTAB views this type of clearance as a key component in the future adoption of hair testing to Federal Workplace Drug Testing Programs. In addition, many companies regulated by Federal Guidelines, like the U.S. Department of Transportation's 49 CFR Part 40, have come to rely on Extended Opiates testing in hair samples because they realize prescription opiate abuse is a critical workplace safety issue. Regulated companies that have safety-sensitive positions, such as motor carriers, pipeline/energy, nuclear power and railroads, are able to conduct expanded drug testing programs under company authority and often do so because of the inherent flaws in the current urine based testing program.

"At Omega we are focused on providing the highest-quality and most reliable testing procedure available," said Dr. John Vitullo, CEO of Omega Laboratories. "This clearance means that we offer our clients an unsurpassed level of expertise and proficiency in our hair testing for drugs of abuse process. This clearance is one more way Omega maintains its position as the industry leader in testing expertise and customer service."

Omega's 510(k) FDA submission contained over 13,000 pages and included extensive studies involving precision, agreement, stability, recovery, effects of contamination, and the effects of different hair cosmetic treatments including multiple coloring products, straighteners/relaxers, and shampoos marketed to evade a drug test. Hair color, curvature and ethnic origin of the samples were also analyzed to ensure that a diverse population was represented in the studies. A shipping study was performed showing there were no effects to the hair samples from extreme temperature and humidity changes, unlike the problems that have plagued the transport of urine samples.

"In addition to being the only hair testing laboratory with clearance for an Oxycodone and Hydrocodone test, Omega was the first hair testing laboratory in the United States accredited to the ISO/IEC 17025 standard," said Dr. Vitullo. "Accrediting agencies have referred to ISO/IEC 17025 as the gold standard of laboratory accreditation, and we feel strongly that it is the most comprehensive quality process available to our industry."

According to the January 2009 FDA Guidance Document entitled *Submission of Laboratory Packages by Accredited Laboratories*, "ISO/IEC 17025 is the most widely used laboratory standard for federal testing laboratories, including FDA's own laboratories, and ISO/IEC 17025 is internationally recognized and accepted world-wide."

**About Omega Laboratories, Inc.** - Omega Laboratories, Inc. is a state-of-the-art facility providing laboratory-based hair and oral fluid testing for drugs of abuse to over 5,000 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.

*\*The third-party trademarks used herein are registered trademarks of their respective owners and not Omega Laboratories, Inc.*

SOURCE Omega Laboratories, Inc. <http://www.omegalabs.net/>