

Guidance on the Applicability of the Clinical Laboratory Improvement Amendments of 1988 to Substance Abuse Testing

Director – Survey and Certification Group

This memorandum provides additional guidance regarding the circumstances when laboratories performing drug or alcohol screening and/or testing must be CLIA certified, and should be considered an addendum to the attached February 05, 1993 memorandum "Guidance on the Applicability of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to Substance Abuse Testing."

We are restating our ongoing policy that laboratories performing drug or alcohol screening and/or testing followed by individual treatment must be CLIA-certified. Facilities found to be performing such testing without CLIA certification are in violation of CLIA.

As detailed in 42 CFR 493.2, a laboratory for CLIA purposes is a facility whose examinations of human specimens are "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings."

Exceptions are provided to this general rule of applicability where: a "facility or component of a Facility" "only performs testing for forensic purposes" (emphasis added); for "research laboratories" that do not report out patient specific test results; and for "laboratories

certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. [42 CFR 493.3(b)1)-(3)]

The preamble to the February 28, 1992 Federal Register notice (HSQ-176FC) included an important discussion concerning this subject at 57 FR 7014, as follows:

"In the forensic testing context, laboratory results are generated purely for the purpose of detecting illegal substances or illegal amounts of certain substances in the body that may be relevant to legal proceedings. There is no concern in such testing for developing accurate and reliable data for use by health care professionals for the purpose of diagnosis or treatment, which we believe to be the focus of the CLIA legislation. However, if the entity conducts testing for the purpose of providing information for the diagnosis, prevention or treatment of any disease, or impairment of, or the assessment of health of human beings, the entity would be subject to CLIA. The determining factor is not the test itself, but the purpose for which the test is conducted."

It Further States:

"Based on the CLIA law and its legislative history, we have determined that forensic testing is excluded un-

der CLIA since forensic testing is conducted to determine if there has been a violation of the law and is not done for the purpose of providing remedial treatment. Urine drug testing that is conducted for non-forensic purposes is covered by this rule. [Webster's defines treatment as "medical application of remedies so as to effect a cure: therapy."

Although the February 05, 1993 memorandum to the Regional Offices refers specifically to employment entities that perform drug and alcohol testing for the purpose of hiring and firing, when such testing serves as the basis for treatment, entity is considered a laboratory subject to CLIA. This policy applies to all entities (facilities), not just those performing employment-related drug and/or alcohol testing.

Therefore, any entity or facility performing drug or alcohol testing and/or screening where the test results are used for the purpose of referring, offering, or making available to the test subjects treatment, must either obtain an appropriate CLIA certificate and meet the applicable CLIA standards or cease testing.

If you have any questions regarding this guidance, please contact Judy Yost in the Division of Laboratory Services at Judith.Yost@cms.hhs.gov or 410-786-3407.

	Forensic Testing	Employment Testing	Treatment Testing
Substances of Abuse	Not Subject to CLIA	Not Subject to CLIA	Subject to CLIA
Alcohol	Not Subject to CLIA	Not Subject to CLIA	Subject to CLIA

One Source Toxicology Laboratory to Launch Metal Testing

One Source Toxicology Laboratory will offer a Metals Testing Program in 2009. These are the metals commonly associated with occupational hazards and their toxic effects on humans:

Silver - Argyria is a rare condition associated with chronic exposure to silver-containing products; it involves the deposition of silver granules in the skin, mucous membranes, and internal organs including the central nervous system. In skin, silver is mostly deposited around adnexal structures in the dermis; it is associated with a bluish-gray to slate-gray hue.¹

Arsenic - The remaining non-excreted arsenic ($\leq 10\%$) accumulates in cells, which over time may lead to skin, bladder, kidney, liver, lung, and prostate cancers. Other forms of arsenic toxicity in humans have been observed in blood, bone marrow, cardiac, central nervous system, gastrointestinal, gonadal, kidney, liver, pancreatic, and skin tissue.²

Beryllium - According to the International Agency for Research on Cancer (IARC), beryllium and beryllium compounds are Category 1 carcinogens; they are carcinogenic to both animals and humans.³

Cadmium - Inhalation of cadmium-containing fumes can result initially in metal fume fever but may progress to chemical pneumonitis, pulmonary edema, and death.⁴

Chromium - Most chromium (VI) compounds are irritating to eyes, skin and mucous membranes. Chronic exposure to chromium (VI) compounds can cause permanent eye injury, unless properly treated.⁵

Copper - Copper toxicity can occur from eating acid food that had been cooked in Copper cookware. Cirrhosis of the liver in children (Indian Childhood Cirrhosis) has been linked to boiling milk in copper cookware. The Merck Manual states that recent studies suggest that a genetic defect is associated with this cirrhosis, but this should not be regarded as an endorsement of the practice since other toxicity besides cirrhosis can occur as in adults.⁶

Lead - Lead may cause irreversible neurological damage as well as renal disease, cardiovascular effects, and reproductive toxicity.¹⁰

Mercury - Acute exposure to mercury vapor has been shown to result in profound central nervous system effects, including psychotic reactions characterized by delirium, hallucinations, and suicidal tendency. Occupational exposure has resulted in broad-ranging functional disturbance, including erethism, irritability, excitability, excessive shyness, and insomnia.⁷

Manganese - Manganese poses a particular risk for children due to its propensity to bind to CH-7 receptors. Manganese poisoning has been linked to impaired motor skills and cognitive disorders.⁸

Nickel - Sensitized individuals may show an allergy to nickel affecting their skin, also known as dermatitis. Nickel is an important cause of contact allergy, partly due to its use in jewelry intended for pierced ears.⁹

Selenium - Symptoms of selenosis include a garlic odor on the breath, gastrointestinal disorders, hair loss, sloughing of nails, fatigue, irritability and neurological damage. Extreme cases of selenosis can result in cirrhosis of the liver, pulmonary edema and death.¹¹

Thallium - Among the distinctive effects of thallium poisoning are loss of hair (which led it to its initial use as a depilatory before its toxicity was properly appreciated) and damage to peripheral nerves (victims may experience a sensation of walking on hot coals). Thallium was once an effective murder weapon before its effects became understood, and an antidote (Prussian blue) discovered.¹²

Zinc - Excessive absorption of zinc can also suppress copper and iron absorption.¹³

For additional information regarding Metals Testing with One Source Toxicology Laboratory contact the sales department (713) 920-1335.

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- 2 - Effects of Arsenic Toxicity at the Cellular Level: A Review. Texas Journal of Microscopy
- 3 - International Agency for Research on Cancer (1993). Retrieved on 2008-09-18
- 4 - Principles and Methods of Toxicology (fourth edition). A. Wallace Hayes. Taylor and Francis Publishing Inc.; Philadelphia, 2001.
- 5 - Chromium Toxicity on the Corrosion Doctors Web site maintained by Canadian Physical Chemist, Pierre R. Roberge, PhD, P.Eng.
- 6 - Merck Manulas -- Online Medical Library: Copper". Merck (November 2005)
- 7 - WHO (1976) Environmental Health Criteria 1: Mercury, Geneva, World Health Organization, 131 pp.
- 8 - "Risk Assessment Information System Toxicity Summary for MANGANESE". Oak Ridge National Laboratory
- 9 - Thyssen JP, Linneberg A, Menné T, Johansen JD (2007). "The epidemiology of contact allergy in the general population—prevalence and main findings"
- 10 - Agency for Toxic Substances and Disease Registry
- 11 - "Public Health Statement: Health Effects" (PDF). Agency for Toxic Substances and Disease Registry.
- 12 - Douglas, Kenneth T.; Bunni, Marlene A.; Baidur, Swati R. (1990). "Thallium in biochemistry". International Journal of Biochemistry
- 13 - "Mechanisms of chronic waterborne Zn toxicity in *Daphnia magna*"