DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the Federal Register on April 11, 1988 (53 FR 11970), and subsequently revised in the Federal Register on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the Federal Register during the first week of each month. If any laboratory’s certification is suspended or revoked, the laboratory will be omitted from subsequent lists, until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at http://www.workplace.samhsa.gov and http://www.drugfreeworkplace.gov.

FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Divison of Workplace Programs, SAMHSA/CSAP, Room 2–1042, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Mandatory Guidelines, “Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,” sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

Incorporated: LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
Maxxam Analytics*, 6740 Campello Road, Mississauga, ON, Canada L5N 2L8, 905–817–5700. (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.)
MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295.
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088.
One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774. (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).
Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942. (Formerly: Continenla Hospital Airport Toxicology Laboratory).
Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555.
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x1276.
St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052.
STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438.
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273.
US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.
The following laboratory will be voluntarily withdrawing from the National Laboratory Certification Program on December 1, 2009:
Clendo Reference Laboratory, Avenue Santa Cruz #58, Bayamon, Puerto Rico 00959, 787–620–9095.

*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (Federal Register, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the Federal Register on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Dated: December 1, 2009.
Elaine Parry,
Director, Office of Program Services, SAMHSA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.” This guidance describes how FDA reviews and evaluates patient-reported outcome (PRO) instruments used to measure treatment benefit in medical product clinical trials. It also provides recommendations on how sponsors can use study results measured by PRO instruments to support claims in approved medical product labeling. This guidance finalizes the draft guidance published on February 3, 2006.

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or Office of Communication, Education, and Radiation Programs, Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850–4307. Send one self-addressed adhesive label to assist in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http:// www.regulations.gov. See the SUPPLEMENTARY INFORMATION section for...