

FDA's GGP regulation provides that the public may comment on any guidance at any time, including Level 1 guidance documents for immediate implementation and Level 2 guidance documents, and FDA may delay implementation of any guidance document.

a. In light of the above, we seek input on whether there are any additional circumstances, categories of guidance documents, or topics for guidance for which it may be appropriate and consistent with the FD&C Act and FDA's GGP regulation for FDA to consider issuance as a Level 1 guidance document for immediate implementation without prior public comment.

b. We also seek comment on whether there are additional categories or types of guidance documents that FDA should consider issuing as Level 2 guidance documents to streamline the guidance process and allow the Agency to better leverage its resources for the timely development of more guidance documents.

3. FDA requests comment on any novel guidance document formats that would be of particular utility, such as use of templates to accompany a guidance document, Q&A formats, flowcharts, etc., that are used in FDA guidance documents or that were used in guidance documents issued in response to the COVID-19 PHE.

4. FDA makes robust use of guidance documents to assist industry in making regulatory submissions. As described in the report, examples of such guidances include device-specific guidance documents, disease or indication specific guidance documents that include recommendations on developing drugs intended to treat a specific disease or for a specific indication to support submissions of New Drug Applications (NDAs) or Supplemental NDAs, product specific guidances for generic drug development to support submission of Abbreviated New Drug Applications (ANDAs), Data Technical Conformance Guides to accompany guidance documents, and guidance documents that provide assistance with registration and listing requirements. FDA requests comment on the utility of guidances in streamlining regulatory submissions and whether there are additional categories or types of guidance that would be helpful to streamline processes for regulatory submissions to the Agency.

5. Currently, FDA's GGP regulation (§ 10.115) provides that interested persons can suggest areas for guidance document development and that such suggestions should address why a

guidance document is necessary. (§ 10.115(f)(2)). In addition, proposed guidance documents can be submitted to a specified docket for FDA consideration. (§ 10.115(f)(3)). FDA requests comments on whether the currently available mechanisms for submitting suggested areas for guidance development and proposed guidance documents are useful and sufficient or whether additional mechanisms, for example, a Center-specific or Office-specific mailbox for such suggestions would ease the process for such submissions.

6. FDA Centers publish guidance agendas on their web pages to give interested parties and the public notice of the areas in which FDA is considering upcoming guidance. We request comment on the utility of these guidance agendas and what, if any, modifications to these agendas would be helpful for the Agency to consider.

III. Electronic Access

Persons with access to the internet may obtain the draft report and plan at <https://www.fda.gov/about-fda/reports/reports-agency-policies-and-initiatives> or <https://www.regulations.gov>.

Dated: December 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-28872 Filed 1-2-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid 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 and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

FOR FURTHER INFORMATION CONTACT: Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240-276-

2600 (voice); *Anastasia.Flanagan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: In accordance with section 9.19 of the Mandatory Guidelines, a notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF 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 <https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list>.

The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine 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); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for Federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three

rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare*, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780-784-1190, (Formerly: Gamma-Dynacare Medical Laboratories).

HHS-Certified Laboratories Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215-2802, 800-445-6917

Desert Tox, LLC, 5425 E Bell Rd. Suite 125, Scottsdale, AZ, 85254, 602-457-5411/623-748-5045

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800-235-4890

Dynacare*, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630, (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-5295/800-950-5295, (Formerly: Legacy Laboratory Services Toxicology MetroLab)

Laboratory Corporation of America Holdings, 7207 N Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651-636-7466/800-832-3244

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612-725-2088. Testing for Veterans Affairs (VA) Employees Only

Omega Laboratories, Inc., * 2150 Dunwin Drive, Unit 1 & 2, Mississauga, ON, Canada L5L 5M8, 289-919-3188

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800-328-6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888-635-5840

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610-631-4600/877-642-2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755-5235, 301-677-7085, Testing for Department of Defense (DoD) Employees Only

* 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 (61 FR 37015) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). 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.

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[FR Doc. 2023-28882 Filed 1-2-24; 8:45 am]

BILLING CODE 4160-20-P