DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Detection of HIV for Self-Testing (R41/R33 Clinical Trial Not Allowed).

Date: June 30, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3C21A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Dimitrios N. Vatakis, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3C21A, Rockville, MD 20852, 301–716–7176, dimitrios.vatakis@nih.gov.

 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If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing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...
Laboratory Corporation of America
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ElSohly Laboratories, Inc., 5 Industrial
Dynacare*, 245 Pall Mall Street,
Desert Tox, LLC, 5425 E Bell Rd, Suite
Alere Toxicology Services, 450
Alere Toxicology Services, 1111 Newton
specimens:

• 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:

Laboratory Corporation of America

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, 450
Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917
Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800–422–9438 (Formerly: STERLING Reference Laboratories)
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
Laboratory Corporation of America Holdings, 2707 N Gessner Road, Houston, TX 77040, 713–856–8288/800–437–4986

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

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,

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 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.

Anastasia Marie Donovan,
Public Health Advisor, Division of Workplace Programs.

Federal Emergency Management Agency

[DOcket ID FEMA–2020–0016]

Meetings To Implement Pandemic Response Voluntary Agreement Under Section 708 of the Defense Production Act


ACTION: Announcement of meetings.

SUMMARY: The Federal Emergency Management Agency (FEMA) is holding quarterly status meetings under each of the six Plans of Action, in the corresponding order listed below, to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic.

• Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID–19.

• Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID–19.

• Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Diagnostics Test Kits and other Testing Components to Respond to COVID–19.

• Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic.

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPS) effective May 12, 1998. Laboratories accredited 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 LAPS

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