

context can demonstrate which oncogene derived neopeptides are presented by common HLA alleles, and can provide the data necessary to rapidly develop TCRs against the desired antigens.

Using the MS approach, inventors at the National Cancer Institute (NCI) have identified neopeptides derived from a mutated isoform of Epithelial Growth Factor Receptor (EGFR) presented by HLA A\*11:01 across multiple biological replicates. From this MS data, the inventors were able to successfully isolate murine TCRs that specifically recognize HLA A\*11:01 restricted neopeptides targeting EGFR L858R. According to various cancer genome databases, EGFR L858R is highly prevalent in lung adenocarcinoma, non-small cell lung carcinoma, and non-squamous non-small cell lung carcinoma, making this driver mutation an excellent target to develop off-the-shelf cellular therapies. The clinical potential of these TCRs has not been explored.

*Therapeutic Area(s):* Cancer.

Research uses include: TCRs may be used as positive controls to identify HLA-A\*11:01 EGFR L858R reactive T cells from different sources such as patients or animal models; TCRs recognize the common EGFR L858R driver mutation in the context of HLA-A\*11:01; EGFR; the prevalence of EGFR L858R substitutions, relative to the overall EGFR mutation population, ranges from 27.7% to 41.1% in non-small cell lung cancer patients; HLA-A\*11:01 allele frequency is particularly high (up to 60%) in Asian and Oceanian populations. This research has validated the effectiveness of using mass spectrometry to detect amino acid sequences on specific HLA complexes.

Achieving expeditious commercialization of federally funded research and development is consistent with the goals of the Bayh-Dole Act, codified as 35 U.S.C. 200–212 and 37 CFR 404.4.

*Development Stage:* Research Tool.

Dated: February 26, 2024.

**Richard U. Rodriguez,**

*Associate Director, Technology Transfer Center, National Cancer Institute.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Population Sciences and Epidemiology Integrated Review Group, Aging, Injury, Musculoskeletal, and Rheumatologic Disorders Study Section, March 14, 2024, 09:00 a.m. to March 15, 2024, 08:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on February 26, 2024, 89 FR 14081, Doc 2024–03762.

This meeting is being amended to change the location to Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314. The meeting time will remain the same. The meeting is closed to the public.

Dated: February 26, 2024.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## 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 (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

#### 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:** The Department of Health and Human Services (HHS) publishes a notice listing all HHS-certified laboratories and Instrumented Initial Testing Facilities (IITFs) in the **Federal Register** during the first week of each month, in accordance with Section 9.19 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and Section 9.17 of the Mandatory Guidelines using Oral Fluid. 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/drug-testing-resources/certified-lab-list>.

HHS separately notifies Federal agencies of the laboratories and IITFs currently certified to meet the standards of the 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); January 23, 2017 (82 FR 7920); and on October 12, 2023 (88 FR 70768).

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, and subsequently revised in the **Federal Register** on October 12, 2023 (88 FR 70814).

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 effective October 10, 2023 (88 FR 70814), 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 effective February 1, 2024 (88 FR 70768), 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 effective February 1, 2024 (88 FR 70768), 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 continued 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 as meeting the minimum standards of the current Mandatory Guidelines published in the **Federal Register**. 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. DOT established this process in July 1996 (61 FR 37015) to allow foreign laboratories to participate in the DOT drug testing program.

**Anastasia D. Flanagan,**

*Public Health Advisor, Division of Workplace Programs.*

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