context can demonstrate which oncogene derived neoepitopes 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 neoepitopes 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 neoepitopes 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.

[FR Doc. 2024–04251 Filed 2–29–24; 8:45 am]

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.

[FR Doc. 2024–04306 Filed 2–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration


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 for Federal Workplace Drug Testing Programs (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 for Federal Workplace Drug Testing Programs (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, Minneapolis, MN 55417, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline BioScience 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.

Upon finding a Canadian laboratory to meet 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 laboratories in Canada and the United States to conduct drug testing plus periodic on-site inspections of those LAPSA-accredited laboratories that 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.