Laboratory NGS assay has adequate sensitivity and specificity. Laboratory tests tumor tissue for rare variants as described in NCI-ComboMATCH.

Laboratory agrees to provide needed information for evaluation of the analytical validity of the test.

Laboratory is likely to screen at least 200 patients at NCTN sites per month for NCI-ComboMATCH.

Laboratory agrees to contact sites regarding NCI-ComboMATCH eligibility.

Laboratory agrees to a collaboration with NCI as detailed above.

Review criteria for full application:

Laboratory supplies evidence that the assay meets analytical requirements as detailed above.

Laboratories are capable of contacting clinical sites, tracking activity, and screening at least 200 patients at NCTN sites per month to the study based on detection of potential variants.

Laboratories agree to execute a collaboration agreement with NCI, as well as to data sharing and sharing publication rights.

Laboratories agree to abide by the procedures in place for the NCI-ComboMATCH study and to collaborate fully with the NCI-ComboMATCH team.

For more information, contact NCICOMBOMATCHLabApps@nih.gov.

Dated: June 24, 2020.

James V. Tricoli,
Chief, Diagnostic Biomarkers and Technology Branch, Cancer Diagnosis Program, National Cancer Institute.

[FR Doc. 2020–14044 Filed 6–29–20; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration


AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Health and Human Services (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 Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); Anastasia.Donovan@samhsa.hhs.gov (email).

SUPPLEMENTARY INFORMATION: 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/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 for oral fluid testing.

HHS-Certified Laboratories Certified 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 Certified 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:

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

HHS-Certified Laboratories Certified 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:

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

Aldre Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–379–9130 (Formerly:
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB No. 0930–0158)—Revision

SAMHS will request OMB approval for a revision of the Federal Drug Testing Custody and Control Form (CCF) for Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Workplace Drug Testing Programs using Urine (UrMG) dated January 23, 2017 (82 FR 7920) and using Oral Fluid (OFMG) dated October 25, 2019, and OMB approval for information provided by test facilities (laboratories and Instrumented Initial Test Facilities, IITFs) for the National Laboratory Certification Program (NLCP).

The CCF is used by all Federal agencies and employers regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) to document the collection and chain of custody of urine specimens at the collection site, for HHS-certified test facilities to report results, and for Medical Review Officers (MROs) to document and report a verified result. SAMHSA allows the use of the CCF as a paper or electronic form.

The current OMB-approved CCF has an August 31, 2020 expiration date. SAMHS has resubmitted the CCF with revisions to the form for OMB approval. During 60-day public comment period, the CCF comments were comprised of individuals, organizations, and private sector companies. All comments were reviewed and taken into consideration in the preparation of the revised CCF. The issues and concerns raised in the public comments for the CCF are set out www.reginfo.gov/public/do/PRAMain.

These revisions are listed below:

*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.