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.

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 Laboratories Certified To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid 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:

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:

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

Southlake Blvd., Richmond, VA 23226, 804–379–9130 (Formerly: Laboratory Specialists, 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)
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.)
Legacy Laboratory Services Toxicology, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295, (Formerly: Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc.)
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only.
Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–326–6004, (Formerly: Centinela Hospital Airport Toxicology Laboratory)
Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7
Pharmatech, Inc., 15175 Innovation Park Drive, Norcross, GA 30093, 770–476–2910, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Beecham Clinical Laboratories)
Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Biopharmaceuticals Laboratories)
Quest Diagnostics Incorporated, 400 Egypt Road, Northport, NY 11768, 631–640–9177, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Biopharmaceuticals Laboratories)
Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159, U.S. 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
Anastasia Marie Donovan, Policy Analyst.

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

SAMHSA 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. SAMHSA has resubmitted the CCF with revisions to the form for OMB approval. During 60-day public comment 7 commenter’s submitted comments on the proposed changes to the CCF. These commenters 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: