This document is scheduled to be published in the
Federal Register on 11/19/2025 and available online at
https://federalregister.gov/d/2025-20290, and on https://govinfo.gov

le 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Methods for the Diagnosis And Prognosis of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute and the National Institute of Arthritis and Musculoskeletal and Skin Diseases, institutes of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice to BioncoDx, LLC, a company organized in Delaware.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Todd Testerman, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, Telephone: 240-620-0822; E-mail: todd.testerman@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. US Provisional Patent Application No. 61/845,055 filed July 11, 2013, and entitled "Method for the Diagnosis And Prognosis of Cancer" [HHS Reference No. E-121-2013-0-US-01];

2. International PCT Application No. PCT/US2014/046294 filed July 11, 2014, and entitled "Method for the Diagnosis And Prognosis of Cancer" [HHS Reference No. E-121-2013-0-PCT-02];
3. US Patent No. 10,393,745 issued 8/27/2019, and entitled "Method for the Diagnosis And Prognosis of Cancer" [HHS Reference No. E-121-2013-0-US-04];
4. US Patent No. 11,555,818 issued 1/17/2023, and entitled "Method for the Diagnosis And Prognosis of Cancer" [HHS Reference No. E-121-2013-0-US-05];
5. Europe Patent No. 3019871 issued 10/16/2019, and entitled Method for the Diagnosis And Prognosis of Cancer" [HHS Reference No. E-121-2013-0-EP-03];
6. German Patent No. 3019871 issued 10/16/2019, and entitled "Method for the Diagnosis And Prognosis of Cancer" [HHS Reference No. E-121-2013-0-DE-06];
7. French Patent No. 3019871 issued 10/16/2019, and entitled "Method for the Diagnosis And Prognosis of Cancer" [HHS Reference No. E-121-2013-0-FR-07]; and
8. United Kingdom Patent No. 3019871 issued 10/16/2019, and entitled "Method for the Diagnosis And Prognosis of Cancer" [HHS Reference No. E-121-2013-0-GB-08].

The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide where patent rights exist and the field of use may be limited to the following: "Use of the Patent Rights to develop, manufacture and commercialize a Food and Drug Administration (FDA) Premarket Approval (PMA) - creatine riboside, metabolite 561+, cortisol sulfate, and N-acetylneuraminic acid metabolite-based prognostic, diagnostic/companion diagnostic, and general screening tests for cancers of the lung/thoracic, breast, colorectal, kidney/bladder, prostate, liver, stomach, pancreatic, GYN (ovary, uterine, cervix) and brain from urine samples." After a negotiated

period of time, the exclusive field of use will be reduced to a subset of three cancer indications with strict developmental benchmarks for each indication.

The subject technology is a unique, non-invasive screening tool and diagnostic that can detect cancers, including lung cancer, at an early stage utilizing liquid chromatography-mass spectrometry for the detection of four biomarkers - creatine riboside, metabolite 561+, cortisol sulfate, and N-acetylneuraminic acid - from human clinical samples, particularly urine samples. Urine samples minimize patient discomfort, unlike current early detection methods that are invasive, such as blood or tissue biopsy or bronchoscopy, and can be performed easily during a routine exam.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: November 17, 2025.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

[FR Doc. 2025-20290 Filed: 11/18/2025 8:45 am; Publication Date: 11/19/2025]