

Scientists at NIAID have developed novel topical formulations that promote the growth of health-associated strains of commensal bacteria and inhibit disease-associated bacteria, thereby enhancing skin health.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

*Potential Commercial Applications:*

- Over-the-counter formulations—this invention could be readily incorporated into popular body lotions or other skincare products to make “enhanced”/“microbiome-friendly” versions that promote the growth of health associated bacterial

*Competitive Advantages:*

- Benign safety profile with multiple mechanisms of action
- Proven enhancement of beneficial microbiota
- Can be readily incorporated into existing products

*Development Stage:*

- Pre-clinical

*Inventors:* Carlos Castillo and Ian Myles, MD, MPH, both of NIAID.

*Publications:* Castillo, Carlos, et al. “Assessing the effects of common topical exposures on skin bacteria associated with atopic dermatitis”, *Skin Health and Disease*, 2021.05.07.

*Intellectual Property:* HHS Reference No. E-100-2021-0; US provisional application No. 63/175,368 filed on April 15, 2021.

*Licensing Contact:* To license this technology, please contact David Yang at 240-695-6406 or [yangp3@mail.nih.gov](mailto:yangp3@mail.nih.gov) and reference E-100-2021-0.

*Collaborative Research Opportunity:* The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact David Yang at 240-695-6406 or [yangp3@mail.nih.gov](mailto:yangp3@mail.nih.gov).

Dated: June 24, 2021.

**Surekha Vathyam,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License, Inter-Institutional Agreement-Institution Lead: Biomarkers and Immunogenic Compositions for Filarial Parasites**

**AGENCY:** National Institutes of Health, National Institute of Allergy and Infectious Diseases, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to New York Blood Center, Inc. (“NYBC”), located in New York, New York, in its rights to the technologies and patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, on or before July 16, 2021 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive License should be directed to: Theodoric Mattes, Ph.D., Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804, phone number 240-627-3827, or [theodoric.mattes@nih.gov](mailto:theodoric.mattes@nih.gov).

**SUPPLEMENTARY INFORMATION:** The following and all continuing U.S. patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to NYBC: United States Provisional Patent Application Number 62/317,342, filed May 1, 2016, the title of which is “Biomarkers and Immunogenic Compositions for Filarial Parasites” (HHS Reference No. E-288-2016-0-US-01); PCT Patent Application Number PCT/US2017/025554, filed March 31, 2017, the title of which is “Biomarkers and Immunogenic Compositions for Filarial Parasites” (HHS Reference No. E-288-2016-00-PCT-02); United States Patent Application Number 16/090,013, filed September 28, 2018, the title of which is “Biomarkers and Immunogenic Compositions for Filarial Parasites”

(HHS Reference No. E-288-2016-0-US-03); and United States Patent Application Number 17/076,616, filed October 21, 2020, the title of which is “Biomarkers and Immunogenic Compositions for Filarial Parasites” (HHS Reference No. E-288-2016-0-US-04).

The patent rights to this technology have been assigned to New York Blood Center, Inc. and the Government of the United States of America as represented by the Secretary, Department of Health & Human Services, by each institution’s respective inventors.

The prospective patent license will be for the purpose of consolidating the patent rights to New York Blood Center, Inc., for the development and commercialization of the technology.

Consolidation of these co-owned rights is intended to expedite development of the technology, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212.

The prospective interinstitutional agreement may include an exclusive license for NIAID’s rights in these jointly owned patents. It will be sublicensable, and any sublicenses granted by NYBC will be subject to the provisions of 37 CFR part 404. NIAID will retain its rights to non-exclusively license its rights to the patent applications to third parties for internal research use.

In the subject technology, researchers at NIAID and NYBC isolated and analyzed the transcriptome and proteome of the parasite at various life stages as well as its *Wolbachia sp.* endosymbiont to identify potential biomarkers for diagnostic assays and vaccine candidates. In all, they identified forty-seven (47) biomarkers. The associated patents claim the use of two or more of these biomarkers in conjunction with an adjuvant as an immunological composition, or the detection of any of these biomarkers in a serological-type assay.

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 may be granted unless within fifteen (15) days from the date of this published notice the National Institute of Allergy and Infectious Diseases 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.

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.

Complete 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 U.S.C. 552.

Dated: June 25, 2021.

**Surekha Vathyam,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

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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 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:** In accordance with Section 9.19 of the Mandatory Guidelines, 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 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); and on January 23, 2017 (82 FR 7920).

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.

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 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 Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), 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 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., 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

Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800-442-0438 (Formerly: STERLING Reference Laboratories)

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)