

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Amy F. Petrik, Ph.D., 240-627-3721; [amy.petrik@nih.gov](mailto:amy.petrik@nih.gov). Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

**Structure-Based Design of SARS2-CoV-2 Spike Immunogens Stabilized in the RBD-All Down Conformation***Description of Technology:*

SARS-CoV-2 has emerged as a global pathogen, sparking urgent vaccine development efforts. The trimeric SARS-CoV-2 spike appears to be a leading vaccine antigen. However, the inability of antibodies such as CR3022, which binds tightly to a cryptic spike epitope, to neutralize SARS-CoV-2 suggests a spike-based means of neutralization escape.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) sought to understand how antibodies with high affinity fail to neutralize the SARS-CoV-2. To that end, the researchers characterized the SARS-CoV-2 spike protein conformational changes as a function of pH and observed that at endosomal pH the spike protein has a conformation in which all of the receptor binding domains (RBD) are in a down conformation which

could explain the virus' ability to escape neutralization in the endosome.

Hypothesizing that SARS-CoV-2 escapes neutralization through pH-dependent conformational masking, the researchers designed spike proteins with mutations to stabilize the spike in the RBD-all down conformation. Such designs include cavity-filling mutations, disulfides, aspartic acid to asparagine mutations, proline mutations, and other sequence modifications to fix the spike protein in its RBD-all down conformation so that immunization at a physiological pH will elicit antibodies that can recognize the low pH-stabilized all RBD-down conformation of the spike protein and no longer be susceptible to pH-induced neutralization escape.

Immunogenicity studies are underway to determine which of the designs will yield a neutralizing immune response in mice. Pending results in mice, a lead candidate will be selected for studies in nonhuman primates.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

*Potential Commercial Applications*

- An improved stabilized spike immunogen for the development of protective SARS-CoV-2 vaccine.

*Competitive Advantages*

- Stabilized SARS-CoV-2 spike variants with potential to elicit higher levels of neutralizing antibodies than current related vaccine development.
- Identification of a methodology to screen for improved spike variants (by assessing binding by neutralizing versus non-neutralizing antibodies).

*Development Stage:* Preclinical Research.

*Inventors:* Peter Dak-Pin Kwong (NIAID); Tongqing Zhou (NIAID); Yaroslav Tsybovsky (NCI); Adam Shabbir Olia (NIAID); John R. Mascola (NIAID).

*Publications:* Zhou, T *et al.*, (2020). Cryo-EM Structures Delineate a pH-Dependent Switch that Mediates Endosomal Positioning of SARS-CoV-2 Spike Receptor-Binding Domains. *BioRxiv*.

*Intellectual Property:* HHS Reference Number E-187-2020 includes U.S. Provisional Patent Application Number 63/046,603, filed 06/30/2020.

*Licensing Contact:* To license this technology, please contact Amy F. Petrik, Ph.D., 240-627-3721; [amy.petrik@nih.gov](mailto:amy.petrik@nih.gov).

Dated: September 17, 2020.

**Surekha Vathyam,**

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

[FR Doc. 2020-21708 Filed 9-30-20; 8:45 am]

**BILLING CODE 4140-01-P**

**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](mailto: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 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-

\* 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.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as

679-1630 (Formerly: Gamma-Dynacare Medical Laboratories) ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609

Laboratory Corporation of America Holdings, 7207 N Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc., CompuChem Laboratories, 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

MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651-636-7466/800-832-3244

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, 800-328-6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888-635-5840

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800-729-6432 (Formerly: SmithKline

meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). 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.

Beecham Clinical Laboratories;  
SmithKline Bio-Science Laboratories)  
Quest Diagnostics Incorporated, 400  
Egypt Road, Norristown, PA 19403,  
610-631-4600/877-642-2216  
(Formerly: SmithKline Beecham  
Clinical Laboratories; SmithKline Bio-  
Science Laboratories)  
Redwood Toxicology Laboratory, 3700  
Westwind Blvd., Santa Rosa, CA  
95403, 800-255-2159  
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

Anastasia Marie Donovan,  
Policy Analyst.

[FR Doc. 2020-21692 Filed 9-30-20; 8:45 am]

BILLING CODE 4160-20-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2020-0047]

### Towing Safety Advisory Committee; October 2020 Teleconference

**AGENCY:** Coast Guard, Department of  
Homeland Security.

**ACTION:** Notice of Federal Advisory  
Committee teleconference meeting.

**SUMMARY:** The Towing Safety Advisory  
Committee (Committee) will meet via  
teleconference to discuss Task 16-01,  
Subchapter M Implementation. The  
Committee is expected to receive the  
final report from the subcommittee  
tasked with identifying the parameters  
Coast Guard officials should use to  
determine whether a vessel inspected  
under subchapters other than  
Subchapter M performs occasional  
towing. Additional items to be  
discussed are also included as agenda  
items in the **SUPPLEMENTARY  
INFORMATION** section below.

**DATES:** *Meeting:* The full Committee will  
meet by teleconference on Thursday,  
October 29, 2020, from 1 p.m. until 3  
p.m. Eastern Standard Time. Please note  
that this meeting may close early if the  
Committee has completed its business.

*Comments and supporting  
documents:* To ensure your comments  
are received by Committee members  
before the teleconference, submit your  
written comments no later than October  
20, 2020.

**ADDRESSES:** To join the teleconference  
or to request special accommodations,  
contact the individual listed in the **FOR  
FURTHER INFORMATION CONTACT** section

no later than 1 p.m. on October 20,  
2020, to obtain the needed information.  
The number of teleconference lines are  
limited and will be available on a first-  
come, first-served basis.

*Instructions:* You are free to submit  
comments at any time, including orally  
at the teleconference, but if you want  
Committee members to review your  
comments before the teleconference,  
please submit your comments no later  
than October 20, 2020. We encourage  
you to submit comments through the  
Federal eRulemaking Portal at <https://www.regulations.gov>. If your material  
cannot be submitted using <https://www.regulations.gov> call or email the  
individual in the **FOR FURTHER  
INFORMATION CONTACT** section of this  
document for alternate instructions. You  
must include the docket number  
[USCG-2020-0047]. Comments received  
will be posted without alteration at  
<https://www.regulations.gov>, including  
any personal information provided. For  
more about privacy and submissions in  
response to this document, see DHS's  
eRulemaking System of Records notice  
(85FR 14226, March 11, 2020). If you  
encounter technical difficulties with  
comment submission, contact the  
individual listed in the **FOR FURTHER  
INFORMATION CONTACT** section of this  
notice.

*Docket Search:* Documents mentioned  
in this notice as being available in the  
docket, and all public comments, will  
be in our online docket at <https://www.regulations.gov> and can be viewed  
by following that website's instructions.  
Additionally, if you go to the online  
docket and sign-up for email alerts, you  
will be notified when comments are  
posted.

**FOR FURTHER INFORMATION CONTACT:** Mr.  
Matthew D. Layman, Alternate  
Designated Federal Officer of the  
Towing Safety Advisory Committee,  
2703 Martin Luther King Jr Ave. SE,  
Stop 7509, Washington, DC 20593-  
7509, telephone 202-372-1421, fax  
202-372-8382 or [Matthew.D.Layman@uscg.mil](mailto:Matthew.D.Layman@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The  
Towing Safety Advisory Committee  
provides advice and recommendations  
to the Department of Homeland Security  
on matters related to shallow-draft  
inland and coastal waterway navigation  
and towing safety. It was established by  
Public Law 96-380 in 1980 and was an  
active committee on December 3, 2018,  
the day before the Frank LoBiondo  
Coast Guard Authorization Act of 2018  
(Pub. L. 115-282) was enacted, and  
operates under provisions of Sec. 601  
(d) of that Act.

## Agenda

The agenda for the October 29, 2020,  
teleconference meeting is as follows:

(1) Final report from the  
Subcommittee on "Recommendations  
on the Implementation of 46 Code of  
Federal Regulations Subchapter M—  
Inspection of Towing Vessels (Task 16-  
01).

(2) Update on the National Towing  
Safety Advisory Committee and the  
December 4, 2020 termination date for  
the Towing Safety Advisory Committee.

(3) Update from the Office of  
Commercial Vessel Compliance on the  
status of Subchapter M Implementation.

(4) Awards and recognition.

(5) Public Comment period.

A copy of all pre-meeting  
documentation will be available at  
<https://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/Commercial-Regulations-standards-CG-5PS/Office-of-Operating-and-Environmental-Standards/vfos/TSAC/>.  
Alternatively, you may contact Mr.  
Matthew Layman as noted in the **FOR  
FURTHER INFORMATION CONTACT** section  
above.

During the October 29, 2020  
teleconference, a public comment  
period will be held from approximately  
2:45 p.m. to 3 p.m. Eastern Standard  
Time. Speakers are requested to limit  
their comments to 3 minutes. Please  
note that this public comment period  
may start before 2:45 p.m. if all other  
agenda items have been covered and  
may end before 3 p.m. if all of those  
wishing to comment have done so.  
Please contact Mr. Matthew D. Layman,  
listed in the **FOR FURTHER INFORMATION  
CONTACT** section to register as a speaker.

Dated: September 18, 2020.

Jeffrey G. Lantz,

Director of Commercial Regulations and  
Standards.

[FR Doc. 2020-21742 Filed 9-30-20; 8:45 am]

BILLING CODE 9110-04-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R5-ES-2020-N128;  
FXES11130500000-201-FF05E00000]

### Endangered Species; Receipt of Recovery Permit Applications

**AGENCY:** Fish and Wildlife Service,  
Interior.

**ACTION:** Notice of receipt of permit  
applications; request for comments.

**SUMMARY:** We, the U.S. Fish and  
Wildlife Service, have received