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).


Licensing Contact: To license this technology, please contact Amy F. Petrik, Ph.D., 240–627–3721; amy.petrik@nih.gov.
(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 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 23264, 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

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


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)

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., ComputChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche ComputChem 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


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 Dr., Southlake, TX 76092, 817–329–0420

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.

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

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.
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.
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. 115–242) 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:
(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.
Jeffrey G. Lantz,
Director of Commercial Regulations and Standards.
[FDoc. 2020–21742 Filed 9–30–20; 8:45 am]
BILLING CODE 9110–04–P
DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
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...