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); Yarooslav 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration


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: 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 (NCLP) 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 standards 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 ITFs 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)


DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare, * 245 Fall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohl 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., CompChem Laboratories, Inc.; CompChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6399 (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, 800–326–6942 (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.

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

(1) Final report from the Subcommittee on "Recommendations for 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.


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.