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*. 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.*

Dated: September 17, 2020.

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: 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