

Public Health Service

National Institutes of Health Freedom of Information Office Building 31, Room 58-35 31 Center Drive, MSC 2107 Bethesda, Maryland 20892-2107 phone: (301) 495-5633 fax: (301) 402-4541

Via Email:	
September 3, 2021	

Re: FOIA Case Number: 56905

## Dear

This is our final response to your Freedom of Information Act (FOIA) request addressed to National Institutes of Health (NIH), dated August 18, 2021, and received in this office on the same day. You requested copies of public records that demonstrates the NIAID or NIH has a physical sample of the isolated and purified SARS-CoV-2 virus, to produce any and all evidence of this External Standard or Certified Reference Material (CRM) for calibration of RT-PCR test kits and any or all documentation and evidence of whether the Whole Genome Sequencing (WGS) occurred from the isolate, as well as evidence and information on the current modality/test being used to determine and identify the difference from the original SARS-CoV-2 virus and the "Delta Variant" and/or other variants with all evidence and documentation demonstrating the initial discovery of the other variants.

Please be advised that your request is improper as defined by FOIA given that you have not specified where (named office or institute) or what (i.e. named grant number, report, etc) you would like searched at the NIH. Considering the omission of the aforementioned information necessary for a proper search to be conducted, the NIH cannot process your request as it is written. In good faith, we provide the following information that may prove useful to you.

Much of the information on the isolation of the virus from the diseased host, which requires growth in cell culture, is already publicly available. Viruses do not replicate outside of a host or in a pure culture (devoid of other cells). Koch's postulates were formed prior to the identification of viruses as the causative agents of some diseases and also pre-date modern microbiological techniques, including the ability to isolate viruses from hosts. As such, Koch's postulates have limitations when evaluating viruses and do not adequately account for the way viruses are isolated and propagated given that viruses are obligate intracellular parasites.

SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). Active infection with SARS-CoV-2 is detected by <u>diagnostic tests</u>. Currently there are two types of diagnostic tests – molecular tests that detect the virus's genetic material and antigen tests that detect specific proteins on the surface of the virus. For current data showing the total number of SARS-CoV-2-positive cases and deaths, visit the <u>CDC COVID-19 Data Tracker</u>, which shows cases and deaths in the United States broken down by state and county, daily trends in the number of cases by state, and other parameters.

Evidence of SARS-CoV-2 infection can be found in a study entitled, <u>Pathology and Pathogenesis</u> of <u>SARS-CoV-2</u> <u>Associated with Fatal Coronavirus Disease</u>, which includes electron microscopy images of SARS-CoV-2 in infected lung and upper airway tissues as well as staining of lung and upper airway tissues using an antibody against SARS-CoV-2.

The specimens analyzed in this study were from patients with common signs and symptoms associated with COVID-19, including fever, cough, and shortness of breath. All patients had abnormal findings on chest radiographs.

There are other similar studies publicly available online. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's <u>PubMed entry</u>.

The SARS-CoV-2 virus may be isolated from human clinical specimens by culturing in cells. In January 2020, CDC <u>isolated the SARS-CoV-2 virus</u> from a clinical specimen from the first confirmed case of COVID-19 in the United States. There are other similar studies published describing the isolation and characterization of SARS-CoV-2 from human clinical specimens. To aid in locating other related studies, please see the articles suggested in the "Similar Articles" and "Cited by" section on the manuscript's <u>PubMed entry</u>. There are also <u>several</u> publications documenting SARS-CoV-2 infection and transmission among pre-symptomatic and asymptomatic individuals.

For information about the SARS-CoV-2 genome sequence, see the NIH GenBank website (<u>https://www.ncbi.nlm.nih.gov/genbank/sars-cov-2-seqs/</u>), which includes over 1 million sequences. For information about isolation, purification, amplification, and identification of the COVID-19 virus, please see the following articles

https://www.microbiologyresearch.org/content/journal/jgv/10.1099/jgv.0.001453 and refer to PubMed: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3352184/

If you are not satisfied with the processing and handling of this request, you may contact the OD FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison Denean Standing-Ojo Public Affairs Specialist Office of Communications and Public Liaison Building 31, Room 5B52S 31 Center Drive Bethesda, MD 20814 301-496-5077 (phone) 301-496-0818 (fax) nihfoia@od.nih.gov (email)

## <u>OGIS</u>

National Archives and Records Admin 8601 Adelphi Rd - OGIS College Park, MD 20740-6001 202-741-5770 (phone) 1-877-684-6448 (toll-free) 202-741-5769 (fax) ogis@nara.gov (email)

In certain circumstances, provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there are no charges for search time.

Sincerely,

Roger Bordins

Roger Bordine Freedom of Information Office, NIH