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To: Clinical and reference laboratory directors, laboratory-based and public health researchers, local and tribal health officers, health care providers

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# Guidance related to viral whole genome sequencing of SARS-CoV-2 for the public health response

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## Summary

Genome sequencing of the SARS-CoV-2 virus is a valuable tool for understanding the epidemiology of COVID-19, and may enhance Wisconsin's capacity to investigate and respond to disease clusters and outbreaks. The purpose of this memo is to notify clinical, laboratory, and public health partners about the commitment by the Department of Health Services (DHS) to support scientific collaboration around viral sequencing as a key strategy in Wisconsin's COVID-19 response. DHS is also providing guidance related to the sharing of specimens obtained from patients, and the appropriate use of viral sequence data derived from these specimens.

## Background

COVID-19 is a Category I reportable condition in Wisconsin, subject to reporting requirements described in Wis. Stat. ch. 252 and Wis. Admin Code. ch. DHS 145. Universal reporting of probable, suspected and confirmed cases of COVID-19 occurring in Wisconsin residents comprises the backbone of public health surveillance and outbreak investigations, which are the necessary components of the pandemic response.

Genomic epidemiology involves using advanced laboratory methods to provide an enhanced understanding of disease patterns and transmission dynamics. Techniques to sequence the genome of SARS-CoV-2, the virus that causes COVID-19, promise to enhance the impact of investigations and responses to outbreaks in community, health care, and occupational settings across the state. To realize this potential, DHS is supporting the efforts of laboratories to collect, share, and perform SARS-CoV-2 viral whole genome sequencing (WGS) on samples collected within Wisconsin.

As of this writing, four Wisconsin laboratories are able to perform viral WGS of SARS-CoV-2, and submit limited sequence data into the GISAID database, an international data repository used to understand epidemiology of COVID-19 on both a local and global scale. The United States Health and

Human Services, Center for Disease Control and Prevention (CDC) is one of GISAID's partners. DHS requests that laboratories conducting diagnostic testing for COVID-19 for Wisconsin residents will agree to share residual specimens containing detectable SARS CoV-2 RNA for viral WGS when requested for the purpose of public health investigations. Specimens may be requested by the Wisconsin State Laboratory of Hygiene (WSLH), or requested by DHS to be sent to another laboratory designated by DHS per Wis. Admin Code. ch. DHS 145.04(1)(bg). Requests for sharing specimens containing SARS-CoV-2 will be communicated from WSLH to laboratory directors, either directly via secure email, or via a memo through the Wisconsin Clinical Laboratory Network (WCLN). Individual specimens or groups of specimens may also be requested via secure electronic communication from the State Epidemiologist or a designee in the DHS Bureau of Communicable Diseases.

## Transporting Residual Specimens to Laboratories for Genomic Sequencing

Clinical microbiology laboratories in Wisconsin routinely share residual specimens with public health laboratories upon request, for surveillance of infectious diseases that include influenza and other respiratory viruses, foodborne diseases, Tuberculosis, and others. To help facilitate this, the WSLH coordinates the Wisconsin Clinical Laboratory Network, a network of all clinical microbiology laboratories in the state. Through the WCLN, the WSLH requests residual specimens, which are sent to WSLH for additional testing such as influenza subtyping and bacterial whole genome sequencing. These activities fall under public health practice, not research per 45 CFR §46.102(l)(2). As such, institutional review board (IRB) review and approval is not required for this activity.

## Considerations for sharing patient-level data associated with residual samples

To protect the privacy and confidentiality of Wisconsin residents, the minimum amount of patient information should be transmitted between laboratories when specimens are shared for the purpose of genome sequencing for public health surveillance and outbreak investigations, permitted by Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and State laws as described in this memo.

## Depositing or uploading data in global sequence repositories

Collaboration and public sharing of scientific data has been an area of significant progress during the COVID-19 pandemic. Real-time public sharing of pathogen sequence data helps accelerate and coordinate the response to outbreaks across states and countries. The availability of sequences from multiple states and countries allows local public health officials to understand how pathogens might be spreading into, within, and out of, their jurisdictions. CDC and other global health partners are actively supporting collaboration around genomic analysis to support the pandemic response, epidemiology and surveillance.

Wisconsin researchers and public health laboratory staff performing viral genome sequencing on SARS-CoV-2 should participate in this process through depositing sequence data and a limited amount of associated patient data into appropriate public data repositories. After consultation with the DHS Office of Legal Counsel and the HIPAA Privacy Officers at multiple Wisconsin institutions, DHS, under its public health authority, has established a common standard for publicly reporting sequence data into the National Center for Biotechnology Information (NCBI) and Global Initiative on Sharing All Influenza Data (GISAID) repositories.

Under DHS public health authority, DHS requests that laboratories sharing residual specimens for SARS-CoV-2 WGS with sequencing laboratories to provide the **date of collection** and **county of residence** associated with each sample. It is the responsibility of the sequencing laboratory to directly share only these two pieces of data to public databases along with viral genome sequence information derived from the specimen.

Public sharing of these limited data fields is permissible under a public health authority as specified in the HIPAA Privacy Rule. DHS, as a public health authority, is authorized by law to collect or receive such information for the purpose of preventing and controlling disease as well as conducting public health surveillance, investigations or interventions. In addition, DHS is requesting the minimum necessary information to be provided to the global sequence repository to accomplish the intended public health purpose of the disclosure. [45 CFR §164.514(d)(3)(iii)(A)]

The HIPAA Privacy Rule permits a covered entity to disclose protected health information without individual authorization to a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability, such as for purposes of reporting disease, injury, or vital events, or for public health surveillance, investigations, or interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority. [45 CFR §164.512(b)(1)(i)]

A "public health authority" is defined as an agency or authority of the United States government, a state, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. [45 CFR §164.501].

Further, the Privacy Rule permits covered entities to make disclosures that are required by other laws, including laws that require disclosures for public health purposes. Wis. Stat. §252.05(2) indicates each laboratory shall report as prescribed by the department those specimen results that indicate that an individual providing the specimen has a communicable disease, or having a communicable disease, has died, or that the department finds necessary for the surveillance, control, diagnosis, and prevention of communicable diseases. [45 CFR §164.512(a)]