



Missouri Department of Health and Senior Services

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MISSOURI STATE PUBLIC HEALTH LABORATORY

SUBMISSION OF POSITIVE SARS-CoV-2 SPECIMENS FOR VARIANT SURVEILLANCE

Since 2014, CDC's Advanced Molecular Detection (AMD) Program has been integrating next-generation sequencing and bioinformatics capabilities into the U.S. public health system. The Missouri Department of Health and Senior Services (DHSS) and Missouri State Public Health Laboratory (MSPHL) are applying these resources as part of our response to the COVID-19 pandemic.

By participating in the CDC-led consortium SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES), public health experts in MO and nationwide will be able to monitor important changes in the virus as it continues to circulate as well as advance public health research in the areas of transmission dynamics, host response, and evolution of the virus.

Why is this important?

Routine analysis of genetic sequence data enables scientists and public health experts to identify and characterize variant viruses—either new ones identified here or those already identified abroad—and to investigate how variants impact COVID-19 disease severity and how variants impact the effectiveness of vaccines and therapeutics. Surveillance of emerging variants can help detect variants with:

- **Ability to spread more quickly in people**
- **Ability to cause either milder or more severe disease in people**
- **Ability to evade detection by specific diagnostic tests**
- **Decreased susceptibility to therapeutics that employ monoclonal antibodies**
- **Ability to evade natural or vaccine-induced immunity**

SEQUENCING CAPACITY

The MSPHL maintains a capacity to sequence up to 380 specimens per week. If the laboratory would exceed this capacity at any given time the MSPHL would utilize its regional laboratory network to aid in timely sequencing of all samples submitted. All samples that meet the sequencing criteria should be submitted to the MSPHL and if necessary the MSPHL will send samples to its regional laboratory network. The testing of specimens and subsequent identification of variant viruses is a multi-step process, and final results will take at least one week after the specimen is received.

VARIANT RESULTS

Due to federal regulation, the MSPHL is unable to provide result reports for SARS-CoV-2 variant sequencing surveillance to the submitter or patient. SARS-CoV-2 variant surveillance sequencing is intended for public health surveillance purposes only and cannot be used for diagnostic or individual clinical patient management. This method is not FDA cleared or CLIA regulated and therefore,

www.health.mo.gov

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sequence results for individual patients cannot be provided to the submitter. DHSS will continue to work closely with Missouri's local public health agencies, medical providers, and laboratories to promptly detect and respond to SARS-CoV-2 variants. Variant surveillance data for Missouri, regionally, and in the United States is available on the CDC Webpage at [CDC Data Tracker Variant Proportions](#).

SUBMISSION REQUIREMENTS:

- Specimens must meet the required MSPHL submission criteria for COVID-19 testing available at <https://health.mo.gov/lab/ncov.php>, **and** must be received by the MSPHL within 72 hours of collection, **or** have been stored frozen -70°C and shipped frozen using dry ice.
- Prior approval from DHSS is obtained prior to specimen submission. Call the Missouri Department of Health and Senior Services at 800-392-0272 for approval.

SELECTION CRITERIA:

- Specimens submitted for SARS-CoV-2 variant analysis should have a previous positive viral diagnostic test, such as RT-PCR, other nucleic acid amplification test, or an antigen test.
- Specimens being submitted for SARS-CoV-2 variant analysis should have a RT-PCR Ct value that is ≤ 28 (Not required if Ct value is not available)
- **Any specimens with RT-PCR test results that demonstrate S-gene target failure (SGTF) should be submitted to the MSPHL for SARS-CoV-2 variant analysis.**
- Specimens from individuals within international travel within the 14 days prior to onset of symptoms of COVID-19.
- Specimens from fully-immunized individuals with an approved COVID-19 vaccine **AND** who present with a clinically severe disease presentation should be submitted for SARS-CoV-2 variant analysis.
- Specimens from individuals suspected of COVID-19 reinfection, including persons previously treated with monoclonal antibody, convalescent plasma, or antivirals should be submitted for SARS-CoV-2 variant analysis.

SPECIMEN SUBMISSION

Submission of specimens to the MSPHL for testing and identification of variant SARS-CoV-2 viruses requires adherence to the following criteria:

- Complete a MSPHL Test Request Form (TRF) for each specimen. The TRF is available online at <http://health.mo.gov/lab/>.
 - In the "MOLECULAR (PCR)" section of the TRF, check "Other" and specify "SCV2 Sequencing"
- On the TRF, indicate what test was used to generate the positive result and the Ct values, if available.
- Contain at least 500 μ L of Viral Transport Media (VTM), Universal Transport Media (UTM), or saline
- Specimens should be shipped to the MSPHL within 72 hours of collection on freezer packs. If this is not possible, the specimen **must** be frozen and shipped to the MSPHL on dry ice.

TEMPORARY STORAGE OF SPECIMENS

- If specimens cannot be submitted within 72 hours of collection. Store the specimens at -70°C pending shipment and ship on dry ice.

PACKING FOR SHIPMENT OF SPECIMENS

- Place dry ice in Styrofoam box. Dry ice is required for specimens to remain frozen during shipping.
- Place each specimen tube in its own 95kpa safety container and close the lid securely
- Place 95kpa tube inside ziptop biohazard bag and seal
- Fold Test Request Form and slide into pocket on outside of bag
- Place 95kpa tubes into the large bag, seal, and place the bag inside Styrofoam box with dry ice
- Close lid on Styrofoam box
- Place Styrofoam box inside cardboard box and tape cardboard box shut
- Affix shipping label to the outside of box and write: **SARS-CoV-2 Variant Surveillance Project** on box

****DO NOT USE ICE MADE WITH WATER WHEN SHIPPING SPECIMENS****

SHIPMENT OF SPECIMENS

The MSPHL will provide all shipping materials and cover shipping costs. Please contact the MSPHL to have collection kits sent to your facility.

****Please use these collection kits for SARS-CoV-2 Surveillance specimens only****

Specimens may be sent to the MSPHL via the MSPHL Courier System. If utilizing the MSPHL Courier, samples should be sent out **no later than** the Thursday courier pickup each week.

[GIS map of courier drop off locations Monday-Friday](#)

[List of courier drop off locations by county Monday-Friday](#)

[Sunday Courier Locations](#)

If you do not have access to the MSPHL Courier, samples may be sent via FedEx. If utilizing FedEx to send in samples, ensure that they will not arrive in Jefferson City on Saturday, Sunday, or a holiday. Please contact the Molecular Unit at the MSPHL and a FedEx shipping account number will be provided for your facility to use.

DO NOT SHIP CLINICAL SPECIMENS VIA UPS

Please send all specimens to this address:

Missouri State Public Health Laboratory
101 North Chestnut Street
Jefferson City, MO 65102
Phone# 573-751-3334, Fax # 573-526-2754