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CONTRA COSTA
PUBLIC HEALTH
COMMUNICABLE DISEASE
PROGRAMS

597 Center Avenue, Suite 200-A Martinez, California 94553 PH (925) 313-6740 Fax (925) 313-6465 www.cchealth.org

Provider and Laboratory Health Advisory COVID-19 Cases of Interest for Whole Genome Sequencing Contra Costa County Public Health Department April 22, 2021

COVID-19 Cases of Interest for Whole Genome Sequencing (WGS)

The currently available COVID-19 vaccines have high efficacy for prevention of symptomatic SARS-CoV-2 infection. However, breakthrough cases among fully vaccinated people are expected. The Contra Costa Public Health Department is seeking to investigate whether these cases and other high-risk scenarios may be caused by particular SARS-CoV-2 variants or current Variants of Concern (VOC). As such, the department is encouraging clinicians and clinical laboratories located within Contra Costa County to forward positive specimens (≥500uL) for WGS that meet criteria.

- Vaccine Breakthrough: Person who has SARS-CoV-2 RNA detected by a molecular test (e.g., PCR or NAAT) on a respiratory specimen collected ≥14 days after completing the primary vaccination series (i.e., ≥14 days following receipt of the second dose in a 2-dose series or ≥14 days following receipt of one dose of a single-dose FDA-authorized COVID-19 vaccine). Symptomatic breakthrough cases (also referred to as Vaccine Breakthrough cases of interest [VBCI]) will be prioritized for WGS, but asymptomatic vaccine breakthrough cases can be reviewed to see if potential follow up with WGS is appropriate;
- Hospitalized Patients (or ICU Patients);
- Outbreaks with high attack rate in a given outbreak or more cases than expected;
- Concerns for variants due to drop in diagnostic assay target (ex: N target, ORF target, S target) or any marked difference in real-time RT-PCR viral target(s) cycle threshold values (CT);
- Concern for variants due to other clinical history, such as, patient is immunocompromised, prolonged infection, failed to improve after receiving monoclonal antibody, death, etc.;
- **Travel Associated**: (1) case with recent travel or (2) case with contact to someone that had recent international travel;
- **Reinfection**: positive SARS-CoV-2 PCR or NAAT >90 days after first positive test. (please submit original specimens from both original infection and subsequent infection.

AND

Original positive respiratory specimen must be available for WGS and the Cycle threshold (Ct) value ≤30 (if Ct available) or RLU ≥1150. (e.g. nasal or NP swabs in viral transport medium (VTM), saline, or molecular transport medium, Hologic Aptima media, sputa. Please note that dry swabs, are not acceptable for WGS.)

Notify Contra Costa Public Health of Request for WGS

When a potential variant case is identified, please report the case to Contra Costa County by:

1. sending a secure email to <u>CICT-LabLiaison@cchealth.org</u> or <u>cocohelp@cchealth.org</u> with "WGS Case of Interest" in the subject line.



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- 2. Provide the following information in the notification and/or laboratory requisition https://cchealth.org/laboratory/pdf/lab test form.pdf:
 - o Patient Demographics: Name, DOB, description of symptoms and onset, clinical information (hospitalization, death, etc).
 - Test Information: collection date, Ct ≤30 or or RLU ≥1150, COVID-19 test type, lab that performed test.
 - Reason WGS is being requested. If Vaccine Breakthrough, please provide dates of vaccination and manufacturer.

Sample Storage and Shipment:

Include a requisition form- <u>Indicate the request is for WGS/Variant Sequencing</u>. <u>Include CT/RLU</u> value.

For both WGS, please request the lab store the original positive sample or a portion of the original positive sample (≥500 uL) frozen until shipment and shipped on dry ice to the CCPHL. Please ship using the following:

"Ship To" address:

Attn: Stephanie Trammell or Kelly Riddle Contra Costa County Public Health Laboratory 2500 Alhambra Ave, Rm. 209 Martinez, CA 94553 925-370-5775

WGS is not currently a validated assay and you will not receive laboratory reports from the Contra Costa Public Health Laboratory or California Department of Public Health (CDPH). However, the Contra Costa Public Health may reach out for purposes of Contact Tracing to control the spread of SARS-CoV-2 and certain variants.

WGS will be performed at the Contra Costa Public Health Laboratory, however, testing may be performed at CDPH's Viral Rickettsial Disease Laboratory (VRDL) or a partnering laboratory if there is a high demand for WGS. VRDL is also able to perform viral isolation and serology for suspected vaccine-breakthrough cases. A serum may be requested, if available, in order to better understand vaccine effectiveness. The VRDL will accept and test serum samples from VBCIs to examine antibody responses (including anti-spike, anti-nucleocapsid, and neutralizing antibodies) of those cases. If a serological evaluation is requested, please submit 1 ml of serum from a red top or serum separator tube.

Find more information at:

https://cchealth.org/covid19/providers/

Questions should be addressed to CICT-LabLiaison@cchealth.org.

For questions regarding Contra Costa County's other COVID-19 surveillance efforts for which you are a participant, please contact Stephanie Trammell at Contra Costa Public Health Laboratory, stephanie.trammell@cchealth.org.



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Those facilities performing whole genome sequencing on positive SARS-CoV-2 specimens should report results to the local public health department.

"CDC requests laboratories that are sequencing SARS-CoV-2 positive specimens to report those data to state, local, tribal, or territorial public health departments... It is critically important for the nation's COVID-19 pandemic response to understand the genetic diversity, spread, and evolution of SARS-CoV-2, including variant viruses."

CMS guidelines:

CLIA SARS-CoV-2 Variant Testing Frequently Asked Question (cms.gov)
CDC guidance on Electronic Laboratory Reporting of WGS results:
Guidance for Reporting SARS-CoV-2 Sequencing Results | CDC

Title 17 update (effective 4/9/2021):

"(p) Upon written request and submission instruction by the Department or a local health officer, a laboratory that tests any specimen for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), shall submit the specimen and any nucleic acid extract to either the local public health laboratory designated in Section 1075 for the local health jurisdiction where the patient resides, the State Public Health Laboratory, or their designee. The specimen submission shall include the information identified in subdivision (b), the Cycle Threshold (CT) or Relative Light Units (RLU) value, and the federal Clinical Laboratory Improvement Amendments certificate number."

View Document - California Code of Regulations (westlaw.com)