COMMUNICABLE DISEASE UPDATE

COMMUNICABLE DISEASE CONTROL AND PREVENTION SECTION
THURSTON COUNTY PUBLIC HEALTH AND SOCIAL SERVICES DEPARTMENT
412 LILLY RD NE
OLYMPIA, WA, 98506-5132
DISEASE REPORTING: (360)786-5470
Diana Yu, MD, MSPH, Acting Health Officer

THURSTON COUNTY
WASHINGTON

4/22/20

** NOTICE: This health alert provides written guidance for health care professionals and others who may need to take action to prevent or control a notifiable condition. It is not intended to provide guidance for the general public.*

COVID-19 Testing Guidance Update

Requested Action:

1. Expand testing to include all individuals who are symptomatic with fever, cough, shortness of breath. Persons who are known contacts of a confirmed case may have milder or fewer symptoms at onset.
2. Antibody testing is NOT recommended for diagnostic purposes of symptomatic individuals. Antibody tests may cross react with ordinary Coronaviruses, so test results are not possible to interpret see: https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf
3. Ask symptomatic patients who are tested to:
   - Remain in quarantine until results are available (see resources below for one-page guidance documents)
   - Practice social distancing and
   - Practice good hand hygiene and cough etiquette.
4. Please report all confirmed cases to Thurston County Public Health immediately. Please inform patients that they will be hearing from us.
5. Recommend all individuals to wear a homemade or surgical mask when they must be within 6 feet of another person.
6. Require healthcare workers caring for COVID suspect or positive patients to use droplet precautions, including surgical mask, face shield, gown and gloves. If treatment involves an aerosolizing procedure, they should use a properly fit-tested N95 mask.
7. Consider having patients perform, health care provider observed, self-swab nasal collection for COVID-19 using kits with nasal swabs rather than nasopharyngeal swabs as a means to conserve personal protective equipment see: https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/Self-SwabNasalCollectionInstructions.pdf. When sampling from the inner nares, the sample can be collected by the patient and the observer only needs to wear a surgical mask and gloves when they are handling the specimen.

Future Considerations:

Public health has been conducting case/contact investigation and case management of confirmed COVID-19 cases in Thurston County since our first case was reported March 11th. We are working to expand our capacity to respond to a surge of new cases we expect as testing expands and community restrictions are relaxed and/or lifted. In addition to expanding our Disease and Prevention team, we have activated our Thurston County Medical Reserve Corps in the last few weeks and have many trained volunteers ready to assist.

As part of the plans to modify community mitigation strategies, there will be an increased focus on community wide testing. The plan is for the State Department of Health to push out more test collection kits through the Thurston County Emergency Management. We will send information about how to

COMMUNICABLE DISEASE UPDATE

COMMUNICABLE DISEASE CONTROL AND PREVENTION SECTION
THURSTON COUNTY PUBLIC HEALTH AND SOCIAL SERVICES DEPARTMENT
412 LILLY RD NE
OLYMPIA, WA, 98506-5132
DISEASE REPORTING: (360)786-5470
Diana Yu, MD, MSPH, Acting Health Officer

order the test collection kits when we receive them. Your clinic/facility will be responsible for arranging to have the specimens processed through a commercial laboratory.

All individuals tested must be self-quarantined until results are available. Symptomatic individuals need to be isolated until results are available. Confirmed cases must be reported immediately.

As testing resources increase, we anticipate more positive cases. At some point, we may recommend testing for asymptomatic patients – preferentially it would be for health care workers, essential workers, residents and staff of congregate facilities like long term care, childcare, homeless shelters or correctional facilities

The virus causing COVID-19, emerged in December 2019 and has since spread around the world causing a global pandemic. Eighty percent of cases are reported to be mild, but severe disease and deaths are more common in the elderly (older than 60 years) and in those with underlying health conditions. As of April 22nd, there were 12,495 confirmed cases and 688 deaths in Washington State with all but one county reporting cases, 96 confirmed cases and 1 death in Thurston County and 802,583 confirmed cases and 44,575 deaths in the US and territories.

Thank you, for all you are doing to lessen the impact COVID-19 is having on our community and to flatten the curve

Resources:

DOH one page patient guidance for stopping spread, isolating and quarantining: https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020COVID19/HealthcareProviders

CDC Infection Prevention and Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

CDC Guidelines for collecting, handling, and testing clinical specimens: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

CDC COVID-19 Evaluation and testing - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Fidentify-assess-flowchart.html

CDC Health care Professionals Guidance - https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html

DOH - Provider guidance on testing: https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/Interim-2019NovelCoronavirusQuicksheetProviders.pdf

DOH – Specimen Collection and Submission: https://www.doh.wa.gov/Portals/1/Documents/5240/SCSI-2019-nCoV.pdf

DOH – Healthcare Provider Guidance: https://www.doh.wa.gov/Emergencies/NovelCoronavirusOutbreak2020/HealthcareProviders

Infectious Disease Society of America, COVID-19 Antibody Testing Primer - https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf

COMMUNICABLE DISEASE UPDATE

COMMUNICABLE DISEASE CONTROL AND PREVENTION SECTION
THURSTON COUNTY PUBLIC HEALTH AND SOCIAL SERVICES DEPARTMENT
412 LILLY RD NE
OLYMPIA, WA, 98506-5132
DISEASE REPORTING: (360)786-5470
Diana Yu, MD, MSPH, Acting Health Officer

THURSTON COUNTY
WASHINGTON

THANK YOU FOR REPORTING

TO REPORT A NOTIFIABLE CONDITION IN THURSTON COUNTY	
Voice mail for reporting **non-immediately reportable conditions (24 hours a day)**	Phone: 360-786-5470 Fax: 360-867-2601
Day time immediately reportable conditions – Call detailed information to the 24-hour Notifiable Condition Reporting Line at 360-786-5470. Messages are picked up hourly. If a call back can't wait call 360-867-2500 and ask staff to locate a Communicable Disease staff.	Phone: 360-786-5470
After hours immediately and 24-hour reportable conditions or a public health emergency	Call 1-800-986-9050
No one is available with Thurston County Public Health and condition is **immediately notifiable**	1-877-539-4344

Communicable Disease Updates are posted online at: http://bit.ly/CDUpdatePHSS

IDSA COVID-19 Antibody Testing Primer

Updated: April 20, 2020

As serological testing for SARS-CoV-2 advances, there are multiple issues that need to be addressed, from test quality to interpretation. Unlike molecular tests for COVID-19 (e.g., PCR), antibody tests may be better suited for public health surveillance and vaccine development than for diagnosis. The current antibody testing landscape is varied and clinically unverified, and these tests should not be used as the sole test for diagnostic decisions. Further, until more evidence about protective immunity is available, serology results should not be used to make staffing decisions or decisions regarding the need for personal protective equipment.

The sections below outline the current state of antibody testing for SARS-CoV-2, along with research questions and additional testing and policy considerations. This information will be updated regularly as new research, tests, and increased public health capacity become available.

BACKGROUND ON ANTIBODY TESTING FOR SARS-CoV-2 INFECTION

- The antibody response in infected patients remains largely unknown, and the clinical values of antibody testing have not been fully demonstrated. Seroprevalence data will be important in understanding the scale of the pandemic and future vaccine utility.
- Potential utility of serology in SARS-CoV-2:
    - Detection of PCR-negative cases, especially for patients who present late with a very low viral load below the detection limit of RT-PCR assays, or when lower respiratory tract sampling is not possible;
    - Identification of convalescent plasma donors;
    - Epidemiologic studies of disease prevalence in the community;
    - Verification of vaccine response once antibody correlate(s) of protection identified.
- Potential drawbacks if serological assays are not well-validated:
    - False negative risks if performed early in disease course, especially in mild disease;
    - False positive risks, particularly with tests for Immunoglobulin M (IgM) and potential cross-reactivity with common cold coronaviruses (e.g. HKU1, NL63, OC43, 229E).

TEST QUALITY & INTERPRETATION

- There are a multitude of different antibody tests for COVID-19 with variable performance. Tests vary in the viral antigen(s) they target, e.g., nucleoprotein (N protein) or spike protein (S protein). It is not yet clear which antibody responses, if any, are protective or sustained.
- The Foundation for Innovative New Diagnostics (FIND), a global non-profit organization driving innovation in the development and delivery of diagnostics, is conducting an independent evaluation of performance data for SARS-CoV-2 immunoassays to help inform procurement and implementation decisions for countries and health programs. The dataset could also help inform clinical validation studies for these tests.

- A "positive" test is exceptionally difficult to interpret because the performance of these tests is not well known. For some assays both sensitivity and specificity may be poor, or at the very least undefined.
- Clinical laboratories will need to perform validation studies of commercial reagents.
- **Some FDA-authorized COVID-19 antibody tests are estimated to have 96-98% specificity, which would mean that a positive test result is more likely a false-positive result than a true positive result if the prevalence or pretest probability is 5% or less.**

ADDITIONAL CONSIDERATIONS

- No universal standard for reporting is available and test detection limits are variable. Some assays provide semi-quantitative results and others are designed to be qualitative (i.e. antibody detected or not).
- Several tests are combination IgG/IgM, which provide unclear value given the poor specificity of IgM.
- Currently available commercial assays do not have titers, and without this information it is unclear how to identify "qualified" individuals for plasma donation.
- Nucleic acid amplification tests (NAATs) perform differently than antibody testing, and this has implications for interpretation. The NAATs that were developed for SARS-CoV-2 are very specific. In patients with signs and symptoms of infection, a positive NAAT result has a very high positive predictive value (PPV) for true infection. Conversely, both the negative and PPV of antibody testing are likely to be lower, given the low prevalence of prior exposure to SARS CoV-2 in the U.S. population and imperfect sensitivity and specificity of the test.
- As a result, antibody tests will be most useful as surveillance tools to estimate (with surrounding confidence intervals) relative proportions of different populations that have been exposed to SARS CoV-2. They will have less utility as diagnostic tools for individual patient assessment.
- Privacy concerns: As we roll out antibody tests, the federal government should clarify several key questions regarding privacy: Who will collect antibody samples? How might they be saved and used in the future (i.e. by government, by law enforcement)? Will there be federal privacy protections for patient samples? What type(s) of applications are intended?
    - Applications must mitigate concerns about privacy violations and hacking; advertiser tracking; potential test error; and faulty phone/wireless signals.

OUSTANDING RESEARCH NEEDS

- While extrapolation from other coronavirus infections allows us to be optimistic that detection of an IgG response will likely confer at least some protection to most people, we have no direct evidence of this for SARS-CoV-2.
- Understanding which antibodies (if any) are protective is required for vaccine development. There are many different SARS CoV-2 IgG antibodies that may be produced, and each may have a different role. This should also be a consideration in assessing the clinical utility of tests designed to target specific antibodies.
- Determine limits of protective immunity (e.g., antibody amount, duration, and efficacy) and correlations with disease severity.
- Address concerns about potentiation of cytokine release syndrome (CRS) by a vaccine or hyperimmune plasma administration: Patients with COVID-19 infection can develop CRS about day 7-10 of illness, which often leads to death. There is some concern that a vaccine against the "wrong" antigens or infusion of hyperimmune plasma from COVID-19 survivors could worsen the inflammatory immune

response in patients with COVID-19 infection. This immune enhancement is seen for some flaviviruses such as dengue.
- Development of accurate serologic tests that can be used with fingerstick capillary blood would be ideal for seroprevalence field studies. Most commercial assays require venipuncture blood draw to obtain serum or plasma.

POLICY CONSIDERATIONS: ADDITIONAL FUNDING PRIORITIES

- Increased research, public health, and laboratory funding for test development, supplies, and PPE, and for the routine application of serological testing, once available and well-validated, in the diagnosis and management of COVID-19 patients.
- Federal funding for longitudinal studies of immune response and risk of re-infection

ADDITIONAL RESOURCES

- 10,000-participant NIH "serosurvey" planned to quantify undetected COVID-19 cases (*NIH*)
- Antibodies for COVID-19 vaccine design (*Science*)
- Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19) (*CID*)
- The convalescent sera option for containing COVID-19 (*JCI*)
- The Importance of Antibody Testing in Addressing COVID-19 (*Mayo Clinic*)
- Virological assessment of hospitalized patients with COVID-2019 (*Nature*)
- FDA Letter to Health Care Providers re: Serological Testing for COVID-19
- FDA FAQs on Diagnostic Testing for SARS-CoV-2
- FDA Fact Sheet - Serological Testing for Antibodies to SARS-CoV-2 Infection