WASHOE COUNTY HEALTH DISTRICT
ENHANCING QUALITY OF LIFE

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EPI-NEWS

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COVID-19 OUTBREAK IN WASHOE COUNTY (4)

Laboratory Testing for COVID-19

Introduction

The Washoe County Health District (WCHD) reported the first case of COVID-19 on March 5, 2020. As of May 15, a total of 1,190 cases have been reported, which corresponds to an incidence rate of 252 cases per 100,000 population. The epidemiological investigations and contact tracing are very labor-intensive. Many investigations are still ongoing. WCHD has published a series of Epi-News on COVID-19. Previously published Epi-News can be found here:

- April 5: Epidemiological Findings from the First 115 cases
- April 17: Therapeutic options and statistical updates
- May 5: Asymptomatic infection and its role in transmission and statistical updates

This newsletter will focus on laboratory testing for SARS-CoV-2, the virus that causes COVID-19, using a Q&A format.

Q1: How many types of laboratory tests are there so far and what are they?

It is important to note that thus far there have been no FDA cleared or approved tests for COVID-19 testing yet; however, after the secretary of Health and Human Services (HHS) declared COVID-19 as a public health emergency in January in the United States, FDA used its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, uses of approved medical products, to diagnose, treat, or present COVID-19 when certain criteria are met. There are several types of tests for SARS-CoV-2. The following is a list of tests and their utilities.

1. Viral tests including molecular tests and antigen tests. Viral tests tell if someone has a recent infection. There are more than 20 different molecular tests authorized for EUA use. All testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider. Specimens should be collected as soon as possible once a decision has been made to pursue testing, regardless of the time of symptom onset. The type of specimen collection should be based on the specific type of test being used. Generally speaking, these specimens are frequently collected: nasopharyngeal (NP) swab, oropharyngeal (OP) swab, nasal mid-turbinate swab, or anterior nasal swab, NP wash/aspirate or nasal wash/aspirate, or sputum for patients with cough. So far, a couple of tests for testing antigen were applied but no FDA EUA has been issued as of May 12, 2020.
2. Serology tests, also known as antibody test, tells if someone has recent or past infection by testing SARS-CoV-2 specific IgM, IgG, or total antibody. As of May 12, 2020, only two serology tests have been approved by FDA for EUA use.[i] Two are used for testing anti-SARS-CoV-2 total antibody or IgG antibody.
3. Virus culture of SARS-CoV-2 was done at the CDC lab during early February and the virus was isolated for scientific research and medical community. Such research activities include antiviral research, vaccine development, pathogenesis research, and virus stability research.[ii]

Q2: Why laboratory tests should be used correctly?

Generally speaking, a good laboratory test should be applied among an appropriate population and its performance efficacy can then be maximized. Three major parameters affect a test's performance. The sensitivity and specificity of a test and the prevalence of a disease in a population. Even if a test with a very high sensitivity and specificity is applied into a population with a very low prevalence rate of disease, a larger proportion of test results can be false positive or false negative, therefore produce a misleading interpretation and subsequently mislead a public health response for a disease like COVID-19. The following table illustrates a relationship among these three measurements.

Scenario	Sensitivity	Specificity	Prevalence	PPV	NPV	Accuracy
1	95%	98%	1%	32.00%	99.95%	97.97%
(Reality)			2%	49.22%	99.90%	97.94%
			5%	71.43%	99.73%	97.85%
			10%	84.07%	99.44%	97.70%
2	99%	99%	1%	50.00%	99.99%	99.00%
(Ideal)			2%	66.89%	99.98%	99.00%
			5%	83.90%	99.95%	99.00%
			10%	91.67%	99.89%	99.00%
3	100%	100%	1%	100.00%	100.00%	100.00%
(Perfect)			2%	100.00%	100.00%	100.00%
			5%	100.00%	100.00%	100.00%
			10%	100.00%	100.00%	100.00%

Sensitivity: probability that a test result will be positive when the disease is present.
Specificity: probability that a test result will be negative when the disease is not present.
Positive Predictive value (PPV): probability that the disease is present when the test is positive.
Negative predictive value (NPV): probability that the disease is not present when the test is negative.

Accuracy: overall probability that a patient is correctly classified.

When a new test becomes available on the market, its sensitivity and specificity are constant, the only variable is the disease prevalence. Based on the previous table, it is reasonable to say when the disease prevalence is very low, say 1% or lower, even though the test has 99% sensitivity and 99% specificity, PPV will be 50% or lower, which means when the test is positive, the probability that there is a 50% chance the disease is truly present. One serology test recently implemented by the Nevada State Public Health Laboratory (NSPHL) called Abbott Architect SARS-CoV-2-IgG is a high throughput ELISA method and has extremely high sensitivity (100%) and specificity (99.6%).[iii] If this serology test is used for seroprevalence survey of COVID-19 infection in a population with an estimated prevalence of 1-2%, the accuracy will be almost 100% as long as correct interpretation is conducted.

Q3: When should a patient or an individual receive a test?

CDC does not recommend using serology testing to diagnose acute infection. It is recommended to use a viral molecular test to diagnose acute infection. Although testing capacity has been greatly expanded since the middle of March, CDC recommends testing should be offered to following individuals:[iv]

High Priority

- Hospitalized patients with symptoms.
- Healthcare facility workers, workers in congregate living settings, and first responders with symptoms.
- Residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms.

Priority

- Persons with symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat.
- Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.

The rationale behind this prioritization is also consistent with the theory stated in Q2. In Washoe County, testing decision can be made by either clinician or WCHD with an appropriate risk assessment. Because the increased role of asymptomatic infection in the COVID-19 transmission has been recognized, WCHD and the community partners are planning on a seroprevalence survey using a random sampling approach. It is hopeful to understand the real number of infections in Washoe County through seroprevalence surveys.

Q4: How many tests have been done in Nevada?

As of May 12, 2020, 76,914 tests from 64,075 (83.3%) persons were performed. A total of 6,311 persons were positive, which corresponds a positivity rate at 9.8%. Of 76,914 tests, 24,224 (31%) were performed by the Nevada State Public Health Laboratory, 26,570 (35%) were performed by either LabCorp or Quest, and the remaining 34% were performed by large acute care facilities or other commercial labs.[v] The testing rate in Nevada was 21 per 1,000 population as of May 12, lower than average US testing rate (including NY state) at 29 per 1,000 population.

Q5: What tests are available at the local level?

In Washoe County, hospitals and healthcare providers use clinical labs, commercial labs like LabCorp and Quest, and NSPHL for COVID-19 diagnosis and/or public health surveillance purposes. There are several molecular tests available at the local level including CDC 2019-nCoV real-time RT-PCR diagnostic panel (NSPHL), Abbot ID Now COVID-19 (clinical labs), Cepheid's Xpert Xpress SARS-CoV-2 (Renown), COVID-19 RT-PCR test (LabCorp), Quest SARS-CoV-2 rRT-PCR (Quest), and one serology test such as Abbot's SARS-CoV-2 IgG Assay (NSPHL). The turn-around-time varies from 15 minutes to a couple of days depending on tests.[vi] All these tests were authorized by FDA for EUA use.

The following page is the White House's guidance on interpreting COVID-19 test results[vii]. Should you have any specific questions regarding the tests offered by the Nevada State Public Health Laboratories (NSPHL), please contact NSPHL at 775-688-1335. For COVID-19 reporting, call WCHD at 775-328-2447. For all other COVID-19 related questions, call the Washoe County Hot Line at 775-328-2427 (24/7).

[i] https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd
[ii] https://www.cdc.gov/coronavirus/2019-ncov/php/grows-virus-cell-culture.html
[iii] https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance
[iv] https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html
[v] https://app.powerbigov.us/view?r=eyJrIjoiMjA2ZThiOWUtM2FlNS00MGY5LWFmYjUtNmQwNTQ3Nzg5N2I2IiwidCI6ImU0YTM0MGU2LWI4OWUtNGU2OC04ZWFhLTE1NDRkMjcwMzk4MCJ9
[vi] Internal communication with local hospitals.
[vii] https://www.whitehouse.gov/wp-content/uploads/2020/05/Testing-Guidance.pdf

GUIDANCE ON

INTERPRETING COVID-19 TEST RESULTS

	RESULT	INTERPRETATION	RECOMMENDED ACTION
VIRAL TESTING† (testing for current infection)	**Positive**	*Most likely** you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Negative	*Most likely** you DO NOT currently have an active COVID-19 infection.	If you have symptoms, you should keep monitoring symptoms and seek medical advice about staying home and if you need to get tested again. If you don't have symptoms, you should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.
ANTIBODY TESTING‡ (testing for past infection with the virus)	**Positive**‡	You *likely** have HAD a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. Take steps to protect yourself and others.
	Negative	You *likely** NEVER HAD (or have not yet developed antibodies to) COVID-19 infection.	You could still get COVID-19. Take steps to protect yourself and others.
BOTH (antibody and viral testing)	Viral **Positive,** Antibody **Positive**‡	*Most likely** you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Viral **Positive,** Antibody **Negative**	*Most likely** you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Viral **Negative,** Antibody **Positive**	You *likely** have HAD and RECOVERED FROM a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.
	Viral **Negative,** Antibody **Negative**	You *likely** have NEVER HAD a COVID-19 infection.	You could still get COVID-19. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.

**No test is ever perfect. All tests occasionally result in false positive results (the test result should be negative because you DO NOT have COVID-19 but comes back positive) or false negative results (the test result should be positive because you DO have COVID-19, but comes back negative). Sometimes the results are not definitive (the result is unclear, and you don't know if it is positive or negative). For this and other reasons, results should always be reviewed by a healthcare professional.*

† Viral tests are typically performed on respiratory specimens such as nasal swabs or throat swabs. They test for the presence of the virus, usually by testing for the virus's RNA or sometimes by testing for the virus's proteins ("antigen testing"). Antigen testing may be less sensitive than tests for the virus's RNA. If your antigen test is negative, please ask your healthcare provider if additional testing with an RNA test is needed and how long you should stay home.

‡ Antibody testing, also called "serologic testing" or "serology", is typically performed on a blood sample. Ideally, the results show whether you have ever been infected with the virus in the past or may be currently infected. Antibody tests check for antibodies that appear in the blood between about one and three weeks after symptom onset and may remain as long as a lifetime. Antibody tests may be positive while a person is infected. It is not yet known whether these antibodies protect against reinfection with the COVID-19 virus. For many other similar viruses, antibodies are protective for years or longer, but we do not yet have adequate data to know for COVID-19.