VOLUME 5, ISSUE 5

MAY 2020

Dr. Katherine A. Kelley Public Health Laboratory Connecticut Department of Public Health Sentinel Laboratory Newsletter

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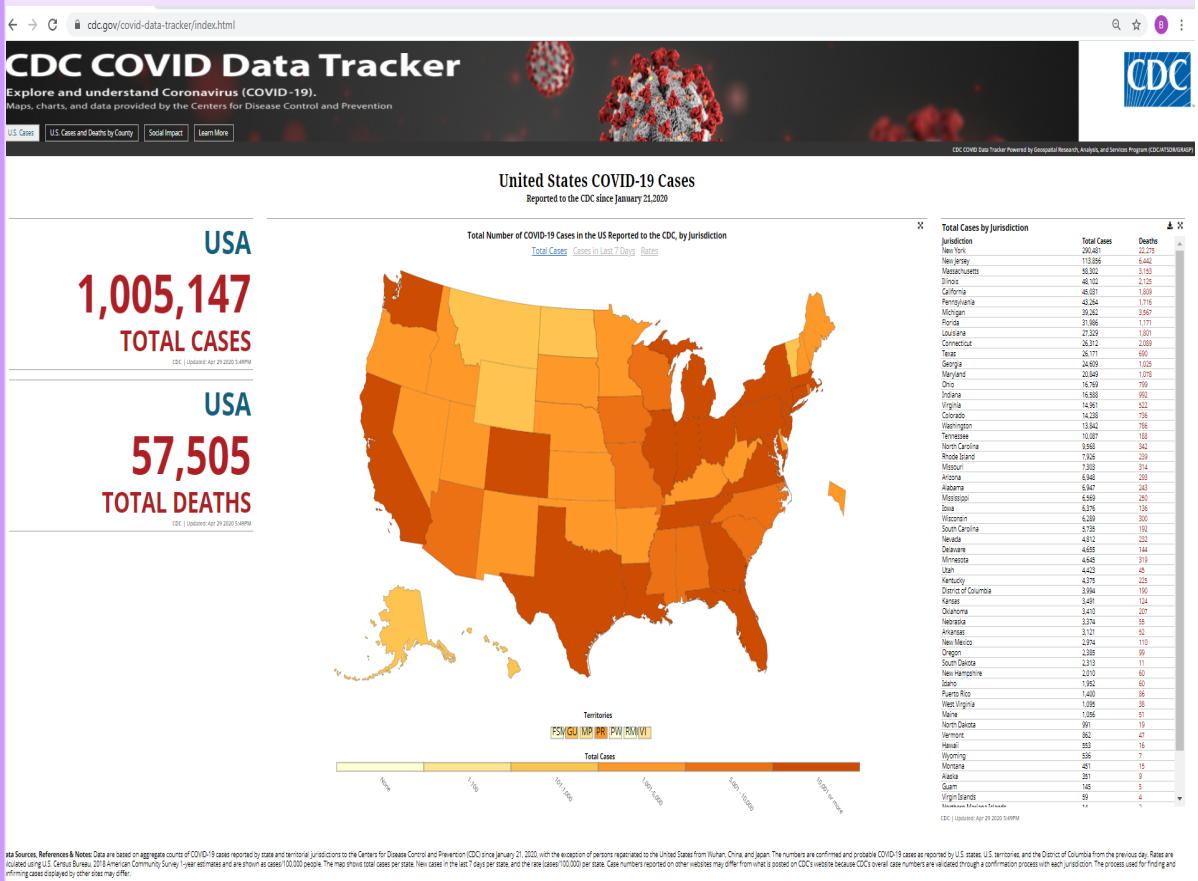
CDC COVID-19 Data Tracker

The Centers for Disease Control and Prevention (CDC) has been tracking data in the U.S. since January 21, 2020 based on aggregate counts of COVID-19 cases reported by state and territorial jurisdictions. On their CDC COVID Data Tracker website an interactive map shows total cases per state, new cases in the last 7 days per state, and the rate (cases/100,000) per state. If you're interested in tracking cases state by state this site is worth a visit. Go to https://www.cdc.gov/covid-data-tracker/index.html to check it out..



Considerations for SARS-CoV-2 Serology Tests Approved for Diagnostic Use in the U.S.

Serology testing for SARS-CoV-2 is at increased demand across the country. From the public health perspective this testing is crucial to better quantify the number of cases of COVID-19 for surveillance, including those cases that may be asymptomatic or have recovered. In March, the CDC and public health partners began serology studies on community transmission of SARS-CoV-2 using serum samples collected in the state of Washington and New York City, with plans to later expand serologic testing to include more areas of the country with high numbers of people with diagnosed infections. Their overarching strategy for surveillance with serology testing is to learn more about how many people have been infected with SARS-CoV-2, and to give insight into how it is spreading through the U.S. population. From the healthcare perspective, many clinical hospital laboratories are currently weighing whether to bring on the COVID-19 serology testing. As a diagnostic tool, serology tests have limitations. The serologic test can identify whether a patient has been exposed to the virus by looking at immune response, in contrast to PCR assays which indicate the presence of viral material during infection and can not indicate whether that person was infected and subsequently recovered. Typically it's patient symptoms that help providers decide whether PCR or serology is appropriate. One thing to consider when deciding to test by serology is that a patient needs time to form antibodies after exposure, so testing too soon could yield a false perception that the patient has not been not infected.

Currently in the U.S. there are at least seven serologic tests available for diagnostic use approved by the FDA for Emergency Use Authorization. These include: Cellex qSARS-CoV-2 IgG/IgM Rapid Test, Chembio DPP COVID-19 IgM/IgG System, Ortho-Clinical Diagnostic's VITROS Anti-SARS-CoV-2 IgG test, Mount Sinai COVID-19 ELISA IgG Antibody Test, Autobio Anti-SARS-CoV-2 Rapid Test, DiaSorin LIAISON® SARS-CoV-2 S1/S2 IgG System, Bio-Rad Platelia SARS-CoV-2 Total Ab assay, and Abbott's SARS-CoV-2 IgG.

The table below summarizes some of the accuracy figures that selected manufacturers claim for their serological COVID-19 tests, but keep in mind validation tests by these companies have been varied in size with some manufacturers having tested more specimens than others. Accuracy is another aspect to consider. Prevalence of COVID-19 is estimated at around 5% in the US, and at this low a level the risk of false positives is a valid consideration.

Sensitivity and Specificity of COVID-19 Antibody Tests Approved by FDA EUA

Device name	Sensitivity (%)	Specificity (%)
Abbott Sars-CoV-2 IgG Test	100	99.5
Cellex qSars-CoV-2 IgG/IgM Cassette Rapid Test	93.8	95.6
Ortho-Clinical Diangnostic's Vitros Immunodiagnostic Product Anti-Sars-CoV-2 Total Reagent Pack	83.3	100
Chembio DPP COVID-19 IgM/IgG System	91	99
Mount Sinai COVID-19 ELISA IgG Antibody Test	Not available	Not available
Autobio Anti-SARS-CoV-2 Rapid Test	95.7 (IgM) 99 (IgG)	99 (both IgM and IgG)
DiaSorin LIAISON® SARS-CoV-2 S1/S2 IgG System	90-97	98
Bio-Rad Platelia SARS-CoV-2 Total Ab assay	98	99

To review available FDA EUA approved tests for COVID-19 please go to https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

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The Connecticut Public Health Laboratory serves all communities in the state through the analysis of clinical specimens and environmental samples submitted by federal and state agencies, local health departments, clinical laboratories, health care providers, and water utilities.
Our mission is to keep Connecticut healthy!

APHL Webinar: Coronavirus Disease (COVID-19): Biosafety on the Frontlines

Please consider attending this free webinar on May 7, 2020 at 3:00PM ET. This webinar will provide attendees with knowledge on how laboratories are safely testing and handling specimens during the COVID-19 response. Speakers will present on the necessary personal protective equipment for laboratories to utilize to reduce the likelihood of a laboratory acquired infection. Participants will also hear recommendations on how to handle potential positive samples and methods on how to mitigate the risk of a laboratory exposure. This webinar will be recorded and made available for those unable to listen live.

Link to register:
https://aphl.zoom.us/webinar/register/WN_wCf0iNSpQWytXZKWfVQUVw

2020 CT DPH Links to Current Forms and Testing Services:

Clinical Test Requisition Form OL-9B

Link: https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/laboratory/labhome/lab-forms/ClinTestReq_OL9B_FILL.pdf?la=en

Laboratory Report of Significant Findings Form OL-15C

Link: https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/infectious_diseases/pdf_forms_/OL15C_Form.pdf?la=en

Directory of Clinical Testing Services

Link: http://www.portal.ct.gov/DPH/Laboratory/Clinical-Testing-Services/DCTS-101915