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COVID-19 Vaccine: How did we get here so quickly?

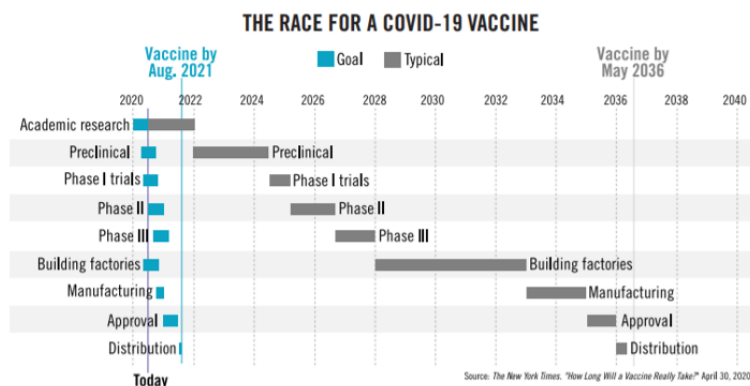
Jane Kelly, MD
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How is it possible to develop and get a COVID-19 vaccine to market in record time?

Developing COVID-19 vaccine in record time was possible because of some unprecedented events related to an earlier disease from more than 15 years ago – SARS. The SARS outbreak in 2003 prompted work on vaccine development that was abandoned when the disease was contained. The COVID-19 vaccine developers had that prior work upon which to build.

By January 10, 2020, the SARS-CoV-2 (responsible for COVID-19) genome had been sequenced and released publicly. On January 11, scientists around the world began using that genetic information to create multiple vaccine approaches for COVID-19. Critically, the timetable for vaccine development was shortened for “business case” reasons.

According to the New York Times, the longest times periods in a typical vaccine development timeline belong to the Preclinical, Building factories, and Manufacturing phases, and none of the phases overlap (Thompson, 2020). Unlike this usual timeline and because of the federal government’s commitment to purchasing vaccine, companies did not have to proceed sequentially to ensure return on investment. In the COVID-19 vaccine timeline, Academic Research and Preclinical had a head start from previous SARS work and the published genome; Phases I, II, and III trials had some overlap; and Building factories and Manufacturing phases began early on.



No steps have been skipped in COVID-19 vaccine development in the United States but instead have overlapped. Vaccine development acceleration can be done without sacrificing efficacy and short-term safety. Long-term immunity persistence and safety evaluation must continue.

Reference:

Thompson, S. A. How long will a vaccine really take? The New York Times, April 30, 2020. Accessed November 8, 2020 from: <https://www.nytimes.com/interactive/2020/04/30/opinion/coronavirus-covid-vaccine.html>

Historical Perspective on Vaccine Hesitancy

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The era of COVID-19 offers a new twist to vaccine hesitancy. Even persons with confidence in the emergency use authorization (EUA) approval process assuring safety and at least 50% efficacy for upcoming vaccines are asking: "Would I recommend taking the first vaccine available or wait to see if a more efficacious one comes out?" This isn't the first time this scenario has come up in US history.

After World War II, as more Americans moved to crowded urban settings, and, ironically, hygiene improved such that children were not exposed to polio at a young age when they were less likely to be symptomatic, polio incidence began to rise (Table 1). By peak year 1952, there were more than 58,000 cases, 21,000 permanently paralyzed, and 3,000 dead. Two vaccines, inactivated polio vaccine (IPV) and oral polio vaccine (OPV) were under development, but clinical trials for IPV were completed by 1954. Some scientists argued that OPV would offer better protection in preventing infection and recommended postponing mass vaccination until trials were completed (likely a two-year wait). Americans would not hear of it. People were clamoring for a vaccine. Three thousand dead and 21,000 paralyzed in one year was intolerable.

Mass vaccination with the IPV began in 1955, and annual cases decreased successively to 30,000 (1955), then 15,000 (1956) and 7,000 (1957). The urgency of the polio public health crisis dictated using the first vaccine available known to be safe and efficacious, even though some thought OPV, when eventually offered, would be better.

Table 1.
Polio Incidence, US

Year	Rate per 100,000 people
1920-1930s	4
1940-1944	8
1945-1949	16
1950-1954	25

We are in a comparable situation qualitatively in that it is likely more than one COVID-19 vaccine will be given EUA status, though some earlier than others. Should we wait to see which one is best? Would you recommend waiting six months to see if a later vaccine might prove more efficacious in the elderly before vaccinating nursing home residents?

People clamored for a vaccine in 1955 because the number of cases and deaths were compelling. Contrast these numbers with COVID-19 (Table 2). The case rate for COVID-19 are more than 210 times higher and deaths/100,00 more than 160 times higher as of this writing in February 2021 than polio was in 1952.

The FDA has assured any vaccine application for EUA will undergo rigorous scrutiny to assure safety and efficacy. COVID-19 has killed more than 10 times as many people in 2020 than influenza has annually the past several years. As public health professionals, we weigh risks and benefits and provide clear information to the public. Comparison to historical experiences offer a sobering perspective

Table 2.
Polio vs. COVID-19: Cases, Case Rates, and Deaths

Disease	Year	Number of Cases	Rate per 100,000	Number of Deaths
Polio	1952	58,000	37	3,000
COVID-19	2/2020-2/2021	27,669,556*	8,334*	489,067*

*As of 2/18/2021, CDC

References:

1. Centers for Disease Control and Prevention. COVID-19 Tracker. https://covid.cdc.gov/covid-data-tracker/#cases_casesper100k. Accessed November 8, 2020

2. Oshinsky, DM. Polio: An American Story. Oxford University Press, New York, NY. 2006

New mRNA Vaccine Technology

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At this time, it seems likely that one or both mRNA vaccines (made by Pfizer and Moderna) will be the first ones available. These vaccines use a novel platform of delivery. Rather than inactivated or attenuated whole virus, or antigen vaccines presenting protein subunit with or without a vector, the mRNA vaccines deliver a segment of genetic code containing the directions for making the spike protein (which is the virus's attachment site to enter the cell). The vaccine delivers the mRNA instructions, the cells make spike protein, which is released and induces antibody production and memory T cell activation to the spike protein. Ideally, this dual response of B and T cells will provide a robust response when an individual is exposed to SARS-CoV-2.

There are, however, lots of logistical challenges. Both vaccines require two doses (separated by 21 and 28 days for the Moderna and Pfizer vaccines, respectively) and the booster dose must be consistent with the first vaccine administered. Cold-chain considerations will impact vaccine distribution as the Pfizer vaccine needs to be held in storage of -94°F and the Moderna vaccine at -40°F. Although no serious adverse events have been noted in Phase 1-3 trials involving more than 60,000 participants, mRNA vaccine is a new technology and rare events may only arise after many thousands more are vaccinated.

References:

1. Collins, Francis. NIG Director's blog. July 16, 2020 <https://directorsblog.nih.gov/2020/07/16/researchers-publish-encouraging-early-data-on-covid-19-vaccine/>

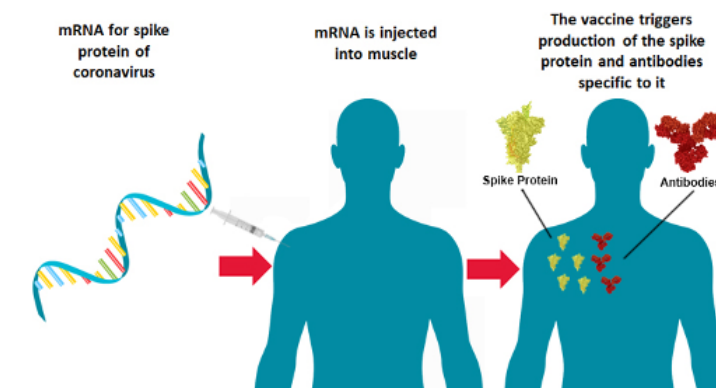


Image credit: NIH

Laboratory Criteria of the Spotted Fever Rickettsiosis and Lyme Disease Case Definitions

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Spotted Fever Rickettsiosis (SFR) and Lyme disease are the two most commonly reported tick-borne diseases in South Carolina. SFR includes cases of Rocky Mountain Spotted Fever (*Rickettsia rickettsii*), *Rickettsia parkeri* rickettsiosis, Pacific Coast Tick Fever (*Rickettsia* species 364D) and other rickettsial species. Between 2006 and 2018, 20 to 95 cases of SFR were reported annually in the state (Division of Acute Disease Epidemiology [DADE], 2019). Between 2006 and 2018, 22 to 77 cases of Lyme disease were reported annually in the state (DADE, 2019). This summary provides information regarding the laboratory criteria used for public health surveillance in the SFR and Lyme disease case definitions, including recent updates to these criteria.

Spotted Fever Rickettsiosis (SFR)

The SFR case definition was updated in 2020 and includes the following changes to the laboratory criteria:

- IgM serology test results are no longer included as part of the laboratory criteria. Previously, positive IgM results by indirect immunofluorescence antibody assays (IFA) were listed as part of the Supportive Laboratory Evidence. However, this has been removed as IgM results may be less specific than IgG results for diagnosing a recent infection (CDC, 2018).
- A category for Presumptive Laboratory Evidence was added to the case definition. This category includes positive IgG serology results >1:128 by IFA.
- The Supportive Laboratory Evidence was amended to include positive IgG serology results <1:128 by IFA.
- Both the Presumptive and Supportive Laboratory Evidence now include a criterion that positive specimens must be collected within 60 days of the patient's illness onset date to be used for surveillance purposes (CDC, 2020).

The specific categories of the current SFR case definition are listed below:

Supportive Laboratory Evidence

- Serologic evidence of elevated IgG antibody at a titer <1:128 reactive with Spotted fever group Rickettsia (SFGR) antigen by IFA in a sample taken **within 60 days of illness onset.**

Presumptive Laboratory Evidence

- Serologic evidence of elevated IgG antibody at a titer ≥1:128 reactive with SFGR antigen by IFA in a sample taken **within 60 days of illness onset.**

Confirmatory Laboratory Evidence

- Detection of SFGR nucleic acid in a clinical specimen via amplification of a Rickettsia genus- or species-specific target by Polymerase Chain Reaction (PCR) assay **OR**
- Serological evidence of a fourfold increase in IgG-specific antibody titer reactive with SFGR antigen by indirect IFA between paired serum specimens (one taken in the first two weeks after illness onset and a second taken 2 to 10 weeks after acute specimen collection) **OR**
- Demonstration of SFGR antigen in a biopsy or autopsy specimen by immunohistochemical methods (IHC) **OR**
- Isolation of SFGR from a clinical specimen in cell culture and molecular confirmation (e.g., PCR or sequence).

The Case Classifications (Confirmed, Probable, Suspect) for SFR were also revised to reflect the changes in the laboratory criteria. The full SFR case definition, including the specific case classifications, can be found at: <https://wwwn.cdc.gov/nndss/conditions/spotted-fever-rickettsiosis/case-definition/2020/>.



Lyme Disease

The current version of the Lyme disease case definition (dated 2017) includes the following criteria for laboratory results for the purposes of public health surveillance. Patients having any of these criteria would be considered to have laboratory evidence of infection for Lyme disease (CDC, 2017).

- A positive culture for Borrelia burgdorferi
- A positive two-tiered test
 - A positive two-tiered test is defined as a positive or equivocal enzyme immunoassay (EIA) or immunofluorescent assay (IFA) followed by a positive Immunoglobulin M (IgM) or Immunoglobulin G (IgG) western immunoblot (WB) for Lyme Disease.
 - An IgM WB is considered positive when at least two of the following three bands are present:
 - 24 kilodalton (kDa) outer surface protein C (OspC)*
 - 39 kDa basic membrane protein A (BmpA)
 - 41 kDa (Fla).
- Additionally, the specimen of a positive IgM WB result must be collected within 30 days of the patient’s illness onset to be used for surveillance purposes.
- An IgG WB is considered positive when at least five of the following 10 bands are present:

▪ 18 kDa	▪ 41 kDa flagellin (Fla)
▪ 24 kDa (OspC)*	▪ 45 kDa
▪ 28 kDa	▪ 58 kDa (not GroEL)
▪ 30 kDa	▪ 66 kDa
▪ 39 kDa (BmpA)	▪ 93 kDa.
- A positive single-tier IgG WB test for Lyme disease (see the details above regarding the band requirements to be considered a positive IgG WB)
 - While a single IgG WB is adequate for surveillance purposes, a two-tier test is still recommended for patient diagnosis.

*Depending upon the assay, OspC could be indicated by a band of 21, 22, 23, 24 or 25 kDa.

Information about reporting cases of SFR and Lyme disease to DHEC can be found on the DHEC List of Reportable Conditions, which is updated annually. This document can be found at: <https://sdcdeh.gov/sites/default/files/Library/CR-009025.pdf>

References:

1. Centers for Disease Control and Prevention. (2017). Lyme disease (Borrelia burgdorferi) 2017 case definition. <https://wwwn.cdc.gov/nndss/conditions/lyme-disease/case-definition/2017/>
2. Centers for Disease Control and Prevention. (2018, October 26). Rocky mountain spotted fever (RMSF): Clinical and laboratory diagnosis. <https://www.cdc.gov/rmsf/healthcare-providers/ClinLab-Diagnosis.html>
3. Centers for Disease Control and Prevention. (2020). Spotted fever rickettsiosis (including rocky mountain spotted fever) (SFR, including RMSF) 2020 case definition. <https://wwwn.cdc.gov/nndss/conditions/spotted-fever-rickettsiosis/case-definition/2020/>
4. Division of Acute Disease Epidemiology. (2019). The South Carolina annual morbidity report on reportable conditions – 2018. Columbia, SC: South Carolina Department of Health and Environmental Control, Bureau of Communicable Disease Prevention and Control. <https://sdcdeh.gov/sites/default/files/Library/CR-012452.pdf>

Parotitis Associated with Mumps and Other Viral Infections

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Parotitis, swelling in one or both parotid glands, has historically been associated with mumps viral infection. However, this symptom has also been reported in individuals who have tested positive for other viral infections, such as influenza and, now, COVID-19.

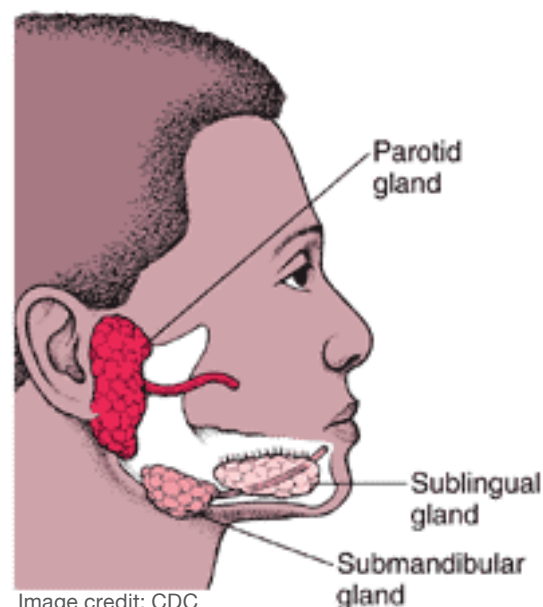


Image credit: CDC

According to Dr. Mariel Marlow, CDC Epidemiologist on the Mumps, Varicella, and Zoster (MuVZ) Epidemiology Team, as of epi week 46 (November 14, 2020), 42 states had reported 592 mumps cases compared with 50 states and 3,323 mumps cases as of the same time in 2019. Mumps cases continued to be reported throughout the period of COVID lockdowns and other control measures, with 31 states reporting 107 cases from April 2020 through November 14, 2020. Because of this, clinical evaluation of patients with parotitis and consideration of mumps and other viral testing in these patients remain important for clinical and public health management.

COVID-19 and Parotitis Case Reports

A case report in the American Journal of Emergency Medicine described a 21-year-old woman who was diagnosed with COVID-19-associated parotitis (Fisher et al, 2020). The patient was not tested for mumps but tested positive for COVID-19 upon evaluation at an emergency department. A study published in Emerging Infectious Diseases reported three patients in France who presented with parotitis-like symptoms as a clinical manifestation of confirmed COVID-19 infection (Lechien et al., 2020). Although the three cases were not tested for mumps, they were fully vaccinated for mumps. All three patients were female, ranging in age from 23 years to 31 years, and all were identified in a short period of time, with illness onsets ranging from March 21, 2020, to April 2, 2020. The patients also exhibited other symptoms consistent with COVID-19 such as loss of smell and taste, myalgia, and headache.

Mumps and Other Viral Testing

Based on these reports, it remains important to test for mumps in patients presenting with parotitis, while also considering other diagnostic testing. Testing for influenza should be considered if influenza is known to be circulating in the community. And testing for COVID-19 may also be appropriate, especially if patients present with other symptoms consistent with this condition. Additionally, mumps should not be ruled out based on patients’ age or vaccination status. Most mumps cases in the US are now adults and fully vaccinated (Marlow, 2020). Therefore, patients with these characteristics who present with parotitis should still be tested for mumps.

To test patients for mumps, collect buccal swab specimens for RT-PCR testing as soon as mumps infection is suspected. RT-PCR has the greatest diagnostic sensitivity when samples are collected within three days of symptom onset. The buccal swab specimens are obtained by massaging the parotid gland area for 30 seconds prior to swabbing the area around Stensen’s duct. If it has been greater than three days since symptom onset, it is still recommended to collect: 1) a buccal swab specimen for RT-PCR testing; and 2) 7–10 mL of blood in a red-

top or serum-separator tube (SST) for IgM detection. If assistance with mumps testing is needed, please contact the regional health department in your area. Contact information for regional health departments can be found at: <https://scdhec.gov/sites/default/files/Library/CR-009025.pdf>

References:

1. J. Fisher, D.L. Monette, K.R. Patel, et al. (2020). COVID-19 associated parotitis: A case report, American Journal of Emergency Medicine, <https://doi.org/10.1016/j.ajem.2020.06.059>
2. Lechien, J. R., Chetrit, A., Chekkoury-Idrissi, Y., Distinguin, L., Circiu, M., Saussez, S....Carlier, R. (2020). Parotitis-Like Symptoms Associated with COVID-19, France, March–April 2020. Emerging Infectious Diseases, 26(9), 2270-2271. <https://dx.doi.org/10.3201/eid2609.202059>

3. Marlow, M. (2020, November 16). Personal interview [Personal interview].

Sources:

1. Centers of Disease Control and Prevention (CDC), Mumps Job-Aid Template for Providers: <https://www.cdc.gov/mumps/health-departments/provider-job-aid.html>
2. Centers of Disease Control and Prevention (CDC), Influenza & Parotitis: Question & Answers for Health Care Providers: <https://www.cdc.gov/flu/about/season/questions-answers-parotitis.htm>
3. Centers of Disease Control and Prevention (CDC), Specimen Collection, Storage, and Shipment: <https://www.cdc.gov/mumps/lab/specimen-collect.html>

Updates to the List of Reportable Conditions for 2021

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South Carolina Law 44-29-10 and Regulation 61-20 require reporting of conditions on the Official List of Reportable Conditions in the manner prescribed by DHEC. South Carolina Law 44-53-1380 requires reporting by laboratories of all blood lead values in children under 6 years of age. Changes to the LORC for 2021 are listed below.

Conditions Added

- *Coronavirus Disease 2019 (COVID-19), has been added to urgently reportable within 24 hours by phone and the following footnote included.*
 - *Footnote 17: COVID-19 cases, deaths, and multisystem inflammatory syndrome in children are urgently reportable within 24 hours. All COVID-19*

test results, including positives, negatives and indeterminates, are required to be reported. For detailed information about reporting COVID-19 test results, please go to: <http://www.scdhec.gov/sites/default/files/Library/CR-012859.pdf>

- *HIV-exposed infants, has been added to reportable within three business days.*
- *HIV 1/2 AB/AG+ and/or detectable viral load with each pregnancy, has been added to reportable within three business days.*

Reporting Updates

1. What to report:

For all suspected and confirmed cases, report the following:

- *Patient's complete name (first, middle and last)*
- *Patient's complete address, phone number, county, date of birth, race, sex, last five digits of social security number*
- *Physician's name and phone number*
- *Name, institution, and phone number of person reporting*
- *Disease or condition*
- *Date of diagnosis*
- *Symptoms*
- *Date of onset of symptoms*
- *Lab results, specimen site, collection date*
- *If female, pregnancy status*
- *Patient status: in childcare, food-handler, healthcare worker, childcare worker, in nursing home, prisoner/detainee, travel in last four weeks*

2. How to report

The “How to Report” section of the LORC has been updated to reflect changes in the mailing address for reporting HIV, AIDS, STDs (excluding Hepatitis) and Lead, and the contact information to establish electronic reporting for Lead.

For HIV, AIDS, and STDs (excluding Hepatitis):

- Do not fax HIV, AIDS, or STD results to DHEC
- Call 1-800-277-0873; or

- Submit electronically via DHEC’s web-based reporting system; or
- Mail to:
Division of Surveillance, Assessment & Evaluation
Mills/Jarrett Complex
2100 Bull St., Columbia, SC 29201

For Lead:

- Mail to:
Bureau of Population Health Data, Analytics and Informatics, Lead Surveillance
Sims-Aycock Building,
2600 Bull St., Columbia, SC 29201
- Fax: (803) 898-3236; or
- Email: scionlead@dhec.sc.gov to establish electronic reporting

The “How to Report Other Conditions” section has been updated to reflect the change in the fax numbers for the Pee Dee region (Chesterfield, Clarendon, Darlington, Florence, Lee, Marlboro, Sumter, Williamsburg). The only fax number to use is (843) 915-6506.

As a reminder, all conditions other than HIV, AIDS, STDs, Lead and TB must be reported to the public health office in the region in which the patient resides. Immediately and urgently reportable conditions must be reported by telephone (for specific information about reporting COVID-19, go to: <https://scdhec.gov/sites/default/files/Library/CR-009025.pdf> Conditions which are routinely reportable must be reported via mail, fax or submitted electronically via DHEC’s web-based reporting system.

Resources for Additional Information

- Reportable Diseases Page on DHEC website <https://scdhec.gov/health-professionals/south-carolina-list-reportable-conditions>
- PDF List of Reportable Conditions <https://scdhec.gov/sites/default/files/Library/CR-009025.pdf>
- SC DHEC Disease Reporting Form <https://scdhec.gov/sites/default/files/Library/D-1129.pdf>

Questions?

For questions about Disease Reporting or to discuss electronic disease reporting via DHEC’s electronic disease surveillance reporting system, call the Division of Acute Disease Epidemiology in Columbia: (803) 898-0861 (M-F 8:30 a.m. to 5 p.m.). To learn about DHEC’s web-based reporting system, call 1-800-917-2093 (M-F 8:30 a.m. to 5 p.m.).

South Carolina 2021 List of Reportable Conditions

REPORT UPON RECOGNITION OF A SUSPECTED CASE, DIAGNOSIS, OR POSITIVE LABORATORY EVIDENCE (SEE “HOW TO REPORT” ON BACK)
Suspected means clinical suspicion and/or initial laboratory detection, isolation, identification, or presence of supportive laboratory results.

- ☞ Potential agent of bioterrorism
- ! Urgently reportable within 24 hours by phone
- All other conditions except lead are reportable within 3 business days
- ☞ ! Any case that may be caused by chemical, biological, or radiological threat, novel infectious agent, or any cluster of cases, or outbreak of a disease or condition that might pose a substantial risk of human morbidity or mortality (1) (5)
- * Animal (mammal) bites (6)
- ! Anthrax (*Bacillus anthracis*) (6)
- * Babesiosis (*Babesia* spp.)
- ☞ ! Botulism (*Clostridium botulinum* or Botulinum toxin)
- ☞ Brucellosis (*Brucella* spp.) (5)
- ☞ Campylobacteriosis (5)
- * *Cardiella auris* or suspected (5) (15)
- Carbapenem-resistant Enterobacteriaceae (CRE) and Acinetobacter baumannii (CRAB) (2) (5) (8)
- Carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) (2) (5) (12)
- Chancroid (*Haemophilus ducreyi*)
- * Chikungunya (5)
- * Chlamydia trachomatis
- * Ciguatera
- * Coronavirus Disease 2019 (COVID-19) (17)
- Cruetzfeldt-Jakob Disease (Age < 55 years only)
- Cryptosporidiosis (*Cryptosporidium* spp.)
- Cyclosporiasis (*Cyclospora cayentensis*) (5)
- * Dengue (5)
- * Diphtheria (*Corynebacterium diphtheriae*) (5)
- * Eastern Equine Encephalitis (EEE) (5)
- * Escherichia coli, Shiga toxin – producing (STEC) (5)
- Giardiasis (*Giardia* spp.)
- Gonorrhea (*Neisseria gonorrhoeae*) (2)
- * *Haemophilus influenzae*, all types, invasive disease (H flu) (2) (3) (5)
- * Hantavirus
- * Hemolytic uremic syndrome (HUS), post-diarthral
- * Hepatitis (acute) A, B, C, D, & E (16)
- Hepatitis (chronic) B, C, & D (16)
- Hepatitis B surface antigen + with each pregnancy
- HIV and AIDS clinical diagnosis
- HIV CD4 test results (all results) (4)
- HIV exposed infants
- HIV subtype, genotype, and phenotype (4)
- HIV 1 or HIV 2 positive test results (detection and confirmatory tests) (4)
- HIV 1/2 AB/AG+ and/or detectable viral load with each pregnancy
- HIV viral load (all results) (4)
- HIV HL A-B5701 and co-receptor assay (4)
- ! Influenza, avian or other novel strain
- Influenza
 - Lab-confirmed cases (eg. culture, RT-PCR, DFA, Molecular assay) (16)
 - Influenza associated hospitalizations (7)
- * La Crosse Encephalitis (LACV) (5)
- Lead tests, all results - indicate venous or capillary specimen (13)
- Legionellosis
- Leptosy (Mycobacterium leprae) (Hansen’s Disease)
- Leptospirosis
- Listeriosis (5)
- Lyme disease (*Borrelia burgdorferi*)
- Lymphogranuloma venereum
- Malaria (*Plasmodium* spp.)
- ! Measles (Rubella)
- ! Meningococcal disease (*Neisseria meningitidis*) (2) (3) (4) (5)
- * Mumps
- * Pertussis (*Bordetella pertussis*)
- ☞ ! Plague (*Yersinia pestis*) (5)
- ! Poliovirus
- ☞ Psittacosis (*Chlamydia psittaci*)
- ☞ Q fever (*Coxiella burnetii*)
- ! Rabies (human)
- Rabies Post Exposure Prophylaxis (PEP) when administered (5)
- * Rubella (includes congenital)
- Salmonellosis (2) (5)
- * Shiga toxin positive (5)
- Shigellosis (2) (5)
- ☞ ! Smallpox (*Varicella*)
- Spotted Fever Rickettsiosis (*Rickettsia* spp.)
- * *Staphylococcus aureus*, vancomycin-resistant or intermediate with a VA >6 MIC (VISA/VISA) (2) (5) (10)
- Streptococcus group A, invasive disease (2) (3)
- Streptococcus pneumoniae, invasive (pneumococcal) (2) (3) (11)
- * St. Louis Encephalitis (SLEV) (5)
- * Syphilis: congenital, primary, or secondary (lesion or rash) or Darkfield positive
- Syphilis: early latent, latent, tertiary, or positive serological test
- Tetanus (*Clostridium tetani*)
- Toxic Shock (specify staphylococcal or streptococcal)
- * Tuberculosis (*Mycobacterium tuberculosis*) (5) (9)
- Tuberculosis test - Positive Interferon Gamma Release Assays (IGRA): Quantiferon-TB Gold Plus (QFT-Plus) and T-SPOT.TB (14) (4)
- * Typhemia (*Francisella tularensis*) (5)
- * Typhoid fever (*Salmonella typhi*) (2) (5)
- * Typhus, epidemic (*Rickettsia prowazekii*)
- Varicella
- * Vibrio, all types, including *Vibrio cholerae* O1 and O139 (5)
- ☞ ! Viral Hemorrhagic Fevers (Ebola, Lassa, Marburg viruses)
- * West Nile Virus (5)
- * Yellow Fever
- Yersiniosis (*Yersinia, not pestis*)
- * Zika (5)

(L) Only Labs required to report.	10. Appropriate specimen types: A pure, low passage isolate submitted on a noninhibitory, non-selective agar plate or slant is preferred. If available submit one original culture plate.
1. An outbreak is the occurrence of more cases of disease than normally expected within a specific place or group of people over a given period of time. Clinical specimens may be required.	11. Specimen submission to the PHL is required for Streptococcus pneumoniae, invasive in cases < 3 years of age.
2. Include drug susceptibility profile.	12. Specimen submission of the first isolate of the month to the PHL is required for Carbapenem-resistant Pseudomonas aeruginosa.
3. Invasive disease = isolated from normally sterile site. Always specify site of isolate.	13. All blood test results are reportable within 30 days. Any elevated results (5 mcg/dL or greater) are reportable within 7 days.
4. Report Gram-negative diplococci in blood or CSF.	14. Positive IGRAe alone do not diagnose TB disease versus Latent TB Infection (LTBI). https://www.cdc.gov/tb/diagnosis/igra/igra-interpretation-2019-2020.pdf
5. Specimen submission to the Public Health Laboratory (PHL) is required. Ship immediately and urgently reportables within 1 business day. Ship 3 day reportables within 3 business days. Contact regional staff if assistance is needed.	15. Send all yeast isolates from any source to PHL except C. albicans, C. krusei, C. dubliniensis, C. lusitanae, C. parapsilosis, C. tropicalis
6. Rabies exposure prophylaxis guidance: https://www.cdc.gov/health-professionals/clinical-guidance-rabies-exposure-prophylaxis-guidance-making-appropriate-decisions-for-rabies-consultation is available from DHEC Regional Public Health Office.	16. Negative results are reportable for Hepatitis B, C and Influenza only for laboratories that report via Electronic Laboratory Reporting (ELR).
7. Report aggregate totals weekly.	17. COVID-19 cases, deaths, and multisystem inflammatory syndrome in children are urgently reportable within 24 hours. All COVID-19 test results, including positives and negatives, are required to be reported. For detailed information about reporting COVID-19 positive and negative results, please go to: www.scdhec.gov/sites/default/files/Library/CR-012859.pdf
8. Report all cases of suspect and confirmed tuberculosis (TB). A suspect case of TB is a person whom a health care provider suspects TB based on signs, symptoms, and/or laboratory evidence of TB. Centers for Disease Control and Prevention case definition of confirmed cases: https://www.cdc.gov/tb/diagnosis/igra/igra-interpretation-2019-2020.pdf	
9. Carbapenem-resistant Enterobacteriaceae and Acinetobacter baumannii from all specimen types.	



**Epi Notes is published by the South Carolina Department of Health and Environmental Control
Bureau of Communicable Disease Prevention and Control.**