

**Department of Health, Emergency Rule 64DER21-8**

**Diseases or Conditions to be Reported.**

STATEMENT OF FACTS AND REASONS FOR FINDING IMMEDIATE DANGER

Novel Coronavirus Disease 2019 (COVID-19) is a severe acute respiratory illness that can spread among humans through respiratory transmission and presents with symptoms similar to those of influenza. COVID-19 is a communicable disease with significant morbidity and mortality and presents a severe danger to public health. On March 1, 2020, a Public Health Emergency was declared by the Surgeon General to exist statewide in accordance with Executive Order 20-51. On March 9, 2020, Governor Ron DeSantis issued Executive Order 20-52 declaring that a state of emergency exists in the State of Florida. The declaration of public health emergency and state of emergency still exist. Therefore, there is an immediate need to adopt rules setting forth the procedures to report the spread of COVID-19 to protect the health, safety and welfare of Florida's citizens.

STATEMENT OF AGENCY REASONS THAT PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES

COVID-19 presents a public health threat to the state of Florida. The Surgeon General has declared a statewide Public Health Emergency due to the spread of COVID-19. There is an immediate need to set forth continued and clarified procedures for the reporting of this communicable disease in the State of Florida.

**64DER21-8 (64D-3.029) Diseases or Conditions to be Reported.**

(1) through (2) No change

(3) “Table of Reportable Diseases or Conditions to Be Reported”

Practitioner Reporting				Laboratory Reporting					
Reportable Diseases or Conditions	Timeframes			Evidence of current or recent infection with etiological agents and all associated testing results performed should be reported (e.g. species, serogroup, serotype, and antimicrobial susceptibility *2 results)	Timeframes				
	Suspect Immediately	Next Business Day Immediately	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Next Business Day	Other
Any case, cluster of cases, outbreak, or exposure to an infectious or non-infectious disease, condition, or agent found in the general community or any defined setting such as a hospital, school or other institution, not listed in this rule that is of urgent public health significance. This includes human cases, clusters, or outbreaks spread person-to-person, by animals or vectors or from an environmental, food or waterborne source of exposure; those that result from a deliberate act of terrorism; and unexplained deaths possibly due to unidentified infectious or chemical causes.	X	X		Detection in one or more specimens of etiological agents of a disease or condition not listed in this Rule that is of urgent public health significance. This includes the identification of etiological agents that are suspected to be the cause of clusters, or outbreaks spread person-to-person, by animals or vectors or from an environmental, food, or waterborne source of exposure; those that result from a deliberate act of		X	X		

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	Suspect Immediately	Next Business Day Immediately	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Next Business Day	Other
				terrorism; and unexplained deaths due to unidentified infectious or chemical causes.					
Acquired Immune Deficiency Syndrome (AIDS)			2 weeks	Acquired Immune Deficiency Syndrome (AIDS)	Laboratory Reporting Not Applicable				
Amebic Encephalitis		X		<i>Naegleria fowleri</i> , <i>Balamuthia mandrillaris</i> , or <i>Acanthamoeba</i> species			X		
Anthrax	X	X		<i>Bacillus anthracis</i>	X	X	X		

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	Suspect Immediately	Next Business Day Immediately	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Next Business Day	Other
Antimicrobial resistance surveillance			Practitioner Reporting Not Applicable	Antimicrobial resistance surveillance (for organisms not otherwise listed in this table), <i>Acinetobacter baumannii</i> , <i>Citrobacter</i> species, <i>Enterococcus</i> species, <i>Enterobacter</i> species, <i>Escherichia coli</i> species, <i>Klebsiella</i> species, <i>Pseudomonas aeruginosa</i> , <i>Serratia</i> species, isolated from a normally sterile site *3				X	
Arsenic Poisoning *4a			X	Laboratory results as specified in the surveillance case definition *4a				X	

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	Suspect Immediately	Immediately	Next Business Day	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day	Other
Arboviral infections, not otherwise listed in this table (disease due to) *5	X				Including but not limited to: Flaviviridae, Togaviridae (e.g. chikungunya, Western equine encephalitis), Bunyaviridae (e.g. Heartland, Rift Valley Fever) *5	X	X				
Babesiosis			X		Babesia spp.	X				X	
Botulism, foodborne, other (includes wound and unspecified)	X	X			<i>Clostridium botulinum</i> or botulinum toxin	X	X	X			
Botulism, infant			X		<i>Clostridium botulinum</i> or botulinum toxin	X				X	
Brucellosis	X	X			<i>Brucella</i> species	X	X	X			
California serogroup viruses-(disease due to)			X		California serogroup viruses such as Jamestown Canyon, Keystone, and Lacrosse	X				X	
Campylobacteriosis *4b			X		<i>Campylobacter</i> species *4b					X	

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	Suspect Immediately	Next Business Day Immediately	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Cancer (except non-melanoma skin cancer, and including benign and borderline intracranial and CNS tumors) *6			6 months	Pathological or tissue diagnosis of cancer (except non-melanoma skin cancer and including benign and borderline intracranial and CNS tumors)					6 months
Carbon monoxide poisoning		X		A volume fraction $\geq 0.09$ (9%) of carboxyhemoglobin in blood				X	
CD-4 absolute count and percentage of total lymphocytes	Practitioner Reporting Not Applicable			CD-4 absolute count and percentage of total lymphocytes *7					3 days
Chancroid		X		<i>Haemophilus ducreyi</i>		X		X	
Chlamydia *8		X		<i>Chlamydia trachomatis</i>				X	
Cholera	X	X		<i>Vibrio cholerae</i>	X	X	X		
Ciguatera fish poisoning		X		Ciguatera fish poisoning	Laboratory Reporting Not Applicable				
Congenital anomalies *9			6 months	Congenital anomalies	Laboratory tests as specified in Rule 64D-3.035, F.A.C.				

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	Suspect Immediately	Immediately	Next Business Day		Other	confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Conjunctivitis in neonates < 14 days old			X		Conjunctivitis in neonates < 14 days old	Laboratory Reporting Not Applicable				
<u>Coronavirus (COVID-19) *23</u>		X			<u>Coronavirus (COVID-19) *23</u>			X		
Creutzfeld-Jakob disease (CJD) *10			X		14-3-3 or tau protein detection in CSF or immunohistochemical test or any brain pathology suggestive of CJD *10				X	
Cryptosporidiosis *4b			X		<i>Cryptosporidium</i> species *4b				X	
Cyclosporiasis			X		<i>Cyclospora cayetanensis</i>	X			X	
Dengue *5	X				Dengue virus *5	X	X			
Diphtheria	X	X			<i>Corynebacterium diphtheriae</i>	X	X	X		
Eastern equine encephalitis			X		Eastern equine encephalitis virus	X			X	
Ehrlichiosis/Anaplasmosis			X		<i>Anaplasma</i> species or <i>Ehrlichia</i> species	X			X	

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	Suspect Immediately	Immediately	Next Business Day		Other	confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
<i>Escherichia coli</i> Shiga toxin-producing (disease due to) *4b			X		<i>Escherichia coli</i> Shiga toxin-producing *4b	X			X	
Giardiasis (acute) *4b			X		<i>Giardia</i> species *4b				X	
Glanders	X	X			<i>Burkholderia mallei</i>	X	X	X		
Gonorrhea *8			X		<i>Neisseria gonorrhoeae</i>				X	
Granuloma inguinale			X		<i>Calymmatobacterium granulomatis</i>				X	
<i>Haemophilus influenzae</i> , meningitis and invasive disease, in children < 5 years old	X	X			<i>Haemophilus influenzae</i> , all ages, isolated from a normally sterile site *11	X	X	X		
Hansen disease (Leprosy)			X		<i>Mycobacterium leprae</i>				X	
Hantavirus infection		X			<i>Hantavirus</i>	X		X		
Hemolytic uremic syndrome		X			Not Applicable					
Hepatitis A *4b, 12		X			Hepatitis A*4b, 12			X		
Hepatitis B, C, D, E and G *12			X		Hepatitis B, C, D, E and G Virus *12				X	
Hepatitis B surface antigen (HBsAg)-positive in a pregnant woman or a child up to 24 months old			X		Hepatitis B surface antigen (HBsAg)				X	



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	Suspect Immediately	Next Business Day Immediately	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Herpes B virus, possible exposure		X		Herpes B virus, possible exposure	Laboratory Reporting Not Applicable				
Herpes simplex virus (HSV) in infants up to 60 days old with disseminated infection with involvement of liver, encephalitis and infections limited to skin, eyes and mouth *13			X	HSV 1 or HSV 2 by direct FA, PCR, DNA or Culture *13				X	
HSV – anogenital in children < 12 years of age *8, 13			X	HSV 1 or HSV 2 by direct FA, PCR, DNA or Culture *13				X	

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	Suspect Immediately	Next Business Day Immediately	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	
Human immunodeficiency virus (HIV) infection			2 weeks	Repeatedly reactive enzyme immunoassay, followed by a positive confirmatory tests, (e.g. Western Blot, IFA): Positive result on any HIV virologic test (e.g. p24 AG, Nucleic Acid Test (NAT/NAAT) or viral culture). All viral load (detectable and undetectable) test results.*14, 15				3 days
Human immunodeficiency virus (HIV) Exposed Newborn – infant < 18 months of age born to a HIV infected woman			X	All HIV test results (e.g., positive or negative immunoassay, positive or negative virologic tests) for those < 18 months of age				3 days

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	Suspect Immediately	Immediately	Next Business Day		Other	confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Human papillomavirus (HPV) associated laryngeal papillomas or recurrent respiratory papillomatosis in children < 6 years of age *8			X		HPV DNA				X	
Human papillomavirus (HPV) – anogenital papillomas in children < 12 years of age *8			X		HPV DNA				X	
Human papillomavirus (HPV)	Practitioner Reporting Not Applicable				HPV DNA *3				X	
Influenza due to novel or pandemic strains	X	X			Isolation of influenza virus from humans of a novel or pandemic strain	X	X	X		
Influenza-associated pediatric mortality in persons aged < 18 years		X			Influenza virus – associated pediatric mortality in persons aged < 18 years (if known)	X		X		
Influenza	Practitioner Reporting Not Applicable				Influenza virus, all test results (positive and negative) *3				X	

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	Suspect Immediately	Immediately	Next Business Day	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Lead poisoning *4, 16			X		All blood lead test results (positive and negative) *3, 4, 16				X	
Legionellosis			X		<i>Legionella</i> species				X	
Leptospirosis			X		<i>Leptospira</i> species				X	
Listeriosis		X			<i>Listeria monocytogenes</i>	X		X		
Lyme disease			X		<i>Borrelia burgdorferi</i>				X	
Lymphogranuloma Venereum (LGV)			X		<i>Chlamydia trachomatis</i>				X	
Malaria			X		<i>Plasmodium</i> species	X			X	
Measles (Rubeola)	X	X			Measles virus *16	X	X	X		
Melioidosis	X	X			<i>Burkholderia pseudomallei</i>	X	X	X		
Meningitis, bacterial or mycotic			X		Isolation or demonstration of any bacterial or fungal species in cerebrospinal fluid				X	
Meningococcal disease	X	X			<i>Neisseria meningitidis</i>	X		X		

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	Suspect Immediately	Immediately	Next Business Day		Other	confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Mercury poisoning *4a			X		Laboratory results as specified in the surveillance case definition *4a				X	
Mumps			X		Mumps virus				X	
Neonatal Abstinence Syndrome *18				6 months	Neonatal Abstinence Syndrome	Laboratory Reporting Not Applicable				
Neurotoxic shellfish poisoning		X			Laboratory results as specified in the surveillance case definition *4a			X		
Pertussis		X			<i>Bordetella pertussis</i>			X		
Pesticide-related illness and injury *4			X		Laboratory results as specified in the surveillance case definition *4				X	
Plague	X	X			<i>Yersinia pestis</i>	X	X	X		
Poliomyelitis	X	X			Poliovirus	X	X	X		
Psittacosis (Ornithosis)			X		<i>Chlamydophila psittaci</i>	X			X	

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	Suspect Immediately	Immediately	Next Business Day	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Q Fever			X		<i>Coxiella burnetii</i>	X			X	
Rabies, animal or human		X			Rabies virus		X	X		
Rabies, possible exposure *19	X	X			Rabies, possible exposure	Laboratory Reporting Not Applicable				
Respiratory syncytial virus	Practitioner Reporting Not Applicable				Respiratory syncytial virus, all test results (positive and negative) *3				X	
Ricin toxicity	X	X			Ricinine (from <i>Ricinus communis</i> castor beans)	X	X	X		
Rocky Mountain spotted fever and other Spotted Fever Rickettsioses			X		<i>Rickettsia rickettsii</i> and other Spotted Fever <i>Rickettsia</i> species	X			X	
Rubella, including congenital	X	X			Rubella virus *17	X	X	X		
St. Louis encephalitis (SLE)			X		St. Louis encephalitis virus	X			X	
Salmonellosis *4b			X		<i>Salmonella</i> species *4b	X			X	
Saxitoxin poisoning including Paralytic shellfish poisoning (PSP)			X		Saxitoxin				X	
Severe acute respiratory disease syndrome-associated with a Coronavirus infection	X	X			Coronavirus associated with severe acute respiratory disease	X	X	X		

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Reportable Diseases or Conditions	Timeframes				Evidence of current or recent infection with etiological agents and all associated testing results performed should be reported (e.g. species, serogroup, serotype, and antimicrobial susceptibility *2 results)	Timeframes					
	Suspect Immediately	Immediately	Next Business Day	Other		confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day	Other
Shigellosis *4b			X		<i>Shigella</i> species *4b					X	
Smallpox	X	X			Variola virus (orthopox virus)	X	X	X			
<i>Staphylococcus aureus</i> isolated from a normally sterile site	Practitioner Reporting Not Applicable				<i>Staphylococcus aureus</i> isolated from a normally sterile site *3					X	
<i>Staphylococcus aureus</i> with intermediate or full resistance to vancomycin (VISA,VRSA)			X		<i>Staphylococcus aureus</i> with intermediate or full resistance to vancomycin (VISA, VRSA); Laboratory results as specified in the surveillance case definition *4	X			X		
Staphylococcus enterotoxin B			X		Staphylococcus enterotoxin B	X			X		
<i>Streptococcus pneumoniae</i> , invasive disease in children < 6 years, drug sensitive and resistant				X	<i>Streptococcus pneumoniae</i> , all ages, isolated from a normally sterile site *20					X	
Syphilis			X		<i>Treponema pallidum</i>					X	

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	Suspect Immediately	Immediately	Next Business Day		Other	confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Syphilis in pregnant women and neonates		X			<i>Treponema pallidum</i>			X		
Tetanus			X		<i>Clostridium tetani</i>				X	
Trichinellosis (Trichinosis)			X		<i>Trichinella spiralis</i>				X	
Tuberculosis (TB) *21			X		<i>Mycobacterium tuberculosis</i> complex *21	X			X	
Tularemia	X	X			<i>Francisella tularensis</i>	X	X	X		
Typhoid fever and paratyphoid fever *4b			X		<i>Salmonella enterica</i> serotype Typhi and <i>Salmonella enterica</i> serotypes Paratyphi A, Paratyphi B, and Paratyphi C *4b	X		X		
Typhus fever (epidemic)	X	X			<i>Rickettsia prowazekii</i>	X	X	X		
Vaccinia disease	X	X			Vaccinia virus	X	X	X		
Varicella (Chickenpox) *22			X		Varicella virus				X	
Varicella mortality			X		Varicella virus				X	
Venezuelan equine encephalitis	X	X			Venezuelan equine encephalitis virus	X	X	X		



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	Suspect Immediately	Immediately	Next Business Day		Other	confirmation *1	Submit isolates or specimens for	Suspect Immediately	Immediately	Next Business Day
Vibriosis (infections by <i>Vibrio</i> species and closely related organisms, other than Cholera)			X		All non-cholera <i>Vibrio</i> species <i>Photobacterium damsela</i> , (formerly <i>V. damsela</i> ); <i>Grimontia hollisae</i> (formerly <i>V. hollisae</i> )	X			X	
Viral hemorrhagic fevers	X	X			Ebola, Marburg, Lassa, Machupo Lujo, new world Arena, or Congo-Crimean hemorrhagic fever viruses	X	X	X		
West Nile virus (disease due to)			X		West Nile virus	X			X	
Yellow fever	X	X			Yellow fever virus	X		X		
Zika fever *5	X				Zika fever virus *5	X	X			

\*1 through \*22 No change.

\*23– Special reporting requirements for COVID-19:

a. All test results (positive, negative, and inconclusive results), including screening test results, must be immediately reported and accompanied by the type of test performed (e.g. PCR, antibody, antigen).

b. Point-of-Care Test Reporting Requirements – Practitioners, laboratories, facilities, and all others using point-of-care tests for the diagnosis of COVID-19, including those operating under CLIA waivers, must report both the negative and positive test results to the Department within 24 hours of test administration.

c. In addition to the data element fields required by Rules 64D-3.030 and 64D-3.031, all test results reported must include the CLIA number of the reporting practitioner, laboratory or facility.

d. All test results must be submitted electronically, using one of the electronic reporting methods listed below. Registration in one of these methods, must be completed within 7 days of the effective date of this rule, or within 7 days of obtaining the ability to conduct testing. Until electronic laboratory reporting has been established, test results must be submitted by facsimile to the Florida Department of Health’s Bureau of Epidemiology confidential fax line, 850-414-6894, or to the patient’s local county health department. List of county health department reporting contact information can be found at [www.FLhealth.gov/chdepcontact](http://www.FLhealth.gov/chdepcontact). For enrollment into electronic laboratory reporting or the direct entry web portal, visit [www.FloridaHealth.gov/ElectronicReportingRegistration](http://www.FloridaHealth.gov/ElectronicReportingRegistration).

1. Electronic laboratory reporting for reporting entities that can generate an electronic comma-separated value (CSV) or Health Level 7 (HL7) formatted message.

2. Web portal for entities that perform COVID-19 testing and are unable to generate an electronic CSV or HL7 formatted message. Such entities may include long-term care facilities, assisted living facilities, nursing homes, rehabilitation centers, schools, colleges, universities, or other congregate care settings.

3. National Healthcare Safety Network (NHSN) COVID-19 module for CMS-certified long-term care facilities. Test data submitted to NHSN will be reported to appropriate state and local health departments using standard electronic laboratory messages.

*Rulemaking Authority 381.0011(2), 381.003(2), 381.0031(8), 384.33, 392.53(2), 392.66 FS. Law Implemented 381.0011(3), (4), 381.003(1), 381.0031(2), (4), (5), (6), (8), 383.06, 384.25, 385.202, 392.53 FS. History–New 11-20-06, Amended 11-24-08, 6-4-14, 10-20-16, \_\_\_\_.*