

Laboratory Reporting Guidelines of Notifiable Diseases or Conditions in Florida



Based on Chapter 64D-3 revisions, November 24, 2008
Version 1.1

To all Florida State Licensed Laboratories and Blood Banks

Dear Colleagues:

Reporting suspect and confirmed notifiable diseases or conditions in the State of Florida is mandated under the Florida Statute 381.0031, Rule 64D-3, *Florida Administrative Code* (F.A.C.). Persons in charge of laboratories, practitioners, hospitals, medical facilities, schools, nursing homes, state institutions, or other locations providing health services are required to report diseases or conditions and the associated laboratory orders or test results listed in the Table of Notifiable Diseases or Conditions, Rule 64D-3, F.A.C.

The included list of reportable laboratory findings is current as of November 2008. The list is not static, and will change as the technology of laboratory diagnostics evolves.

Laboratories are required to report the receipt of a laboratory test order for some diseases, as this is considered suspicion of the disease. Diseases warranting *report upon suspicion* (termed "*Suspect Immediately*") should be reported 24 hours a day, seven days a week, so the necessary public health response can be initiated in a timely and effective manner.

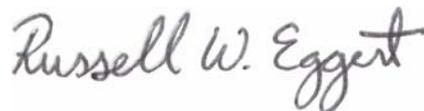
In an effort to assist laboratories to meet their obligations to report notifiable diseases or conditions, the Florida Department of Health has prepared this guide. This guide is not intended to cover every aspect of Rule 64D-3, F.A.C., but rather to provide a summation and explanation of laboratory reporting requirements. To obtain more information such as the updated version of Rule 64D-3, F.A.C., or other important reporting documents and guidelines, please visit www.floridadiseasecontrol.com/epi/topics/surv.htm or contact the Florida Department of Health State Offices (specific contact information is found on page 1 of this guide), or your local county health department.

We hope you will find this guide a useful aid as we all work to improve notifiable disease and condition reporting, prevention, and control in the state of Florida. Thank you for your partnership.

Sincerely,



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AFTER-HOURS reporting of *Suspect Immediately* and *Immediately* notifiable diseases or conditions, accessible 24 hours a day, 7 days a week (24/7):

Reports that need to be made outside of the county health department (CHD) business day shall be made to the CHD after-hours duty official.

- Locate CHD after-hours disease reporting contact information:
http://www.doh.state.fl.us/disease_ctrl/epi/topics/contact.htm

▶ CHD after-hours: _____ (record telephone number)

- Bureau of Epidemiology after-hours: 850-245-4401 (if unable to contact the CHD after-hours official)
- Bureau of Laboratories after-hours: 1-866-FLA LABS (866-352-5227)

I. Contact Information, Florida Department of Health

To report notifiable diseases or conditions, or receive consultation regarding diagnosis and management of patients and contacts, contact your local county health department (CHD).

To obtain CHD contact information visit: http://www.doh.state.fl.us/disease_ctrl/epi/topics/contact.htm

For technical consultation or consultation regarding disease reporting, diagnosis and management of patients and contacts, contact the State Health Offices:

Electronic Laboratory Reporting

ELR@doh.state.fl.us

Division of Disease Control

Telephone: 850-245-4300
 Physical: 2585 Merchants Row Boulevard
 Mailing: 4052 Bald Cypress Way, Bin #A-09
 Tallahassee, FL 32399-1720

Bureau of Environmental Public Health Medicine

Telephone: 850-245-4299
 Confidential Fax: 850-922-8473
<http://www.doh.state.fl.us/environment/medicine/index.html>

- **Childhood Lead Poisoning Prevention Program**

<http://www.doh.state.fl.us/environment/community/lead/>

Bureau of Epidemiology

Telephone: **850-245-4401, accessible 24/7**
 Confidential Fax: 850-414-6894
http://www.doh.state.fl.us/disease_ctrl/epi/

- **Florida Cancer Data System**

Telephone: 305-243-4600
<http://www.fcds.med.miami.edu>

Bureau of HIV/AIDS

Telephone: 850-245-4430
http://www.doh.state.fl.us/disease_ctrl/aids/

- **Hepatitis Prevention Program**

Telephone: 850-245-4334
http://www.doh.state.fl.us/disease_ctrl/aids/hep/

Bureau of Immunization

Telephone: 850-245-4342
 Confidential Fax: 850-922-4195
http://www.doh.state.fl.us/disease_ctrl/immune/
 OR <http://www.immunizeflorida.org/>

Bureau of Sexually Transmitted Diseases Prevention and Control

Telephone: 850-245-4604
 Confidential Fax: 850-414-8103
http://www.doh.state.fl.us/disease_ctrl/std/

Bureau of Tuberculosis and Refugee Health

Telephone: 850-245-4350
 Confidential Fax: 850-921-9906
http://www.doh.state.fl.us/disease_ctrl/tb/

For laboratory consultation or to arrange for receipt of specimens, contact the Bureau of Laboratories:

Bureau of Laboratories: <http://www.doh.state.fl.us/lab/index.html>

Bureau of Laboratories-Jacksonville

Physical: 217 Pearl Street Zip: 32202
 Mailing: P.O. Box 210 Zip: 32231
 Jacksonville, FL
 Telephone: 904-791-1500 Fax: 904-791-1567

Bureau of Laboratories-Miami

1325 N.W. 14th Avenue
 Miami, FL 33125
 Telephone: 305-324-2432 Fax: 305-324-2429

Bureau of Laboratories-Tampa

3602 Spectrum Boulevard
 Tampa, FL 33612
 Telephone: 813-974-8000 Fax: 813-974-3425

Bureau of Laboratories-Lantana

A.G. Holley Complex
 Physical: 1199 W Lantana Road, Bldg #31
 Zip: 33462
 Mailing: P.O. Box 3738 Zip: 33462
 Lantana, FL
 Telephone: 561-540-1170 Fax: 561-540-1172

Bureau of Laboratories-Pensacola

50 West Maxwell Street
 Pensacola, FL 32501
 Telephone: 850-595-8895 Fax: 850-595-6380

Bureau of Laboratories after-hours:

1-866-FLA LABS (866-352-5227), accessible 24/7
(During business hours, please utilize contact information above)

II. Frequently Asked Questions

1. Are laboratories required to report notifiable diseases or conditions?

Yes, each person or designee who is in charge of a public, federal, private, military, or hospital laboratory located in Florida responsible for receiving the initial order to perform laboratory analyses derived from a human or animal source or for collecting the specimen, **shall report any laboratory test result suggestive or diagnostic of diseases or conditions listed in the Table of Notifiable Diseases or Conditions 64D-3.029, Florida Administrative Code (F.A.C.).**

Laboratories located out of state, licensed under Part 1, Chapter 483, F.S., that collect specimens in Florida or that receive the initial order for testing from a practitioner, blood bank, plasmapheresis center, or other health care provider located in Florida, shall report laboratory findings to the Florida Department of Health in the same way as if the findings had been obtained by a laboratory located in Florida. Please refer to page 3, Question 3 of this guide for further information about where reports should be submitted.

2. What information is required to be reported by laboratories?

Information should include:

(a) The patient's:

1. First and last name, including middle initial;
2. Address including street, city, state and zip code;
3. Phone number, including area code;
4. Date of birth;
5. Sex;
6. Race;
7. Ethnicity (Hispanic/non-Hispanic);
8. Pregnancy status, if applicable;
9. Social Security number.

(b) The laboratory's:

1. Name, address and telephone number of laboratory performing test;
2. Type of specimen (for example stool, urine, blood, mucus, etc.);
3. Date of specimen collection;
4. Specimen collection site (for example cervix, eye, etc., if applicable);
5. Date of report;
6. Type of tests performed;
7. Results, including but not limited to: reference range, titer when quantitative procedures are performed, and including all available results concerning additional characterization of the organism as appropriate;
8. National Provider Identification (NPI) number.

(c) Submitting provider's:

1. Name, address including street, city, zip code, and telephone number, including area code of the provider requesting the test.

3. Where should reports of notifiable diseases or conditions be submitted?

Any report of a notifiable disease or condition should be reported to the county health department (CHD). Please note the following exceptions:

- Cancer is not reportable through the local CHD, but rather directly to the statewide cancer registry, the Florida Cancer Data System (FCDS).
- HIV/AIDS reports should be submitted to the local county health department where the laboratory is located.
- Blood lead tests are reportable directly to the statewide Childhood Lead Poisoning Prevention Program (CLPPP).
- Human papillomavirus (HPV) laboratory findings should be reported directly to the Bureau of Sexually Transmitted Diseases Prevention and Control.

4. When should reports of notifiable diseases or conditions be submitted?

Reports of notifiable diseases or conditions should be submitted according to timeframes specified in the Table of Notifiable Diseases or Conditions pages 7-12 of this guide. For a description of the requirements for each Reporting Timeframe, see page 6 of this guide. (Reporting via telephone should be followed with a subsequent written report within 72 hours, by facsimile, electronic data transfer, or other confidential means of communication.)

5. How do I obtain disease reporting contact information for local county health departments?

Please visit: http://www.doh.state.fl.us/disease_ctrl/epi/topics/contact.htm to find a listing of current county health department epidemiology contacts. It is important to know how to contact the local county health department epidemiology staff during business hours as well as after hours to report diseases with reporting timeframes of “*Suspect Immediately*” and “*Immediately*” in the Table of Notifiable Diseases or Conditions.

6. Are laboratories required to report laboratory test results electronically?

Yes, laboratories are required to report laboratory results electronically. The Florida Department of Health (FDOH) has established an Electronic Laboratory Reporting (ELR) process that includes transmitting test results in Health Level Seven (HL7) messaging format or ASCII delimited flat files which reflect comparable content to HL7 version 2.3.1 utilized by the FDOH. Laboratories should contact the ELR Project Manager via email at ELR@doh.state.fl.us for enrollment information and guidelines to begin the process of meeting this standard in the shortest possible timeframe. **Please note: Electronic laboratory reporting does not remove the requirement to report by telephone those diseases with reporting timeframes of “*Suspect Immediately*” and “*Immediately*” in the Table of Notifiable Diseases or Conditions.**

7. Should *suspect* cases of diseases or conditions of a highly infectious nature designated of urgent public health importance be reported?

Yes, laboratories and practitioners are required to report *suspected* cases of certain diseases of urgent public health importance. Providers should refer to the column labeled “*Suspect Immediately*” to determine which diseases or conditions should be reported upon suspicion of disease or laboratory test order. Requests for laboratory test identification of an organism are considered evidence that the disease is considered as part of the clinician’s differential diagnosis and should be reported. Diseases warranting *report upon suspicion* (“*Suspect Immediately*”) should be reported immediately 24 hours a day, seven days a week, to the local county health department.

8. Is it a requirement for laboratories to send isolates or specimens to the Florida Department of Health, Bureau of Laboratories for confirmation or additional characterization of the organism?

Yes, laboratories are required to send specimens (isolates, sera, slides, or diagnostic preparations) for certain etiologic agents to the Florida Department of Health, Bureau of Laboratories for confirmation and/or additional characterization of the organism. Please refer to the column entitled “Submit Isolates or Specimens for Confirmation”  in the Table of Notifiable Diseases or Conditions to determine if specimens must be sent. Submission of specimens by laboratories is encouraged in any instance where additional characterization and/or confirmation of the organism is needed in order to confirm the etiology of diseases of public health importance. During epidemiological investigations, public health investigators may, in addition to designated required submissions, request specimens to be sent to the Bureau of Laboratories in order to further characterize or confirm the etiology of the disease.

Contact information for the Bureau of Laboratories can be obtained on page 1 of this guide, from the website <http://www.doh.state.fl.us/lab/index.html> or after-hours 1-866-FLA LABS (1-866-352-5227). The Bureau of Laboratories Clinical Specimen Submission Form can be obtained from the website: http://www.doh.state.fl.us/lab/PDF_Files/doh_form.pdf. Persons submitting specimens are required to supply the Bureau of Laboratories with information specified in Question 2, page 2 of this guide, “What information are laboratories required to report?”

9. Are there special laboratory reporting requirements for HIV/AIDS?

Yes, laboratories must report all repeatedly reactive enzyme immunoassays, followed by a positive confirmatory test (e.g. Western Blot, IFA), as well as positive results on any HIV virologic test (e.g. p24 AG, Nucleic Acid Amplification Test [NAT/NAAT] or viral culture). All viral load (detectable and undetectable) test results and all CD-4 absolute count and percentage of total lymphocytes must be reported regardless of value.

Each laboratory that reports a confirmed positive HIV test must submit a sample for additional testing using STARHS (Serologic Testing Algorithm for Recent HIV Seroconversion). Additional information regarding STARHS testing is available in part V. Notations, Table of Notifiable Diseases or Conditions on page 14 of this guide, Special requirements for STARHS™.

If a genotype is performed, the fasta files containing the nucleotide sequence data, including the protease and reverse transcriptase regions, must be reported.

10. Are there special reporting requirements for tuberculosis (TB)?

Yes, a copy of the laboratory test results must also be submitted to the Department of Health, Bureau of Tuberculosis and Refugee Health. The 15-digit spoligotype (octal code) must also be reported. If spoligotyping is not available, the isolate must be submitted to the Department of Health, Bureau of Laboratories—Jacksonville.

11. Are there special reporting requirements for cancer and how should cancer cases be reported?

Yes, all laboratories must electronically submit to the statewide cancer registry, the Florida Cancer Data System (FCDS), every biopsy and surgical resection specimen of cancer and benign and borderline tumors of the brain and central nervous system (CNS) from patient encounters within the State of Florida. Each laboratory has two submission options: 1. Generate a tab-delimited file from an existing database, or 2. Use the web-based software provided by the FCDS. The complete FCDS Clinical Laboratory Cancer Identification Program (CLIP) information, reporting specifications, and pathology laboratory case report record layout can be found on the FCDS website at <http://www.fcds.med.miami.edu>. Click on the 'PATH LABS' icon, then scroll down to the Path Labs File Layout. The document describes in detail the tab-delimited format in which data must be submitted to the FCDS. Additional reference information available under 'PATH LABS' includes the CLIP Announcement, the North American Association of Central Cancer Registries (NAACCR)/FCDS cancer terms, SNOMED codes, and ICD-9 codes files that should be used to filter and select only the pathology laboratory records that identify cancers and brain and CNS benign/borderline tumors as specified in these standard files.

12. Are practitioners also required to report notifiable diseases or conditions?

Yes, practitioners are required to report notifiable diseases or conditions to the county health department. The information contained in the practitioner reports including symptoms, pregnancy status, treatment, occupation, illness in family members, hospitalization, etc., supplements the data provided by laboratories. Reporting test results by a laboratory to a county health department does not nullify the practitioner's obligation to also report the disease or condition. Practitioners also play an important role in supplying laboratories with all necessary information for the laboratories to fulfill specified reporting requirements.

13. Do reporting requirements for practitioners and laboratories differ?

Yes, practitioners and laboratories have slightly different notifiable diseases or conditions to report. Please refer to the Table of Notifiable Diseases or Conditions on pages 7-12 of this guide. Additionally, there are reporting requirements for the practitioner (such as treatment information) that are not required to be reported by laboratories.

Laboratorians, blood banks and practitioners are an invaluable part of Florida's public health and disease surveillance system. For more information, please contact your local county health department or the appropriate bureau within the Florida Department of Health or visit our website:

http://www.doh.state.fl.us/disease_ctrl/epi/topics/surv.htm. **For additional information on disease reporting, consult Chapter 64D-3, Florida Administrative Code (F.A.C.).**

III. Reporting Timeframes

1. **!** **“Suspect Immediately”** – A notifiable disease or condition of a highly infectious nature designated of urgent public health importance. **Report immediately 24 hours a day, seven days a week (24/7), by phone upon initial clinical suspicion or laboratory test order.**

Report without delay upon the occurrence of any of the following: initial clinical suspicion, receipt of a specimen with an accompanying request for an indicative or confirmatory test, findings indicative thereof, or suspected diagnosis. The goal of the **“Suspect Immediately”** reporting timeframe is to notify public health authorities as soon as possible in the case evaluation period so the necessary public health response (issuance of isolation, quarantine, prophylaxis, anti-toxin request, etc.) can be initiated in a timely and effective manner to prevent further exposure or infection. Reports that need to be made outside of the county health department (CHD) business day shall be made to the CHD after-hours duty official. If unable to contact the CHD, the Florida Department of Health, Bureau of Epidemiology after-hours duty official should be contacted at (850) 245-4401.

2. **☎** **“Immediately”** – A notifiable condition of urgent public health importance. **Report immediately 24 hours a day, seven days a week (24/7), by phone.**

Report without delay upon the occurrence of any of the following: an indicative or confirmatory test, findings indicative thereof, or diagnosis. Reports that need to be made outside of the county health department business day shall be made to the county health department after-hours duty official. If unable to do so, the Florida Department of Health, Bureau of Epidemiology after-hours duty official should be contacted at (850) 245-4401.

3. **“Next Business Day”** – Report no later than the close of the county health department next business day following confirmatory testing or diagnosis.

4. **“Other”** – Other reporting timeframe. Specific timeframes are indicated in the **“Other”** column of the Table of Notifiable Diseases or Conditions.

What is the difference between the **“Suspect Immediately” and **“Immediately”** reporting designation?**

Diseases that are listed as **“Suspect Immediately”** or **“Immediately”** should be reported 24 hours a day, seven days a week (24/7), by phone. Diseases that are listed as **“Suspect Immediately”** should be reported upon *initial suspicion*. Reports should occur prior to a confirmatory diagnosis when the disease in question is considered highly suspect. Requests for laboratory test identification of an organism are considered evidence that the disease is considered as part of the clinician’s differential diagnosis and should be reported. The goal of the **“Suspect Immediately”** reporting timeframe is to notify public health authorities as soon as possible in the case evaluation period so the necessary public health response (issuance of isolation, quarantine, prophylaxis, anti-toxin request, etc.) can be initiated in a timely and effective manner to prevent further exposure or infection. **“Immediately”** also applies to high priority diseases but they should be reported following confirmatory testing or diagnosis.

IV. Table of Notifiable Diseases or Conditions



Laboratory Reporting						Practitioner Reporting					
Agents, Notifiable Laboratory Requests and Results	Reporting Timeframe				Submit Isolates or Specimens for Confirmation [†]	Findings to Report to Public Health	Notifiable Diseases or Conditions	Reporting Timeframe			
	Suspect Immediately	Immediately	Next Business Day	Other				Suspect Immediately	Immediately	Next Business Day	Other
Detection in one or more specimens of etiological agents of a disease or condition not listed in this Table that is of urgent public health significance	!	☎				Positive by any method	Any case, cluster of cases, or outbreak of a disease or condition found in the general community or any defined setting such as a hospital, school or other institution, not listed in this Table that is of urgent public health significance. This includes those indicative of person to person spread, zoonotic spread, the presence of an environmental, food or waterborne source of exposure and those that result from a deliberate act of terrorism	!	☎		
Not Applicable						Acquired Immune Deficiency Syndrome (AIDS)					2 Wk
<i>Acanthamoeba</i> species (excluding <i>A. keratitis</i>), <i>Balamuthia mandrillaris</i> , or <i>Naegleria fowleri</i>		☎				Organisms or nucleic acid found in CSF, biopsy, tissue or other specimens	Amebic encephalitis		☎		
<i>Anaplasma phagocytophilum</i> , <i>Ehrlichia chaffeensis</i> , or <i>E. ewingii</i>			X		✉	Positive by any method	Anaplasmosis/ Ehrlichiosis			X	
<i>Anaplasma</i> or <i>Ehrlichia</i> species, other			X		✉	Positive by any method	Anaplasmosis/ Ehrlichiosis, undetermined or unspecified			X	
Arenaviruses (Lassa, Machupo)	!	☎			✉	Positive by any method	Viral hemorrhagic fevers	!	☎		
Arsenic, results indicative of arsenic poisoning [†]			X			Elevated inorganic or total urinary arsenic levels >50 µg/L total for a 24-hr urine or >50 µg/g creatinine (Speciation is required in all cases where total urine arsenic is elevated to differentiate the amount of organic and inorganic arsenic. Positive total arsenic laboratory test results from specimens taken within 72 hours of consumption of seafood are not acceptable.)	Arsenic [†]			X	
<i>Bacillus anthracis</i>	!	☎			✉	Positive by any method	Anthrax	!	☎		
<i>Balamuthia mandrillaris</i> , <i>Acanthamoeba</i> species (excluding <i>A. keratitis</i>), or <i>Naegleria fowleri</i>		☎				Organisms or nucleic acid found in CSF, biopsy, tissue or other specimens	Amebic encephalitis		☎		
<i>Bordetella pertussis</i>		☎				Positive culture or nucleic acid amplification	Pertussis		☎		
<i>Borrelia burgdorferi</i>			X			Positive by any method, if a first step assay is performed, a positive or equivocal result needs to be reported only if a second step assay (immunoblot) is positive, equivocal, or will not be performed	Lyme disease			X	
<i>Brucella abortus</i> , <i>B. canis</i> , <i>B. melitensis</i> , <i>B. suis</i>	!	☎			✉	Positive by any method	Brucellosis	!	☎		

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Laboratory Reporting						Practitioner Reporting					
Agents, Notifiable Laboratory Requests and Results	Reporting Timeframe				Submit Isolates or Specimens for Confirmation [†]	Findings to Report to Public Health	Notifiable Diseases or Conditions	Reporting Timeframe			
	Suspect Immediately	Immediately	Next Business Day	Other				Suspect Immediately	Immediately	Next Business Day	Other
<i>Burkholderia mallei</i>	!	☎			✉	Positive by any method	Glanders	!	☎		
<i>Burkholderia pseudomallei</i>	!	☎			✉	Positive by any method	Melioidosis	!	☎		
California serogroup viruses (California encephalitis, Jamestown Canyon, Keystone, Lacrosse, snowshoe hare, trivittatus)			X		✉	Positive viral culture, nucleic acid amplification, antigen detection or serologic evidence	California serogroup virus neuroinvasive and non-neuroinvasive disease			X	
<i>Calymmatobacterium granulomatis</i>			X			Donovan bodies found	Granuloma inguinale			X	
<i>Campylobacter</i> species			X			Positive by any method	Campylobacteriosis			X	
Cancer, pathological or tissue diagnosis				6 Mo		Pathological or tissue diagnosis of cancer (except non-melanoma skin cancer and including benign and borderline intracranial and CNS tumors)	Cancer (except non-melanoma skin cancer, and including benign and borderline intracranial and CNS tumors) [‡]				6 Mo
Carbon monoxide, results indicative of carbon monoxide poisoning			X			A volume fraction ≥ 0.09 (9%) of carboxyhemoglobin (COHb) in blood	Carbon monoxide poisoning			X	
CD-4 absolute count and percentage of total lymphocytes				3 Day		All CD-4s, with or without confirmed HIV infection	Not Applicable				
<i>Chlamydia trachomatis</i>			X			Positive by any method	Chlamydia including in pregnant women and neonates, children < 12 years of age [‡] ; Lymphogranuloma Venereum (LGV)			X	
Not Applicable							Conjunctivitis in neonates < 14 days old			X	
<i>Chlamydophila psittaci</i> (formerly known as <i>Chlamydia psittaci</i>)			X		✉	Positive culture or serologic evidence	Psittacosis (Ornithosis)			X	
CJD, 14-3-3 protein from CSF or any brain pathology suggestive of CJD			X			Positive by any method; contact Bureau of Epidemiology to arrange appropriate autopsy and specimen collection	Creutzfeldt-Jakob disease (CJD)			X	
<i>Clostridium botulinum</i> or botulinum toxin	!	☎			✉	Positive culture or toxin in food, blood or stool	Botulism, foodborne, other (includes wound and unspecified)	!	☎		
<i>Clostridium botulinum</i> or botulinum toxin			X		✉	Positive culture or toxin in food, blood or stool	Botulism, infant			X	
<i>Clostridium tetani</i>			X			Positive culture	Tetanus			X	
<i>Corynebacterium diphtheriae</i>	!	☎			✉	Positive culture or histopathologic evidence	Diphtheria	!	☎		
<i>Coxiella burnetii</i>			X		✉	Positive by any method	Q Fever			X	
<i>Cryptosporidium</i> species			X			Positive by any method	Cryptosporidiosis			X	
<i>Cyclospora cayatanensis</i>			X		✉	Positive by any method	Cyclosporiasis			X	
Dengue virus			X		✉	Positive viral culture, nucleic acid amplification, antigen detection or serologic evidence	Dengue			X	
Eastern equine encephalitis virus			X		✉	Positive viral culture, nucleic acid amplification, antigen detection or serologic evidence	Eastern equine encephalitis virus neuroinvasive and non-neuroinvasive disease			X	
<i>Ehrlichia chaffeensis</i> , <i>E. ewingii</i> , or <i>Anaplasma phagocytophilum</i>			X		✉	Positive by any method	Ehrlichiosis/Anaplasmosis			X	

IV. Table of Notifiable Diseases or Conditions



Laboratory Reporting						Practitioner Reporting					
Agents, Notifiable Laboratory Requests and Results	Reporting Timeframe				Submit Isolates or Specimens for Confirmation †	Findings to Report to Public Health	Notifiable Diseases or Conditions	Reporting Timeframe			
	Suspect Immediately	Immediately	Next Business Day	Other				Suspect Immediately	Immediately	Next Business Day	Other
<i>Ehrlichia</i> or <i>Anaplasma</i> species, other			X			Positive by any method	Ehrlichiosis/Anaplasmosis-undetermined or unspecified			X	
Encephalitis, isolation from or demonstration in brain or central nervous system tissue or cerebrospinal fluid, of any pathogenic virus			X			Positive culture or nucleic acid amplification or antigen detection	Encephalitis, other (non-arboviral)			X	
<i>Escherichia coli</i> O157:H7						Positive <i>Escherichia coli</i> O157 culture, or positive shiga toxin in stool	Enteric disease due to <i>Escherichia coli</i> O157:H7				
<i>Escherichia coli</i> , non-O157:H7						Positive <i>Escherichia coli</i> culture, or positive shiga toxin in stool, including enterotoxigenic, enteroinvasive, enteropathogenic, enterohemorrhagic, enteroaggregative strains and shiga toxin positive strains <i>E. coli</i> – non O157:H7 that produce Shiga-like toxin should be sent to the Bureau of Laboratories - Jacksonville	Enteric disease due to other pathogenic <i>Escherichia coli</i>				
Not Applicable							Hemolytic uremic syndrome				
Filoviruses (Ebola, Marburg)						Positive by any method	Viral hemorrhagic fevers				
<i>Francisella tularensis</i>						Positive by any method	Tularemia				
<i>Giardia</i> species			X			Positive by any method	Giardiasis			X	
<i>Haemophilus ducreyi</i>			X			Positive by any method	Chancroid			X	
<i>Haemophilus influenzae</i>						Positive culture from any sterile site (such as blood or CSF) or detection of <i>Haemophilus influenzae</i> type b antigen in CSF	<i>Haemophilus influenzae</i> , meningitis and invasive disease				
Hantavirus						Positive IgM or rising IgG titer or positive RNA by nucleic acid amplification or positive immunohistochemistry	Hantavirus infection				
Hepatitis A Virus						Positive serology for IgM anti-HAV; include all results (positive or negative) for additional serologic markers of hepatitis and alanine aminotransferase (ALT)	Hepatitis A				
Hepatitis B, C, D, E and G Virus			X			Positive serology for HBsAg (confirmed by neutralization), IgM anti-HBc, HBeAg, or HBV DNA; Anti-HCV positive (repeat reactive) by screening assay with a signal to cut-off ratio predictive of a true positive as determined by the particular assay (e.g., ≥3.8 for EIA or ≥8 for CIA) and all positive confirmatory assay (e.g., RIBA or nucleic acid amplification); include s/co in the results section of the laboratory report; Detection of any hepatitis D, E or G marker; include all results (positive or negative) for additional serologic markers of hepatitis and alanine aminotransferase (ALT)	Hepatitis B, C, D, E and G; including Hepatitis B surface antigen (HBsAg)-positive in a pregnant woman or a child up to 24 months old			X	

IV. Table of Notifiable Diseases or Conditions

Laboratory Reporting						Practitioner Reporting					
Agents, Notifiable Laboratory Requests and Results	Reporting Timeframe				Submit Isolates or Specimens for Confirmation [†]	Findings to Report to Public Health	Notifiable Diseases or Conditions	Reporting Timeframe			
	Suspect Immediately	Immediately	Next Business Day	Other				Suspect Immediately	Immediately	Next Business Day	Other
Herpes simplex virus (HSV) 1 or Herpes simplex virus 2			X			DFA, PCR, DNA or culture, 4-fold titer rise in paired sera by various serological tests confirmatory of primary infection; presence of herpes-specific IgM suggestive but not conclusive evidence of primary infection	Herpes simplex virus (HSV) in infants up to 60 days old with disseminated infection with liver involvement, encephalitis and infections limited to skin, eyes and mouth; anogenital in children ≤12 yrs of age [‡]			X	
Human immunodeficiency virus (HIV) ^{††}				3 Day		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 amplification test (NAT/NAAT) or viral culture); all viral load (detectable and undetectable) test results	Human immunodeficiency virus (HIV)				2 Wk
Human immunodeficiency virus (HIV) exposed newborn, infant ≤ 18 months of age born to a HIV infected woman				3 Day		All HIV test results, (e.g., positive or negative immunoassay, positive or negative virologic tests) for those < 18 months of age	Human immunodeficiency virus (HIV) exposed newborn, infant ≤ 18 months of age born to a HIV infected woman			X	
Human papillomavirus (HPV)			X			Positive test for any high risk HPV type (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 59, 68, etc.) Abnormal cervical and anogenital cytologies consistent with "Bethesda 2001 Terminology", Abnormal histologies including: cervical vaginal intraepithelial neoplasia (CIN 1, 2, or 3); vulvar intraepithelial neoplasia (VIN 1, 2, or 3); vaginal intraepithelial neoplasia (VAIN 1, 2, or 3); and anal intraepithelial neoplasia (AIN 1, 2, or 3). Send to the Bureau of STD Prevention and Control; reports must be received electronically.	Human papillomavirus, practitioners need not report, unless licensed as a pathologist			X	
Human papillomavirus (HPV)			X			DNA	Human papillomavirus (HPV) associated laryngeal papillomas or recurrent respiratory papillomatosis in children ≤6 yrs; anogenital in children ≤12 yrs of age [‡]			X	
Influenza virus – associated pediatric mortality in persons aged <18 years (if known)						Positive by any method	Influenza-associated pediatric mortality in persons aged < 18 years				
Influenza virus, detection of a novel or pandemic strain of influenza virus from a human						Positive by any method	Influenza due to novel or pandemic strains				
Lead, all blood lead test results			X			All blood lead tests performed (laboratories and practitioners that conduct on site blood lead analysis); report electronically to Bureau of Environmental Public Health Medicine, Childhood Lead Poisoning Prevention Program	Lead poisoning (blood lead level ≥ 10 µg/dL) (Practitioners conducting on site blood lead analysis must also comply with laboratory reporting requirements)			X	

IV. Table of Notifiable Diseases or Conditions

Laboratory Reporting						Practitioner Reporting					
Agents, Notifiable Laboratory Requests and Results	Reporting Timeframe				Submit Isolates or Specimens for Confirmation [†]	Findings to Report to Public Health	Notifiable Diseases or Conditions	Reporting Timeframe			
	Suspect Immediately	Immediately	Next Business Day	Other				Suspect Immediately	Immediately	Next Business Day	Other
<i>Legionella</i> species			X			Positive culture, DFA, positive immunohistochemistry or other similar method using validated reagents, or urine antigen or acute/convalescent serology showing a rising titer to <i>L. pneumophila</i>	Legionellosis			X	
<i>Leptospira interrogans</i>			X			Positive by any method	Leptospirosis			X	
<i>Listeria monocytogenes</i>						Positive by any method from any sterile site (such as blood or CSF)	Listeriosis				
Measles virus	!					Paired sera showing rising IgG titer, single serum showing measles IgM antibody, nucleic acid amplification or positive viral culture; IgM serum antibody or viral culture test orders should be reported as "Suspect Immediately," but not IgG results	Measles (Rubeola)	!			
Meningitis, isolation or demonstration of any bacterial or fungal species in cerebrospinal fluid			X			Positive by any method	Meningitis, bacterial, cryptococcal and other mycotic (meningococcal or <i>H. influenzae</i> or pneumococcal reported separately)			X	
Mercury, results indicative of mercury poisoning			X			Demonstration of mercury blood value of $\geq 10\mu\text{g/dL}$ in urine, $\geq 10\mu\text{g/dL}$ blood, or $> 5\mu\text{g/g}$ hair	Mercury poisoning			X	
Mumps virus			X			Paired sera showing rising IgG titer, single serum showing mumps IgM antibody, nucleic acid amplification or positive viral culture	Mumps			X	
<i>Mycobacterium leprae</i>			X			Demonstration of acid-fast bacilli in biopsy specimens from lepromatous lesions	Hansen's disease (Leprosy)			X	
<i>Mycobacterium tuberculosis</i> complex [Ⓜ]			X			Positive AFB smear, culture, nucleic acid amplification, histologic evidence; 15-digit spoligotype (octal code) must be reported. If spoligotyping is not available, the isolate must be submitted to the Bureau of Laboratories	Tuberculosis (TB) [Ⓜ]			X	
<i>Naegleria fowleri</i> , <i>Balamuthia mandrillaris</i> , or <i>Acanthamoeba</i> species (excluding <i>A. keratitis</i>)						Organisms or nucleic acid found in CSF, biopsy, tissue or other specimens	Amebic encephalitis				
<i>Neisseria gonorrhoeae</i>			X			Positive by any method; Report susceptibility test results (zone sizes for disk diffusion; MICs for E-test or agar dilution) for: fluoroquinolones, cephalosporins	Gonorrhea, including antibiotic resistant and gonorrhea in pregnant women and neonates; children ≤ 12 years of age [‡]			X	
<i>Neisseria meningitidis</i> (serogroup needed)	!					Positive culture from any sterile site (such as blood or CSF), nucleic acid amplification, positive immunohistochemistry or Gram-stain showing Gram-negative diplococci in CSF or blood	Meningococcal disease, includes meningitis and meningococcemia	!			
Neurotoxic shellfish poisoning, indicative results						Detection of neurotoxin from stool or from food samples in epidemiologically implicated shellfish	Neurotoxic shellfish poisoning				
Not Applicable							Ciguatera fish poisoning (Ciguatera)			X	
Not Applicable							Congenital anomalies [Ⓟ]				6 Mo

IV. Table of Notifiable Diseases or Conditions



Laboratory Reporting						Practitioner Reporting					
Agents, Notifiable Laboratory Requests and Results	Reporting Timeframe				Submit Isolates or Specimens for Confirmation [†]	Findings to Report to Public Health	Notifiable Diseases or Conditions	Reporting Timeframe			
	Suspect Immediately	Immediately	Next Business Day	Other				Suspect Immediately	Immediately	Next Business Day	Other
Pesticide, results indicative of pesticide related illness and injury			X			Detection of specific pesticide or its metabolic product in a clinical or biological specimen, or demonstration of abnormal cholinesterase levels in red blood cells or plasma	Pesticide-related illness and injury			X	
<i>Plasmodium falciparum</i> , <i>P. malariae</i> , <i>P. ovale</i> , <i>P. vivax</i>			X			Positive blood smear or nucleic acid amplification	Malaria			X	
Poliovirus	!					Positive viral culture or nucleic acid amplification	Poliomyelitis, paralytic and non-paralytic	!			
Rabies virus	!					Only the State of Florida Bureau of Laboratories is approved for rabies testing	Rabies, animal or human				
Not Applicable							Rabies, possible exposure ⁵	!			
Ricin toxin	!					Positive by any method	Ricin poisoning/toxicity	!			
<i>Rickettsia felis</i> , <i>R. typhi</i>			X			Positive by any method	Typhus fever			X	
<i>Rickettsia prowazekii</i>	!					Positive by any method	Typhus fever	!			
<i>Rickettsia rickettsii</i>			X			Positive by any method	Rocky Mountain spotted fever			X	
Rubella virus	!					Paired sera showing rising IgG titer, single serum showing rubella IgM antibody, nucleic acid amplification or positive viral culture; <i>IgM serum antibody or viral culture test orders should be reported as "Suspect Immediately," but not IgG results</i>	Rubella, including congenital	!			
<i>Salmonella</i> species by species serogroup and serotype			X			Positive by any method	Salmonellosis			X	
<i>Salmonella</i> serotype Typhi						Positive by any method	Typhoid fever				
SARS-associated Coronavirus (SARS-CoV)	!					Positive by any method	Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV) disease	!			
Saxitoxin			X			Toxin detection in urine or epidemiologically linked food specimen	Saxitoxin poisoning including paralytic shellfish poisoning (PSP)			X	
<i>Shigella</i> species by species and serogroup			X			Positive by any method	Shigellosis			X	
St. Louis encephalitis virus			X			Positive viral culture, nucleic acid amplification, antigen detection or serologic evidence	St. Louis encephalitis (SLE) virus neuroinvasive and non-neuroinvasive disease			X	
<i>Staphylococcus aureus</i> - community associated mortality ^{††}			X			Laboratories with an isolate from a patient that died from community associated <i>Staphylococcus aureus</i> must submit isolates to Department of Health, Bureau of Laboratories. When pneumonia was present, a suitable respiratory specimen for viral testing should be submitted if available	<i>Staphylococcus aureus</i> - community associated mortality ^{††}			X	
<i>Staphylococcus aureus</i> isolated from a normally sterile site			X			Antibiotic susceptibilities must be included; reports must be received electronically.	Not Applicable				

IV. Table of Notifiable Diseases or Conditions

Laboratory Reporting						Practitioner Reporting					
Agents, Notifiable Laboratory Requests and Results	Reporting Timeframe				Submit Isolates or Specimens for Confirmation [†]	Findings to Report to Public Health	Notifiable Diseases or Conditions	Reporting Timeframe			
	Suspect Immediately	Immediately	Next Business Day	Other				Suspect Immediately	Immediately	Next Business Day	Other
<i>Staphylococcus aureus</i> with intermediate or full resistance to vancomycin (VISA, VRSA)						<i>Staphylococcus aureus</i> isolate showing reduced susceptibility to glycopeptides (e.g. vancomycin, teicoplanin) detected and defined according to Clinical and Laboratory Standards Institute (CLSI), MIC=4-8 µg/ml (VISA), MIC≥16 µg/ml (VRSA)	<i>Staphylococcus aureus</i> with intermediate or full resistance to vancomycin (VISA, VRSA)				
<i>Staphylococcus enterotoxin B</i>						Positive for toxin in blood or urine by any method	<i>Staphylococcus enterotoxin B</i>				
<i>Streptococcus pneumoniae</i> isolated from a normally sterile site			X			Positive culture from any sterile site (such as blood or CSF), include antibiotic susceptibility pattern	<i>Streptococcus pneumoniae</i> , invasive disease in children < 5 years, drug sensitive and resistant			X	
<i>Streptococcus pneumoniae</i> isolated from a normally sterile site			X			Positive culture from any sterile site (such as blood or CSF), include antibiotic susceptibility pattern	Not Applicable				
<i>Streptococcus pyogenes</i> , Group A, isolated from a normally sterile site			X			Positive culture from any sterile site (such as blood or CSF), does not include throat specimens	Streptococcal disease, invasive, Group A			X	
<i>Toxoplasma gondii</i>			X			Positive by any method	Toxoplasmosis (acute)			X	
<i>Treponema pallidum</i>			X			Reactive/positive by any method	Syphilis			X	
<i>Treponema pallidum</i>						Reactive/positive by any method	Syphilis in pregnant women and neonates				
<i>Trichinella spiralis</i>			X			Positive biopsy or serology	Trichinellosis (Trichinosis)			X	
Vaccinia virus						Positive by any method	Vaccinia disease				
Varicella virus			X			Paired sera showing rising IgG titer, nucleic acid amplification, DFA or positive viral culture	Varicella (Chickenpox) ¹⁰ ; Varicella mortality			X	
Variola virus (orthopox virus)						Positive by any method	Smallpox				
Venezuelan equine encephalitis virus						Positive viral culture, nucleic acid amplification, antigen detection or serologic evidence	Venezuelan equine encephalitis virus neuroinvasive and non-neuroinvasive				
<i>Vibrio cholerae</i>						<i>Vibrio cholerae</i> O1 or O139 positive culture or significant serology	Cholera				
<i>Vibrio</i> species, all non-cholera <i>Vibrio</i> species including, <i>V. alginolyticus</i> , <i>V. damsela</i> , <i>V. fluvialis</i> , <i>V. furnissii</i> , <i>V. hollisae</i> , <i>V. mimicus</i> , <i>V. parahaemolyticus</i> , <i>V. vulnificus</i>			X			Positive by any method	Vibriosis (non-cholera <i>Vibrio</i> infections, cholera reported separately)			X	
West Nile virus			X			Positive viral culture, nucleic acid amplification, antigen detection or serologic evidence	West Nile virus neuroinvasive and non-neuroinvasive disease			X	
Western equine encephalitis virus			X			Positive viral culture, nucleic acid amplification, antigen detection or serologic evidence	Western equine encephalitis virus neuroinvasive and non-neuroinvasive disease			X	
Yellow fever virus						Positive viral culture, nucleic acid amplification, antigen detection or serologic evidence	Yellow fever				
<i>Yersinia pestis</i>						Positive by any method	Plague				

V. Notations, Table of Notifiable Diseases or Conditions

 **Suspect Immediately**, refer to page 7 for additional information regarding reporting timeframes.

 **Immediately**, refer to page 7 for additional information regarding reporting timeframes.

- ¶  Submission of isolates or specimens for confirmation:
 - a. Each laboratory that obtains a human isolate or a specimen from a patient shall send specimens (such as isolates, sera, slides, or diagnostic preparations) to the Florida Department of Health, Bureau of Laboratories for confirmation or additional characterization of the organism.
 - b. Persons submitting specimens for reportable laboratory tests to the Florida Department of Health, Bureau of Laboratories, pursuant to subsection 64D-3.003(4), *F.A.C.*, are required to supply the laboratories with sufficient information to comply with the provisions of this section.
 - c. For the address of your closest Florida Department of Health, Bureau of Laboratories location, refer to page 1. *After* normal business hours contact 1-866-FLA-LABS (1-866-352-5227). This location will receive isolates or specimens and maintain a record to indicate the date that these specimens were submitted to the laboratory.
 - d. Laboratories shall submit isolates or specimens to the Florida Department of Health, Bureau of Laboratories for confirmation or additional characterization of the organism for any notifiable disease as requested by the county health department director or administrator or their designee. Some additional information regarding such requests can be found in the document "Surveillance Case Definitions for Select Reportable Diseases in Florida" available at: http://www.doh.state.fl.us/disease_ctrl/epi/surv/CaseDefinitions.html.
 - e. Laboratories are not prohibited from submitting isolates or specimens from a patient for a disease or condition that is not designated in the Table of Notifiable Diseases or Conditions to be Reported in this Rule.

- † Special reporting requirements for arsenic: Organic arsenic found in fish is not believed to be toxic. Total arsenic tests do not distinguish between the organic arsenic and inorganic, the more toxic form. For this reason, cases with positive total arsenic tests with a history of fish consumption within 72 hours of the sample collection, do not need to be reported.

- ¥ Notification within six months of diagnosis and within six months of each treatment.

- ‡ Child abuse should be considered by a practitioner upon collection of a specimen for laboratory testing in any person 12 years of age or under, excluding neonates. Reporting of a sexually transmitted disease case to a county health department does not relieve the practitioner of their mandatory reporting responsibilities regarding child abuse pursuant to Section 39.201, Florida Statute.

- Ψ Exceptions are located in 64D-3.035, *F.A.C.*

- π Special requirements for STARHS (Serologic Testing Algorithm for Recent HIV Seroconversion):
 - a. Each laboratory that reports a confirmed positive HIV test in persons 13 years of age and older must also report a serologic testing algorithm for recent HIV seroconversion (STARHS) test result.
 - b. In lieu of producing this test result, each laboratory that reports a confirmed positive HIV test must submit a sample for additional testing using STARHS. The laboratory is permitted to send the remaining blood specimen or an aliquot of at least 0.5 ml to the Florida Department of Health, Bureau of Laboratories, 1217 Pearl Street, Jacksonville, Florida 32202.
 - c. Laboratories electing to send a blood specimen will contact the Florida Department of Health, Bureau of Laboratories at (904) 791-1500 to receive specimen maintenance and shipping instructions (see "d" below).
 - d. Nationally based laboratories with an existing contract to ship specimens directly to a STARHS laboratory designated by the Centers for Disease Control and Prevention will not be required to send a specimen to the Bureau of Laboratories.
 - i. Confirmed HIV-1 positive serum or plasma by Western Blot (WB), or Immunofluorescence Assay (IFA) will be shipped to the **Retrovirology Department** at the Bureau of Laboratories-Jacksonville or Bureau of Laboratories-Miami. The optimal quantity of serum required for STARHS testing is 0.5 ml

per aliquot. However, if less than 0.5 ml of the remnant sample is available for STARHS testing the sample should still be sent to the Bureau of Laboratories.

- ii. Short-term (less than one week) storage of samples in the refrigerator (2 to 8°C) is acceptable, but for long term storage (more than one week), samples must be frozen at -20°C or colder. Effort should be made to avoid repeated freezing and thawing of samples, as this may give unreliable results.
- iii. Laboratories are responsible for shipping specimens in conformity with all safety and labeling regulations. The frequency of specimen shipments to the Bureau of Laboratories will be determined by the shipping laboratory, considering factors such as specimen retention policies and freezer/storage space.
- iv. Complete the HIV Incidence Surveillance Laboratory form for each shipment. The form must include the laboratory name and the laboratory-assigned accession number for each specimen. Use black, non-smearing ink and please print clearly.
- v. The Bureau of HIV/AIDS provides specimen mailing containers and labels. The containers are the property of the State of Florida and must not be used for any purpose other than the shipment of STARHS specimens to the Bureau of Laboratories. In addition, the Bureau of HIV/AIDS has established a billing account with FedEx to off-set shipping costs incurred by the screening laboratory. For additional specimen mailing containers or FedEx labels, please contact the Bureau of HIV/AIDS, HIV Incidence Surveillance Coordinator (850) 245-4430. Note: If FedEx does not make regular pick-ups at your facility, call the carrier to schedule pick-up, FedEx (800) 463-3339.

§ If a genotype is performed, the fasta files containing the nucleotide sequence data, including the protease and reverse transcriptase regions must be reported.

Б Includes a bite or other significant exposure to a human or domestic animal (including all pets and livestock) by an animal:

- a. That results in rabies prophylaxis for the person exposed, rabies testing or quarantine of the animal causing the exposure; or
- b. That is capable of transmitting herpes B viruses (includes exposures from non-human primates).

†† As specified in the surveillance case definition for mortality in a person infected with community associated *Staphylococcus aureus*. For *S. aureus* mortality cases, a *S. aureus* isolate shall be sent to the Florida Department of Health, Bureau of Laboratories, 1217 Pearl Street, Jacksonville, Florida 32202, (904) 791-1500. When pneumonia was present prior to death, a suitable respiratory specimen for viral testing should be submitted if available, if the following:

- a. Death occurred outside a hospital setting *or* if death occurred in the hospital setting a clinical culture positive for *S. aureus* that was obtained \leq 48 hours after admission to the hospital.
- b. **Exclusion Criteria:**
 - i. Hospitalized within the year prior to death. For children less than one year old, a hospitalization other than childbirth, OR
 - ii. Admission to a nursing home, skilled nursing facility, or hospice within the last year, OR
 - iii. Dialysis within the last year, OR
 - iv. Surgery within the last year, OR
 - v. Indwelling catheters or medical devices that pass through the skin into the body in the last year.

Ж Special reporting requirements for tuberculosis:

- a. Test results must also be submitted by laboratories to the Bureau of Tuberculosis and Refugee Health;
- b. All initial culture positive isolates must be spoligotyped and the 15-digit octal code reported. Providers may send isolates to the Florida Department of Health, Bureau of Laboratories – Jacksonville.

ю Special reporting requirements for varicella (chickenpox):

In addition to the information required to be reported listed on page 2, practitioners shall also provide dates of varicella vaccination.

VI. Bureau of Laboratories Clinical Specimen Submission Form

The Bureau of Laboratories Clinical Specimen Submission Form can be accessed from the website: http://www.doh.state.fl.us/lab/PDF_Files/doh_form.pdf.

VII. Packaging and Shipping of Infectious Substances and Diagnostic Specimens

Proper packaging and shipping of infectious substances and diagnostic specimens are defined in the International Air Transport Association (IATA), Department of Transportation (DOT), and United States Postal Service (USPS) regulations. It is the sender's responsibility to properly classify, identify, package, mark, label, and document shipments for transport. Consult the following websites to ensure compliance with packaging and shipping regulations:

International Air Transport Association (IATA)

www.iata.org

World Health Organization

www.who.org

U.S. Government Printing Office

www.access.gpo.gov

Office of Health and Safety (OHS)

www.cdc.gov/od/ohs

FDOH Bureau of Laboratories

<http://www.doh.state.fl.us/lab/laboratoryservices.htm>



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