64D-3.029 Diseases or Conditions to Be Reported.

(1) Diseases or conditions listed in (3) below are of public health significance identified by the Department as of the date of these rules which must be reported by the practitioner, hospital, laboratory, or other individuals via telephone (with subsequent written report within 72 hours, see 64D-3.030 – 64D-3.033, F.A.C.), facsimile, electronic data transfer, or other confidential means of communication to the County Health Department having jurisdiction for the area in which the office of the reporting practitioner, hospital, laboratory or patient’s residence is located consistent with the specific section and time frames in (3) below relevant to the practitioners, hospitals and laboratories, respectively. Reporters are not prohibited from reporting diseases and/or conditions not listed by rule.

(3) “Table of Notifiable Diseases or Conditions to be Reported - Pertaining to HIV or AIDS”

<table>
<thead>
<tr>
<th>Notifiable Diseases or Conditions</th>
<th>Practitioner Reporting</th>
<th>Laboratory Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Timeframes</td>
<td></td>
</tr>
<tr>
<td>Acquired Immune Deficiency Syndrome (AIDS)</td>
<td>2 Weeks</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>CD-4</td>
<td>Not Applicable</td>
<td>CD-4 absolute count and percentage of total lymphocytes*3</td>
</tr>
<tr>
<td></td>
<td>2 Weeks</td>
<td>3 days</td>
</tr>
<tr>
<td>Human immunodeficiency virus (HIV)</td>
<td>2 Weeks</td>
<td>Repeatedly reactive enzyme immunoassay, followed by a positive confirmatory test, (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.<em>12</em>13</td>
</tr>
<tr>
<td></td>
<td>X</td>
<td>3 days</td>
</tr>
<tr>
<td>Human immunodeficiency virus (HIV) Exposed Newborn – infant &lt; 18 months of age born to a HIV infected woman</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*3 – All CD4s, with or without confirmed HIV infection.

*12 – 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 (Serologic Testing Algorithm for Recent HIV Seroconversion). 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 32202-3926.
  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.
  d. Nationally based laboratories with an existing contract to ship specimens directly to a STARHS laboratory designated by the National Centers for Disease Control and Prevention will not be required to send a specimen to the Florida Department of Health Laboratory.

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

Specific Authority 381.0011(13), 381.003(2), 381.0031(6), 384.33, 392.53(2), 392.66 FS Law Implemented 381.0011(4), 381.003(1), 381.0031(1), (2), (6), 383.06, 384.23, 384.25, 385.202, 392.53 FS. History- Formerly 10D-3.62, 10D-3.062, and 64D-3.002.

64D-3.030 Notification by Practitioners

(1) Each practitioner licensed under Chapters 458, 459, 460, 462, 464, 467 and 474 F.S., and medical examiner appointed pursuant to Chapter 406, F.S., who diagnoses, treats or suspects a case, or who suspects an occurrence of a disease or condition listed in the Table of Notifiable Diseases or Conditions, Rule 64D-3.029, F.A.C., including in persons who at the time of death were so affected, shall report or cause to be reported all such diagnoses or suspicions per this rule. Reporting of specimen.
results by a laboratory to a county health department director, administrator or designee does not nullify the practitioner’s obligation to report said disease or condition.

(2) Any request for laboratory test identification shall be considered a suspicion of disease. However, practitioners need only to report suspected cases if indicated in the “suspect immediately” column under practitioners in the Table of Notifiable Diseases or Conditions, Rule 64D-3.029, F.A.C.

(3) Any report of a notifiable disease or condition required by this rule…includes the following:
   (a) The Patient’s:
      1. First and last name, including middle initial;
      2. Address, including city, state and zip code;
      3. Telephone number, including area code;
      4. Date of birth;
      5. Sex;
      6. Race;
      7. Ethnicity (specify if of Hispanic descent or not of Hispanic descent);
      8. Pregnancy status if applicable;
      9. Social Security number;
     10. Date of onset of symptoms;
     11. Diagnosis.
        (a) Type of diagnostic tests (for example culture, IgM, serology, Mantoux TB skin test, nucleic acid amplification test or Western Blot);
        (b) Type of specimen (for example stool, urine, blood, mucus, etc.);
        (c) Date of specimen collection;
        (d) Site (for example cervix, eye, etc., if applicable);
        (e) Diagnostic test results;
        (f) For Tuberculosis, the 15-digit spoligotype (octal code) must be reported;
        (g) Treatment given;
        (h) Name, address and telephone number of the attending practitioner;
        (i) Other necessary epidemiological information requested by the county health department director or administrator or their designee.

(4) The practitioner who first authorizes, orders, requests or submits a specimen to a licensed laboratory for testing for any agent listed in Rule 64D-3.029, F.A.C., shall obtain and provide the information required by subparagraph 64D-3.031(3)(a)(1-10), F.A.C., at the time the specimen is sent.

(5) Special reporting requirements for HIV and AIDS:

   (b) HIV exposed newborns shall be reported on the Pediatric HIV/AIDS Confidential Case Report, CDC 50.42B Rev. 01/2003, incorporated by reference in subsection 64D-3.030 (5)(a), F.A.C.

(6) Each practitioner who makes a diagnosis of or treats any notifiable disease or condition shall make their patient medical records for such diseases or conditions available for on-site inspection by the Department or its authorized representatives.

64D-3.031 Notification by Laboratories.

(1) Each person or designee who is in charge of a public, federal, private, military or hospital laboratory responsible for receiving the initial order to perform serologic, immunologic, microscopic, biochemical, molecular or cultural tests on specimens derived from a human body or an animal or for collecting the specimen shall report or cause to be reported any laboratory test suggestive of or diagnostic of diseases or conditions listed in the Table of Notifiable Diseases or Conditions, Rule 64D-3.029, F.A.C. per this rule.

(2) Receipt of a laboratory test order requesting the identification of reportable agents shall be considered by the laboratory as an indication of suspected diagnosis. However, laboratories need only to report suspected cases if indicated in the “suspect immediately” column under laboratories in the Table of Notifiable Diseases or Conditions, Rule 64D-3.029, F.A.C.

(3) To allow follow-up of laboratory findings suggestive of or diagnostic of diseases or conditions in the Table of Notifiable Diseases or Conditions, the form upon which the information will be reported shall be furnished by the laboratory that includes the following information:
   (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 (specify if of Hispanic descent or not of Hispanic descent);
      8. Pregnancy status if applicable;
      9. Social Security number;
   (b) The Laboratory:
      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. Site (for example cervix, eye, etc., if applicable);
      5. Date of report;
      6. Type of tests performed and results, including reference range, titer when quantitative procedures are performed, and including all available results on speciating, grouping or typing of organisms;
      7. Submitting provider’s name, address including street, city, zip code and telephone number, including area code.

(4) Laboratories located out of state, licensed under Part 1, Chapter 483, F.S., who collect specimens in Florida or who receive the initial order for testing from a practitioner, blood bank, plasmapheresis center or other health care provider located in Florida, shall report in the same way as if the findings had been made by a laboratory located in Florida.

(5) Upon the Department’s implementation of its Electronic Laboratory Reporting System (ELR) for laboratory findings suggestive of or diagnostic of diseases or conditions, reports will be submitted electronically to the Department using Health Level Seven (HL7) version 2.3.1 format or ASCII delimited flat files which reflect comparable content to HL7 version 2.3.1 utilized by the Department of Health. The CDC Implementation Guide, Health Level Seven Specifications for Electronic Laboratory-Based Reporting of Public Health Information, October 1997, using version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, incorporated by reference, is available online at http://www.cdc.gov/ncidod/dq/elr/hl7spec.pdf.

(a) The Department’s ELR System shall include:
   1. The initial contact with the reporting laboratory;
   2. A content review and testing of the laboratories’ HL7 transmissions; and
   3. The transition from testing to production for the HL7 laboratory transmissions.

(b) The Department and laboratory will agree on a date of implementation

(c) Laboratories reporting electronically through ELR and the Department shall agree to a date that the transmission of findings suggestive of or diagnostic of diseases or conditions listed in the Table of Notifiable Disease or Conditions, Rule 64D-3.029 F.A.C., electronically in HL7 version 2.3.1 format to the Department is acceptable and considered good faith reporting and the laboratory will no longer be required to submit paper forms pursuant to 64D-3.031(3) F.A.C.
(d) The Department shall ensure access to the laboratory findings suggestive of or diagnostic of disease or conditions listed in the Table of Notifiable Diseases or Conditions to authorized representatives of the department.

(6) This section does not prohibit a laboratory from making a report by telephone, in writing, or facsimile to the county health department having jurisdiction for the area in which the office of the submitting practitioner or the patient’s residence is located.

(7) (Note: See FAC rule for this subsection)

(8) Each laboratory licensed to perform tests for any reportable disease or condition shall make its records for such diseases or conditions available for on-site inspection by the Department or its authorized representatives.

Specific Authority 381.0011(7), 381.0011(13), 381.003(2), 381.003(5), 381.003(6), 384.33, 392.66 FS. Law Implemented 381.0011, 381.003, 381.0031, 384.25(1), 392.53(1) FS.

64D-3.032 Notification by Medical Facilities.

(1) The chief administrative officer of each facility licensed under Chapter 395, F.S., or freestanding radiation therapy centers, as defined in Section 408.07(20), F.S., shall either personally or by appointing an individual from the staff, hereinafter referred to as “reporting individual,” report all cases or suspect cases of diseases or positive laboratory finding indicating the presence of a disease or condition listed in Rule 64D-3.029, F.A.C., in all persons admitted to, attended to, or residing in the facility per this rule.

(2) The chief administrative officer of each Department of Defense or Veterans Administration (VA) facility located in Florida is requested to appoint an individual from the staff, hereinafter referred to as “reporting individual,” to be responsible for reporting all cases or suspected cases of disease or positive laboratory findings indicating the presence of a disease or condition listed in 64D-3.029, F.A.C., in all persons admitted to, attended to, or residing in the facility per this rule.

(3) Reporting of a case or suspected case of disease or condition or positive laboratory findings by a facility or center fulfills the requirements of the licensed practitioner and laboratory director to report. It remains the responsibility of the practitioner or laboratory director to ensure that the report is made as stipulated in Rule 64D-3.029, F.A.C.

(4) Each facility that reports a notifiable disease or condition or a positive laboratory finding indicating the presence of a notifiable disease shall make its records for such diseases or conditions available for on-site inspection by the Department or its authorized representatives.

Specific Authority 381.0011(13), 381.003(2), 381.003(5), 381.003(6), 383.06, 384.33, 385.202(15), 392.66 FS. Law Implemented 381.0011, 381.003, 381.0031, 384.25, 385.202, 392.53 FS. History–New 11-20-06. Editorial Note: Formerly 10D-3.77, 10D-3.077 and 64D-3.006(1),(2).

64D-3.041 Epidemiological Investigations.

(1) The Department and its authorized representatives, when deemed necessary to protect the public’s health, may conduct epidemiological investigations and follow-up to confirm the diagnosis, treatment and causes of any disease or condition to determine appropriate methods of outbreak and communicable disease control. Such investigations shall be considered official duties of the Department and may include, but are not limited to:

(a) Review of pertinent, relevant medical records by authorized representatives of the Department, if necessary to confirm the diagnosis; to investigate causes; to identify other related cases in an area, community, or workplace; to determine if a person with a reportable notifiable disease or condition has received adequate treatment to render themselves non-infectious or if exposed has received prophylaxis, if appropriate. Such review of records may occur without patient consent and shall be conducted at reasonable times and with such notice as is deemed reasonable under the circumstances.

(b) Perform interviews with an infected person or persons knowledgeable about the case to collect pertinent and relevant information about the cause(s) of or risk factors for the notifiable disease or condition.

(c) Conduct notification services by authorized Department representatives to inform persons who may have been in such association with an infected person or animal or a contaminated environment and who have had opportunity to acquire the infection. These will include, but are not limited to: household contacts, sexual partners, correctional facilities inmates and employees, patrons, employees and/or owners of business establishments, preschool staff and students, school staff and students, and other individuals who may have been in an infected persons’ social, business or environmental network.

(d) - (h): (Note: See FAC rule for these subsections)
Information gathered in the course of an epidemiological investigation and follow-up shall be confidential to the degree permitted under the provisions of Sections 119.0712, 381.0031(4), 384.29, and 392.65, F.S.

Specific Authority 381.0011(7), 381.0011(13), 381.003(2), 381.0031(6), 384.25(2), 384.33 FS. Law Implemented 381.0011(4), 381.0031(7), 381.003(1)(c), 384.26, 392.54 FS. History– New 11-20-06. Editorial Note: History -Formerly 10D-3.100 and 64D-3.018.

64D-3.042 STD Testing Related to Pregnancy.

1) Practitioners attending a woman for prenatal care shall cause the woman to be tested for chlamydia, gonorrhea, hepatitis B, HIV and syphilis as follows:
   (a) At initial examination related to her current pregnancy; and again
   (b) At 28 to 32 weeks gestation.

2) Exceptions to the testing outlined in subsection (1) above are as follows:
   (a) A woman, who tested positive for hepatitis B surface antigen (HbsAg) during the initial examination related to her current pregnancy, need not be re-tested at 28-32 weeks gestation.
   (b) A woman, with documentation of HIV infection or AIDS need not be re-tested during the current pregnancy.

3) Women who appear at delivery or within 30 days postpartum with:
   (a) No record of prenatal care; or
   (b) Prenatal care with no record of testing;
   (c) Prenatal care with no record of testing after the 27th week of gestation shall be considered at a high risk for sexually transmissible diseases and shall be tested for hepatitis B surface antigen (HbsAg), HIV and syphilis prior to discharge.

4) Emergency Departments of hospitals licensed under chapter 395, F.S. may satisfy the testing requirements under this rule by referring any woman identified as not receiving prenatal care after the 12th week of gestation, to the county health department.
   (a) The referral shall be in writing; and
   (b) A copy shall be submitted to the county health department having jurisdiction over the area in which the emergency department is located.

5) Prior to any testing required by this rule, practitioners shall:
   (a) Notify the woman which tests will be conducted;
   (b) Inform the woman of her right to refuse any or all tests;
   (c) Place a written statement of objection signed by the woman each time she refuses required testing in her medical record specifying which tests were refused. If the woman refuses to sign the statement, the provider shall document the refusal in the medical record. No testing shall occur for the infections specified in the refusal statement of objection.

6) (Note: See FAC rule for this section)

7) (a) Specimens shall be submitted to a laboratory licensed under part 1 Chapter 483 F.S. to perform tests for chlamydia, gonorrhea, hepatitis B surface antigen (HbsAg), HIV and syphilis.
   (a) The practitioner submitting the specimens for testing to a licensed laboratory shall state that these specimens are from a pregnant or postpartum woman.

8) – (9) (Note: See FAC rule for this section)

Specific Authority 381.0011(13), 381.0031(2), 382.003(7), 384.25, 384.33 FS. Law Implemented 38.0011(4), 381.0031(1)(c), 381.004(3)(c), 382.008(6), 382.013(5), 384.25(2), 384.26, 384.31 FS. History-New 11-20-06. Editorial Note: Formerly 10D-3.101 and 64D3.019.