

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0966877	(X3) Date Survey Completed 01/23/2019
Name of Provider or Supplier Ochsner Clinic Foundation Infectious Disease	Street Address, City, State Benson Cancer Center Rm 1n103, New Orleans, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Certification Survey was performed on January 23, 2019 at Ochsner Clinic Foundation Infectious Diseases, CLIA ID # 19D0966877. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on January 23, 2019, Personnel 2 confirmed the laboratory's current competency procedure did not include the identified six (6) procedures.</p>
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	<p>CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure reagents have not exceeded their expiration date. Findings: 1. Observation by surveyor during the laboratory tour on January 23, 2019 revealed the following expired items located in the walk-in refrigerator: a) RapID Spot Indole Reagent, Lot # 874467, Expiration date: 2018-06-23, Quantity: one (1) box b) RapID Nitrate B Reagent, Lot # 859895, Expiration date: 2018-05-11, Quantity: one (1) box c) RapID Nitrate A Reagent, Lot # 844505, Expiration date: 2018-04-28, Quantity: one (1) box 2. In interview on January 23, 2019 at 1:15 pm, Personnel 2 stated the identified reagents were old and newer reagents were in front.</p>
<p>D6087</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D5417.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.</p>
<p>D6112</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451</p> <p>The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed</p>

basis to provide supervision as specified in (a) of this section.

This STANDARD is not met as evidenced by:

Based on observation and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D5417.