

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0984456	(X3) Date Survey Completed 05/03/2018
Name of Provider or Supplier La Sexually Transmitted Disease Research Center	Street Address, City, State 533 Bolivar Street, Room 711, 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 conducted on May 3, 2018 at LA Sexually Transmitted Disease Research Center, CLIA ID# 19D0984456. 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 ensure written policies and procedures to address competency for the Technical Supervisor and General Supervisor were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 serves as the Technical Supervisor and General Supervisor. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Supervisor and General Supervisor. 3. Review of personnel records for Personnel 2 revealed competency assessments for the duties of Technical Supervisor and General Supervisor were not performed. 4. In interview on May 3, 2018 at 9:40 am, Personnel 2 stated competency assessments for her duties as Technical Supervisor and General Supervisor were not performed.</p>
D6103	<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</p>

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.

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.