

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0984456	<b>(X3) Date Survey Completed</b>  11/23/2020
<b>Name of Provider or Supplier</b>  La Sexually Transmitted Disease Research Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification Survey was conducted on November 23, 2020 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.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of the laboratory's CMS 209 form, personnel records, and interview with personnel, the laboratory failed to ensure the Laboratory Director assessed competency for one (1) of two (2) General Supervisors reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the Technical Supervisor and General Supervisor 2 were listed as the laboratory's General Supervisors. 2. Review of personnel records for General Supervisor 2 revealed the laboratory did not have a documented competency assessment for her duties as General Supervisor. 3. In interview on November 23, 2020 at 10:53 am, the Technical Supervisor confirmed the Laboratory Director did not perform a competency assessment for General Supervisor 2 for her duties as General Supervisor.</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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 during the laboratory tour and interview with personnel, the laboratory failed to ensure media did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on November 23, 2020 at 9:45 am revealed the following expired media: BBL stacker plate Modified Thayer Martin, Lot # 0108058, Expiration date 2020 08 11, Quantity: one (1) box. 2. In interview on November 23, 2020 at 9:45 am, the Technical Supervisor confirmed the identified media plates were expired.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  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 test methods as required. Refer to D5417.</p>
<p><b>D6103</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  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 for assessing personnel competency were maintained. Refer to D5209.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:  Based on review of the laboratory's policy and procedure manual and interview with personnel, the Laboratory Director failed to approve/sign the laboratory's current policies. Findings: 1. In interview on November 23, 2020 at 9:57 am, the Technical Supervisor stated the laboratory started presumptive identification of Neisseria gonorrhoeae in August 2019. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have documentation that the Laboratory Director reviewed/approved the laboratory's policies. 3. In interview on November 23,</p>

2020 at 11. 24 am, the Technical Supervisor stated she did not see the Laboratory Director's signature for the procedures.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the CMS-209 Form, personnel records, and interview with personnel, the Laboratory Director failed to delegate the responsibilities of General Supervisor to one (1) of two (2) General Supervisors. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the Technical Supervisor and General Supervisor 2 were listed as the laboratory's General Supervisors. 2. Review of personnel records for General Supervisor 2 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks of General Supervisor to her. 3. In interview on November 23, 2020 at 10:53 am, the Technical Supervisor confirmed the laboratory did not have documentation of the Laboratory Director delegating responsibilities of General Supervisor to General Supervisor 2.