Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0984456	06/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
La Sexually Transmitted Disease Research Center	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 Recertification survey was performed on June 20, 2022 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.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency test records and interview with personnel, the laboratory failed to ensure the Laboratory Director or designee signed the attestation statements for two (2) of five (5) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's College of American Pathologists (CAP) records for 2021 and 2022 revealed the Laboratory Director or designee did not sign the attestation statement forms for the following events: a) 2021 D3-C b) 2022 D3-A 2. In interview on June 20, 2022 at 10:27 am, Testing Personnel 1 confirmed the Laboratory Director or designee did not sign the attestation statements for the identified events.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, CMS 209 form (Laboratory Personnel Report), personnel records, and interview with personnel, the laboratory failed to follow their established competency assessment policy for three (3) of three (3) testing personnel. Findings: 1. Review of the laboratory's "Competency Assessment" policy revealed "Assessment performed by the Laboratory Supervisor." 2. Review of the laboratory's CMS 209 form revealed the laboratory's three (3) testing personnel also serve as Technical Supervisors and General Supervisors. 2. Review of personnel records revealed the following: a) Three (3) of three (3) testing personnel did not have their 2022 competency assessment performed by a Technical Supervisor. The reviewer signature and date lines were blank. b) Testing Personnel 1 did not have her 2021 competency assessment performed by a Technical Supervisor. There reviewer signature and date lines were blank. 3. In interview on June 20, 2022 at 10:00 am, Testing Personnel 1 confirmed the assessor (Technical Supervisor) of her competency assessment for 2021 was not documented. Testing Personnel 1 stated the laboratory completed the 2022 competency assessments for testing personnel. Testing Personnel 1 confirmed the Technical Supervisor who performed the assessment for the 2022 testing personnel competency assessments was not documented.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, quality control records, patient test logs, and interview with personnel, the laboratory failed to perform Gram Stain quality control (QC) weekly for one (1) of four (4) weeks in February 2021. Findings: 1. Review of the the laboratory's "Quality Control" policy revealed "Control slides containing both gram-positive (S.aureus ATCC 25923) and gram-negative organisms (E. coli ATCC 25922) are available in the microscopy area of the microbiology section. One control slide should be included with the routine smears weekly and results recorded on QC chart." 2. Review of the laboratory's "Gram Stain Quality Control" log for 2021 revealed the laboratory did not perform quality control the week of January 31, 2022 (QC due February 3, 2021). 3. Review of the laboratory's patient test logs revealed the laboratory reported on February 3, 2021 test results for Patient 48842 without performance of weekly QC for Gram Stain. 4. In interview on June 20, 2022 at 10:27 am, Testing Personnel 1 confirmed the laboratory did not perform weekly QC for Gram Stain for the identified patient.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure all

	proficiency test report attestation statements were signed by the Laboratory Director. Refer to D2009.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5503.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) 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. 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.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisors failed to ensure that a quality control program was maintained to assure the quality of Bacteriology testing. Refer to D5503.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8)

	Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisors failed to document their performance of testing personnel competency assessments as required. Refer to D5209.