Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1073160	03/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Laboratory, Inc, The	1100 Andre Street, Suite 100, New Iberia, 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 March 17, 2021 through March 18, 2021 at The Pathology Laboratory, INC, CLIA ID # 19D1073160. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5667	CYTOLOGY CFR(s): 493.1274(h) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control logs, patient test records, and interview with personnel, the laboratory failed to document the quality control for non-gynecologic cytology slides for one (1) of eight (8) random cases reviewed. Findings: 1. Review of the laboratory's "Quality Control Log Cytology Department Non-Gyn" for random cases in 2019, 2020, and 2021 revealed the laboratory failed to document quality control, which includes "staining, coverslipping, and labeling," for the following one (1) of eight (8) patients reviewed: Patient I19-4445 on June 25, 2019 2. In interview on March 17, 2021 at 2:40 pm, the Quality Assurance personnel confirmed the laboratory did not have documentation of quality control for the identified patient.
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 D5667.
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 quality control programs are maintained to assure the quality of laboratory testing. Refer to D5667.