Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1073159	11/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Laboratory, Inc, The	1810 Bertrand Drive, Lafayette, 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 November 30, 2022 at The Pathology Laboratory, INC, CLIA ID # 19D1073159. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: I. Based on observation by surveyor and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on November 30, 2022 at 9:01 am revealed the following expired items: a) CDI Tissue Marking Dye, Yellow, Lot 20282, Expiration date: 2022-10-31, Quantity: one (1) bottle b) a/m Copper Control Slide, Lot 644538J3, Expiration Date: 2022-07-31, Quantity: one (1) 3. In interview on November 30, 2022 at 9:25 am, Compliance Personnel 2 confirmed the yellow marking dye was expired. 4. In interview on November 30, 2022 at 9:55 am, Compliance Personnel 1 confirmed the copper control slide was expired. II. Based on observation by surveyor, review of manufacturer's package insert, patient test logs, and interview with personnel, the laboratory failed to ensure an expired copper control slide was not utilized for Histopathology patient testing for four (4) patients. Findings: 1. Observation by surveyor during the laboratory tour on November 30, 2022 at 9:01 am revealed an expired copper control slide. Refer to D5417 I. 2. Further observation by surveyor during the laboratory tour on November 30, 2022 revealed "Revalidated 7 /20/22 Expires 7/20/23" written on the outside of the copper control slide box. 3. In interview on November 30, 2022 at 9:55 am , Compliance Personnel 1 stated the

	control slides are revalidated and expiration date extended for an additional year. 4. Review of the manufacturer's package insert revealed the manufacturer did not include information related to revalidation of slides or extension of expiration dates. 5. Review of patient test logs revealed the following four (4) patients were reported following the use of an expired copper control slide: a) Received: September 7, 2022; Case T22-6110 b) Received September 30, 2022; Case S22-6841 c) Received October 6, 2022; Case S22-6987 d) Received October 24, 2022; Case S22-7436 6. In interview on November 30, 2022 at 9:55 am, Compliance Personnel 1 confirmed an expired control slide was utilized for the identified patients.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) 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 ensure testing personnel documented the stain quality and reactivity of the iron control slide for histopathology testing for one (1) of twenty two (22) patients reviewed. Findings: 1. Review of quality control logs and patient test records revealed the iron control slide's quality and reactivity were not documented on the laboratory's "Special Stain Quality Control Sheet 06/09/22" for Patient N22-3204. 2. In interview on November 30, 2022 at 11:41 am, Compliance Personnel 1 and 2 confirmed the stain quality and reactivity of the iron control slide were not documented by the testing personnel for the identified patient.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on review of temperature logs and interview with personnel, the laboratory failed to perform corrective actions when room temperatures were not maintained within the acceptable range for six (6) of 334 days reviewed in 2022. Findings: 1. Review of the laboratory's room temperature logs for 2022 revealed the acceptable room temperature range was 20 to 25 degrees Celsius. 2. Further review of the room temperature logs for 2022 revealed no documentation of performance of corrective actions for temperatures exceeding acceptable limits for the following six (6) dates: May 18, 2022: Min: 18.5 degrees Celsius May 19, 2022: Min: 18.5 degrees Celsius May 20, 2022: Min: 19.9 degrees Celsius September 3, 2022: Min: 19.7 degrees

	Celsius September 4, 2022: Min: 19.7 degrees Celsius September 5, 2022: Min: 19.7 degrees Celsius 3. In interview on November 30, 2022 at 12:34 pm, Compliance Personnel 2 confirmed the laboratory did not have documentation of corrective actions for the identified dates. II. Based on review of temperature logs and interview with personnel, the laboratory failed to perform corrective actions when refrigerator temperatures were not maintained within the acceptable range for eight (8) of 334 days reviewed in 2022. Findings: 1. Review of the laboratory's IHC refrigerator temperature logs for 2022 revealed the acceptable refrigerator temperature range was 2 to 8 degrees Celsius. 2. Further review of the IHC refrigerator temperature logs for 2022 revealed no documentation of performance of corrective actions for temperatures exceeding acceptable limits for the following eight (8) dates: July 23, 2022: Max: 13 degrees Celsius July 24, 2022: Max: 13 degrees Celsius October 15, 2022: Max: 10 degrees Celsius October 16, 2022: Max:10 degrees Celsius October 22, 2022: Max: 11 degrees Celsius October 23, 2022: Max: 11 degrees Celsius October 29, 2022: Max: 11 degrees Celsius October 30, 2022: Max: 11 degrees Celsius 3. In interview on November 30, 2022 at 12:34 pm, Compliance Personnel 2 confirmed the laboratory did not have documentation of corrective actions for the identified dates. III. Based on review of temperature logs and interview with personnel, the laboratory failed to perform corrective actions when humidity readings were not maintained within the acceptable range for twenty five (25) of 364 days reviewed. Findings: 1. Review of the humidity logs for December 2021 through November 2022 revealed the acceptable humidity range was 30% to 60%. 2. Further review of the humidity logs revealed no documentation of performance of corrective actions for humidity readings exceeding acceptable limits for the following twenty five (25) dates: December 4, 2021: Min: 26% December 5, 2021: Min: 26 % December 18, 2021: Min: 26 % December 19, 2021: Min: 26% June 18, 2022: Max: 74% June 19, 2022: Max: 74% June 24, 2022: 65% June 25, 2022: Max: 76% June 26, 2022: Max: 76% July 2, 2022: Max: 76% July 3, 2022: Max:76% July 4, 2022: Max: 76% July 7, 2022: 67% July 8, 2022: 70% July 9, 2022: Min: 65%; Max: 76% July 10, 2022: Min 65%; Max: 76% July 23, 2022: Max: 77% July 24, 2022: Max: 77% July 25, 2022: 70% July 26, 2022: 64% July 27, 2022: 68% July 28, 2022: 69% July 29, 2022: 70% July 30, 2022: Min 71%; Max: 77% July 31, 2022: Min 71%; Max 77% 3. In interview on November 30, 2022 at 12:34 pm, Compliance Personnel 2 confirmed the laboratory did not have documentation of corrective actions for the identified dates.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417 I and D5417 II.
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 D5609.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781 I, D5781 II, and D5781 III.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure one (1) of five (5) recently hired Testing Personnel were approved to perform Histopathology testing. Findings: 1. Review of personnel records revealed Technical Supervisor 3 was hired August 2022. 2. Further review of personnel records revealed Technical Supervisor 3, who also serves as Testing Personnel, had documentation of an initial training; however, the laboratory did not have documentation of the Laboratory Director's approval/signature for patient testing. 3. In interview on November 30, 2022 at 10:17 am, Compliance Personnel 1 confirmed the Laboratory Director did not approve/sign-off Technical Supervisor 3 for testing after her initial training.
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 D6128.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 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 basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight for the laboratory. Refer to D5417 I and D5417 II.
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 Histopathology testing. Refer to D5609.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisors failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5781 I, D5781 II, and D5781 III.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually

	after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and interview with personnel, the Technical Supervisors failed to perform competency annually in 2021 for one (1) of three (3) cytotechnologists reviewed. Findings: 1. Review of the laboratory's "Competency Assessment" policy under "For Slide Interpretation by cytotechnologists (Testing Personnel)" section revealed "Competency is documented for all testing personnel at the following intervals: initial (prior to patient testing), six months post hire, twelve months post hire, and annually thereafter." 2. Review of personnel records for cytotechnologists revealed Cytotechnologist 3 did not have an annual competency assessment performed in 2021 for her testing personnel duties. 3. In interview on November 30, 2022 at 10:29 am, Compliance Personnel 1 stated Cytotechnologist 3 did not read any cases in 2021. Compliance Personnel 1 confirmed an annual competency assessment was not performed for Cytotechnologist 3 in 2021.