Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1073159	03/17/2021
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 March 17, 2021 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's gynecology cytology policy, case review logs, and interview with personnel, the laboratory failed to follow their policy for cytology five year retrospective review discrepancies. Findings: 1. Review of the laboratory's "GYN Cytology: Five Year Retrospective Review" policy revealed the following corrective actions: a) "If no discrepancy is found: Corrective action is not needed. the 'Five Year Retrospective Review' is filed. The '5 Year Retrospective Review' form is filed" b) "If a severe discrepancy is found that would affect patient care: The referring physician is notified. An amended report is issued to the referring physician." 2. Review of the laboratory's "5 Year Retrospective Review" logs for 2020 revealed the following patients with documented discrepancies: a) Review performed June 18, 2020 : Date 07 /18/16: Accession # Z16-9216 b) Review performed June 18, 2020: Date 06/17/15: Accession # Z15-8568 The level of discrepancy and corrective action performed was not included 3. In phone interview on March 17, 2021 at 1:47 pm, the Technical Supervisor that performed the review stated the identified patient result discrepancies did not affect patient care and amended reports were not sent. 4. Further review of the laboratory's "GYN Cytology: Five Year Retrospective Review" policy revealed the

	laboratory did not include actions performed for discrepancies that are not classified as"severe."
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance logs and interview with personnel, the laboratory failed to document the flotation bath temperatures for one (1) of twelve (12) months reviewed in 2019. Findings: 1. Review of the laboratory's 2019 "Flotation Bath and Microtome Maintenance #1" logs in 2019 revealed the laboratory did not document the flotation bath temperatures in September 2019. 2. In interview on March 17, 2021 at 1:35 pm the Quality Assurance personnel confirmed the laboratory did not have documentation of the flotation bath temperatures in September 2019.
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: Based on review of the laboratory's maintenance logs and interview with personnel, the laboratory failed to document corrective actions performed when the flotation bath temperature did not meet acceptability limits for eight (8) of twelve (12) months reviewed in 2019. Findings: 1. Review of the laboratory's "Microtome and Flotation Bath" maintenance logs for 2019 revealed for the flotation bath temperature "Should not be lower than 46 degrees C." 2. Further review of the laboratory's "Microtome ad Flotation Bath" maintenance logs for 2019 revealed the following eight (8) months the flotation bath temperature was documented as lower than 46 degrees Celsius without corrective action: a) January 2019: daily temperature recorded as 45 degrees Celsius (twenty two days documented) b) February 2019: daily temperature recorded as 45 degrees Celsius (twenty days documented) c) March 2019: daily temperature recorded as 45 degrees Celsius (twenty one days documented) d) April 2019: daily temperature recorded as 45 degrees Celsius (twenty two days documented) e) May 2019: daily temperature recorded as 45 degrees Celsius (twenty two days documented) f) June

	2019: daily temperature recorded as 45 degrees Celsius (twenty one days documented) g) July 2019: daily temperature recorded as 45 degrees Celsius (twenty one days documented) h) August 2019: daily temperature recorded as 45 degrees Celsius (twenty two days documented) 3. In interview on March 17, 2021 at 1:35 pm, the Quality Assurance personnel confirmed the laboratory did not have documentation of corrective actions performed for flotation bath temperatures that were outside of acceptable limits.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5413.
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.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, case review logs, and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.
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 record review and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to follow their policy for cytology five year retrospective review discrepancies. Refer to D5401. 2. The laboratory failed to document the flotation bath temperatures for one (1) of twelve (12) months reviewed in 2019. Refer to D5413.
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 laboratory's policies occurred. Refer to D5781.