Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2164782	10/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Luis E Alvarez, Md, Apmc	1100 Andre Street, Suite 301, 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 Recertification survey was performed on October 20, 2025 at Luis E. Alvarez, MD, CLIA ID # 19D2164782. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: I. Based on observation, review of manufacturer's storage requirements and the laboratory's temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for one (1) of one (1) rooms where Histopathology supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on October 20, 2025 at 10:05 a.m. revealed the laboratory stored the following supplies in Room 2: a) Histology Connections Differential Rapid Blood Stain, Solution A - Manufacturer's storage requirements 15-30 degrees Celsius. b) Histology Connections Differential Rapid Blood Stain, Solution B - Manufacturer's storage requirements 15-30 degrees Celsius. c) Histology Connections Alcian Blue Stain Solution, 1% w/v, pH 2.5 - Manufacturer's storage requirements 15-30 degrees Celsius. d) Bouin's fluid tissue fixative - Manufacturer's storage requirements 15-30 degrees Celsius. 2. Review of the laboratory's temperature log for Room 2 revealed the laboratory defined the

	acceptable room temperature limits as 55-80 degrees Fahrenheit (12.8-26.7 degrees Celsius) which exceeded the manufacturers' lower temperature limits 3. In interview on October 20, 2025 at 12 p.m., Testing Personnel 1 confirmed the acceptable room temperature limits defined by the laboratory exceeded the manufacturers' lower temperature limits as identified above. II. Based on observation, review of the manufacturer's operating requirements and laboratory temperature records, as well as interview with personnel, the laboratory failed to monitor the room temperature and humidity for one (1) of two (2) rooms where Histopathology testing was performed. Findings: 1. Observation by surveyor during the laboratory tour on October 20, 2025 at 10:05 a.m. revealed the following instruments utilized for Histopathology testing in Room 1: a) Dakewe DP360 Slide Stainer - Manufacturer's operating temperature 15-40 degrees Celsius, manufacturer's operating humidity 10-85%. b) Thermoscientific HistoStar - Manufacturer's operating temperature 17-27 degrees Celsius, manufacturer's operating humidity maximum 80%. 2. Review of the laboratory's temperature and humidity records revealed no documentation of room temperature and /or humidity monitoring for Room 1. 3. In interview on October 20, 2025 at 12 p.m., Testing Personnel 1 confirmed the laboratory did not monitor the room temperature and humidity of Room 1 as identified above.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance records and interview with personnel, the laboratory failed to document weekly maintenance for Histopathology stains as required by the laboratory for thirty-eight (38) of thirty-eight (38) weeks reviewed. Findings: 1. Review of the laboratory's policy "Routine Microtomy and Staining Procedure" section "Quality Control" revealed the following: *"Stainer - Day of Use" - "The containers will be dumped out and cleaned once weekly." 2. Review of the laboratory's maintenance logs from January 2025 through September 2025 revealed the laboratory did not document weekly maintenance of the stain containers. 3. In interview on October 20, 2025 at 11:26 a.m., Testing Personnel 1 stated she performed weekly maintenance but did not document it as identified above.
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 the laboratory's policies and stain logs as well as interview with personnel, the laboratory failed to document all quality control (QC) procedures for nine (9) of nine (9) months reviewed. Findings: 1. Review of the laboratory's policy "Routine Microtomy and Staining Procedure" section "Procedure" revealed "each

	working day a control slide must be stained and reviewed by the Pathologist or Pathology Laboratory Manager." 2. Review of the laboratory's staining logs for Hematoxylin and Eosin (H&E), Alcian Blue/Periodic Acid-Schiff (PAS), and Diff-Quik revealed the laboratory did not document the reagent lot numbers and expiration dates in use for staining slides. 3. In interview on October 20, 2025 at 10:10 a.m., Testing Personnel 1 confirmed she did not document the lot numbers and expiration dates of reagents as identified above.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) 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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for one (1) of one (1) rooms where Histopathology supplies were stored. Refer to D5413 I. 2. The laboratory failed to monitor the room temperature and humidity for one (1) of two (2) rooms where Histopathology testing was performed. Refer to D5413 II.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 review of the laboratory's policies and interview with personnel, the Laboratory Director failed to ensure a complete quality control program was established to assure the quality of laboratory testing results. Refer to D5609.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5433.