Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2164230	06/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pathologists' Laboratory, Pc	890 N Blue Jay Way, Operating Suite, Gallatin, TN	

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
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 observation of the laboratory, a review of the laboratory's procedure, lack of documentation, and staff interviews, the laboratory failed to document maintenance as outlined in the established procedure for the cryostat instrument used to process patient tissue samples for slide examination in 2025 and 2026. The findings include: 1. Observation of the laboratory revealed the Triangle Biomedical Sciences Minotome Plus cryostat instrument used to process patient tissue samples removed during surgical procedures for slide review. 2. A review of the laboratory's procedure titled "Cryostat Maintenance, Cleaning, and Disinfecting" revealed "Day of Use Maintenance", "Weekly", and "Occasionally or when required" maintenance procedures for the cryostat instrument. 3. The laboratory did not have documentation of maintenance procedures for surveyor review on the date of the survey (06/11/2026) for 2025 or 2026. 4.An interview with the laboratory operations manager on 06/11 /2026 at 11:30 a.m. confirmed the survey findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures, patient operating room consultation forms, and staff interview, the laboratory failed to define the predicted characteristics of the Hematoxylin and Eosin (H&E) stain used for frozen tissue slide examination in 2025 through the survey date (06/11/2026). The findings include: 1. A review of the laboratory's procedure titled "Histology Prep Quality" revealed no definition of the predicted characteristics of the H&E stain quality. 2. A review of the laboratory's patient operating room consultation forms (Account 64939 on 10/22/2025 and Account 34647 on 05/27/2026) used to document daily quality control revealed no documentation of the predicted characteristics of the H&E stain quality. 3. An interview with the laboratory operations manager on 06/11/2026 at 11:30 a.m. confirmed the survey findings.
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 observation of the laboratory, a review of the laboratory's procedure, temperature records, and staff interview, the laboratory failed to document corrective action for temperatures that exceeded the laboratory's established acceptable range for the cryostat instrument used to process patient tissue samples for slide review for 15 of 17 months reviewed from 02/01/2025 through the survey date (06/11/2026). The findings include: 1. Observation of the laboratory revealed the Triangle Biomedical Sciences Minotome Plus cryostat instrument used to process patient tissue samples removed during surgical procedures for slide review. 2. A review of the laboratory's procedure titled "Cryostat Maintenance, Cleaning, and Disinfecting" in section "Daily (whether used or not)" revealed, "Check and record the temperature of the cryostat". 3. A review of the laboratory's electronic Cryostat Temperature Log Sheets from 02/01/2026 through 06/11/2026 revealed "Range Limits: -17C to -27C" with temperatures that exceeded the established range as follows: April 2025: 4 of 18 days recorded May 2025: 15 of 15 days recorded June 2025: 14 of 14 days recorded July 2025: 16 of 16 days recorded August 2025: 16 of 16 days recorded September 2025: 17 of 17 days recorded October 2025: 17 of 17 days recorded November 2025: 12 of 12 days recorded December 2025: 16 of 16 days recorded January 2026: 14 of 14 days recorded February 2026: 15 of 15 days recorded March 2026: 21 of 21 days recorded April 2026: 22 of 22 days recorded May 2026: 15 of 20 days recorded June 2026: 8 of 9 days recorded 4. No corrective action documentation was available for surveyor review on the survey date (06/11/2026) for the recorded temperatures that were outside of the laboratory's established range in 2025 and 2026. 5. An interview with the laboratory operations manager on 06/11/2026 at 11:30 a.m. confirmed the survey findings.