Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2052330	11/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pathologists Bio-Medical Laboratories, Pllc	2460 N Interstate Highway 35-E, Ste 230, Waxahachie, TX	

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	An announced survey of the laboratory was conducted on 11/05/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies/procedures, laboratory's records and staff interview, the laboratory failed to follow its own policy for monitoring and documenting temperature to ensure stored slide preservation for two of two rooms with stored specimen slides. Findings included: 1. Surveyor's observations on 11/05/2024 at 0900 hours in the facility revealed the laboratory stored specimen slides in two different rooms, the reception room and a storage room. 2. Review of laboratory's "Specimen and Records Retention Policy" (document Gen Lab 25, last approved 05/08/2024) revealed: "Slides/blocks are stored at ambient room temperature for optimum preservation. Slide/block storage room temperatures are monitored to ensure this." The policy did not define acceptable ambient temperature range for slide storage. 3. Review of laboratory's records revealed there was no documentation of temperature monitoring for the two rooms where specimen slides were stored. 4. In an interview on 11/05/2024 at 1230 hours in the breakroom, the facility's Senior Manager for Safety, Quality and Compliance (as indicated on submitted Survey Entrance/Exit Conference Form) confirmed the findings.
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 laboratory's policies/procedures, electronic quality control (QC) records, patient test records and staff interview, the laboratory failed to ensure stain /slide acceptability was documented in the electronic system as per its own protocol for four of sixty-nine instances documentation was required from January to June 2023. Findings included: 1. Review of laboratory's "Routine Stain Quality" policy (document Histo 55, last approved 02/15/2024) revealed: "The Pathologists perform a quality control assessment of routine stains when reviewing slides for diagnosis." And, "1. The Pathologist completes the PBM Slide Discrepancy Application that accompanies the assigned workload daily ... 2. The Pathologist notes any discrepancies with the workload received. 3. In the event there are no discrepancies present, the Pathologist checks the box indicating, "There were no discrepancies present with today's workload." 4. If there are no issues with the H&E staining, the pathologist checks the box indicating that the H&E stain quality in that day's workload was satisfactory." 2. Review of laboratory's electronic QC records From January to June 2023 revealed the following four of sixty-nine reviewed PBM Slide Discrepancy Application records did not have the boxes for "no discrepancies present" or "H&E stain quality" marked as required: Id: Discrepancy date: 6795 01/13/2023 6797 01/13/2023 6800 01/13/2023 7256 03/27/2023 3. Review of laboratory's patient test records revealed the following patient samples were evaluated within the workload without the required PBM electronic documentation of workload discrepancy and H&E stain quality: Sign-Out Date: 01/13/2024 Cases signed out: PS23-1776 PS23-1864 PS23-1865 PS23-1866 PS23-1868 PS23-1869 PS23-1873 PS23-1875 PS23-1885 PS23-1896 PS23-1963 PS23-2004 PS23-2009 PS23-2012 PS23-2019 PS23-2024 PS23-2028 PS23-2041 Sign-Out Date: 03/27/2023 Cases signed out: PN23-1170 PN23-1185 PS23-16321 PS23-16368 PS23-16369 PS23-16960 PS23-16963 PS23-16966 PS23-16967 PS23-16971 PS23-16977 PS23-16978 4. In an interview on 11/05/2024 at 1130 hours in the breakroom, the facility's Senior Manager for Safety, Quality and Compliance (as indicated on submitted Survey Entrance/Exit Conference Form) confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must 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 surveyor's observations, review of manufacturer's instructions, laboratory's

	policies/procedures, maintenance records and staff interview, the laboratory failed to document microscope maintenance for two of two microscopes in use in 2023 and 2024. Findings included: 1. Surveyor's observations on 11/06/2024 at 0910 hours in the facility revealed two microscopes, one in each of the two pathologists' offices. These were: a. Olympus BX-43F; Serial Number 4J44798 b. Olympus BX-51TF; Serial Number 4B16343 2. Review of manufacturer's "Olympus Instructions BX43" and "Olympus Instructions BX51/52" (www.Manualslib.com) for the above microscopes revealed: "Maintenance and Storage 1. To clean the lenses and other glass components, simply blow dirt away using a commercially available blower and wipe gently using a piece of cleaning paper (or clean gauze). If a lens is stained with fingerprints or oil smudges, wipe it gauze slightly moistened with commercially available absolute alcohol." Manufacturer's instructions did not define required frequency of maintenance. 3. Review of laboratory's "Microscope Maintenance" policy (document Gen Lab 16, last approved 06/18/2024) revealed: "PROCEDURE Cleaning: 1. Using lens paper apply a drop of lens cleaning solution formulated for cleaning microscope lenses, to the lens paper and carefully clean all optical surfaces ... 2. Using a dry piece of lens paper remove any excess liquid and remaining dust particles for(sic) lens surfaces. 3. Use canned air to blow away any remaining dust from the body of the microscope." Laboratory policy did not specify required frequency of microscope maintenance. 4. Review of laboratory's microscope maintenance records revealed the laboratory did not document microscope maintenance/cleaning for either of the above two microscopes in 2023 and 2024. 5. In an interview on 11/05/2024 at 1330 hours in the breakroom, the facility's Senior Manager for Safety, Quality and Compliance (as indicated on submitted Survey Entrance/Exit Conference Form) confirmed the findings.