Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2052327	07/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pathologists Bio-Medical Laboratories, Pllc	1600 West College St - 1st Floor #185, Grapevine, 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 onsite recertification survey was conducted on 07/28/2026. The laboratory was found to be in compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologist (CAP) instructions, proficiency testing (PT) records, and confirmed in interview, the laboratory director and testing persons failed to attest to the routine integration of proficiency samples into the patient workload for two of two histopathology events in 2025 (DNA Mismatch Repair Survey, Events MMR-A-2025 and MMR-B-2025). Findings included: 1. Review of the laboratory's policy "CAP Proficiency Testing" stated: "PROCEDURE ... D. CAP PT Survey Documentation and Reporting 1. Any technical staff who performed testing on the CAP PT survey must sign the Attestation Statement in the Testing Personnel section. Electronic signatures are not acceptable. 2. Attestation statements may be submitted by fax, mail or online through the CAP website. For surveys submitted online, the signature on the attestation statements will appear as the individuals' [sic] typed name. Regardless of submission method, the attestation statement must be manually signed and kept in the CAP PT testing notebook. 3. Completed testing materials (i.e. slides) and documentation are provided to the pathologist for review in ample time prior to the stated survey deadline ... 5. The pathologist and Laboratory Director complete the Attestation Statement in accordance to policy. i. The pathologist who interpreted the survey and the Lab

	personnel who performed the requested stains, signs their name in the Testing Personnel section. Interpretation of CAP PT slides must be rotated between all applicable Lab personnel and pathologists at a particular site. ii. The Laboratory Director or Designee signs their name in the Director (or Designee) section [sic] 1. Designee - The Technical Supervisor for the laboratory (at that CLIA identification number's physical address). 2. This requires a letter from the Laboratory Director designating the physician as Technical Supervisor for that specific laboratory and delegating the authority to perform duties on his/her behalf which includes his/her authority to sign the PT attestation statement and other related PT documentation on his/her behalf." 2. Review of CAP instructions stated: "SUBMITTING RESULTS ... 4. The attestation page is available on the result form and at the end of these instructions for your convenience. For inspection purposes, the laboratory director or designee must either electronically complete (enter and approve) the attestation page online or alternatively print, sign, and retain a hard copy of the attestation page." 3. Review of histopathology PT attestation records for 2025 DNA Mismatch Repair Survey stated: "Attestation Statement As stated In the February 28, 1992 [sic] United States Federal Register under Subpart H 493-801 (b) (1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load [sic] using the laboratory's routine methods. The laboratory director or designee and the testing personnel must sign on the result form. You may use the attestation page provided in the kit Instructions or, alternatively, print, sign, and retain a copy of this page for your records and inspection purposes. If your laboratory requires additional space for signatures, copy this form as needed. We, the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient specimens. We confirm that results were not shared or PT specimens referred or tested outside our CLIA identification number." Further review of the DNA Mismatch Repair Survey attestations revealed the following: Event: MMR-A-2025 - Testing person failed to sign the attestation form. The attestation form was signed by the histotechnician NOT the testing person. Event: MMR-B-2025 - Laboratory director or disgnee failed to sign the attestation form; the form was signed by the personnel who performed the testing. This person was NOT delegated as the laboratory director or technical supervisor. 4. During an interview, in the conference room, on 07/28/2026 at 10:19 AM, the Quality Assurance Specialist, after a review of records, confirmed the laboratory director and testing persons failed to attest to the routine integration of proficiency samples into the patient workload for two of two histopathology events in 2025 (DNA Mismatch Repair Survey, Events MMR-A-2025 and MMR-B-2025).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 laboratory policy, personnel files and confirmed in interview, the laboratory director failed to ensure documentation of site-specific training for one of four testing personnel (TP-3) performing high complexity testing- histopathology and

	cytology slide interpretations. Findings included: 1. Review of the laboratory's policy titled "Onboarding a New Employee" stated: "Training and Orientation Schedule: ... 1. Orientation- The supervisor/manager determines time orientation begins and facilitates getting the employee set up with access ... 5. New Hire Safety Compliance Check List completed by Supervisor/Manager BEFORE employee is allowed in the lab ... 9. Media Lab Training begins and usually lasts 2 days. For PBM employees, please reach out to [XX] at [XX] to set up onboarding SOPs and safety courses. "Release Media Lab Department Specific SOPs as their training moves forward." Further review of laboratory policies revealed an onboarding document to track all required training tasks to be completed by new employees (pathologists). 2. A review of the laboratory's personnel records revealed TP-3 had NO documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory) to perform high complexity testing- histopathology and cytology slide interpretations. 3. During an interview, via electronic mail, on 07/28/2026 at 3:57 PM, the Quality Assurance Specialist, after a review of records, confirmed the laboratory director failed to ensure documentation of site-specific training for one of four testing personnel (TP-3) performing high complexity testing- histopathology and cytology slide interpretations.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals 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 laboratory policy, personnel records, and confirmed in staff interview, the technical supervisor failed to evaluate and document annual competency assessments for one of four testing persons (TP-4) responsible for high complexity testing, histopathology slide interpretations, in 2025. Findings included: 1. Review of the laboratory's policy " Competency Assessment and Educational Requirements for Testing Personnel" stated: "PROCEDURE ... "Competency assessment must include all 6 regulatory requirements for all personnel performing professional interpretations or high complexity laboratory testing and must be performed by an individual who is qualitied to be a General Supervisor, Technical Consultant, Clinical Consultant or Medical Director ... In the first year of employment, competency assessment reviews are conducted on all applicable testing personnel semiannually and 12 months after date of hire. Thereafter, competency assessment reviews are conducted annually in July." 2. Review of personnel records revealed the technical supervisor failed to evaluate and document annual competency assessment for TP-4 in 2025. 3. During an interview, via electronic mail, on 07/28 /2026 at 3:57 PM, the Quality Assurance Specialist, after a review of records, confirmed the technical supervisor failed to evaluate and document annual competency assessments for one of four testing persons (TP-4) responsible for high complexity testing, histopathology slide interpretations, in 2025.