

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1088364	(X3) Date Survey Completed 11/04/2024
Name of Provider or Supplier Ameripath Lubbock 501(A)	Street Address, City, State 1301 Pennsylvania Avenue, Fort Worth, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for one of two events in 2023 (Flow Cytometry Interpretation Event A) and two of two PT events in 2024 (Flow Cytometry Interpretation Events A and B). Findings included: 1. Review of the laboratory policy titled " POLICY FOR PROFICIENCY TEST (PT) HANDLING AND RESULT SUBMISSION " stated: " 5. POLICY ... PT samples must be examined, handled, and tested along with the laboratory's regular workload by testing personnel using routine methods and treated in the same manner as patient samples to the extent possible ... 12. ADMINISTRATIVE REVIEW FOR THE SUBMISSION OF PT RESULTS ... Testing personnel or other designated individual(s) in the department must transfer all required information onto a copy of the PT result form, or into the on-line result entry site of the PT provider. All required information regarding instrumentation, method, results obtained, units of measure, attestation statements, etc. must be recorded and reviewed. Test records must clearly identify the individual(s) who performed the PT. The Technical Supervisor /Consultant, Department Supervisor, Manager, or designee must perform a final review of the paperwork to detect clerical errors, errors in methods, units, factors, etc. This final administrative review may also involve transcription of information from a</p>

copy to the original survey form, into the on-line result entry site of the PT provider, or a review of the information uploaded via CAP Direct Transmission. The attestation form (or copy of the completed form) must be signed by the Laboratory Director, or designee, and all individuals involved in testing. This signature does not have to be obtained prior to reporting results to the PT provider." 2. Review of the CAP proficiency testing records revealed: "Attestation/Use of Other Form Attestation Statement As stated in the February 28, 1992 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 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." 3. Further review of CAP proficiency testing records in 2023 and 2024 revealed the laboratory director or designee and the testing personnel failed to sign the attestation statement for the following Flow Cytometry Interpretation Events: 2023: Event A 2024: Events A and B 4. During an interview at 11:50 a.m. on 11/04/2024, the Quality Assurance Manager and Quality Assurance Specialist, after a review of the records confirmed the above findings.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records and confirmed in interview, the laboratory failed to review and evaluate the ungraded results obtained on proficiency testing for two of two events in 2024 (Flow Cytometry Interpretation Events A and B). Findings included: 1. Review of the laboratory's PT policy "Policy for Review and Evaluation of Proficiency Test Results" stated: "5. POLICY The laboratory director must ensure timely, ongoing evaluation of all proficiency testing (PT) and alternative performance assessment (APA) results. Evaluation must include the following: Results that are formally evaluated (graded). Results that are not formally evaluated (ungraded). Results from educational challenges ... Review and evaluation of PT and APA results must be performed by: The Technical Supervisor/Consultant responsible for the testing area. QA Director/Manager. Laboratory Director. NOTE: If the Laboratory Director does not personally review all reports, they must at least review monthly summaries of laboratory performance and corrective actions taken in response to PT non-conformance ... 6. PROCESS 6.1 Evaluation of Results Step 1 Action Review survey evaluation reports when received by the testing PT provider. For graded results, evaluate for non-conformance and near miss based on the criteria described below in steps 3 and 4. For ungraded results, evaluate for non-conformance based on the criteria described below in step 5 ... Step 5 Action Review and evaluate ungraded results for PT non-conformance. Results that are not formally evaluated by the PT provider must be evaluated by the laboratory and the result of this evaluation must be documented. A check mark or signature is not adequate documentation of the evaluation. The evaluation must include: The criteria applied to determine result acceptability. Identification of the person making the determination. Date of the evaluation. Ungraded PT results include the following CAP Exception Codes: Code

20: No appropriate target/response. Code 26: Educational challenges." 2. Review of the CAP Flow Cytometry, Interpretation Only Immunophenotypic Characterization of Leukemia/Lymphoma Participant Summary revealed: "Actions Laboratories Should Take when a PT Result is Not Graded The CAP uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the result. Your laboratory must identify all analytes with an exception reason code, review, and document the acceptability of performance as outlined below and retain documentation of review for at least 2 years ... Code 26 Exception Reason Code Description Educational challenge Action Required Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 3. Review of the CAP 2024 Flow Cytometry Interpretation Events A and B revealed the following PT results: Event FL5-A 2024 Test Method: Flavored Interpretation Specimen: FL5-01 Your Result: ABERRANT MAST CELLS Intended Response: [blank] Your Grade- See Note [26] Specimen: FL5-02 Your Result: ACUTE MYELOID LEUKEMIA Intended Response: [blank] Your Grade- See Note [26] Specimen: FL5-03 Your Result: CD5+ BCEL FAV MANTLE CEL Intended Response: [blank] Your Grade- See Note [26] Further review of the event revealed the CAP Original Evaluation was NOT reviewed or evaluated by the laboratory director or technical supervisor. No documentation of result evaluation of Specimens FL5-01, FL5-02 or FL5-03 was provided by the laboratory. Event FL5-B 2024 Test Method: Flavored Interpretation Specimen: FL5-04 Your Result: ABN POP T-FOL HELP LYMPH Intended Response: [blank] Your Grade- See Note [26] Specimen: FL5-05 Your Result: T LYMPHOBLASTIC LEUK Intended Response: [blank] Your Grade- See Note [26] Specimen: FL5-06 Your Result: NEG CLON BCELL, ABN TCELL Intended Response: [blank] Your Grade- See Note [26] Further review of the event revealed the CAP Original Evaluation was NOT reviewed or evaluated by the laboratory director or technical supervisor. No documentation of result evaluation of Specimens FL5-04, FL5-05 or FL5-06 was provided by the laboratory. 4. During an interview at 11:50 a.m. on 11/04/2024, the Quality Assurance Manager and Quality Assurance Specialist, after a review of the records confirmed the above findings.