Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1088364	10/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ameripath Lubbock 501(A)	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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of accuracy assessments and interview, the laboratory failed to verify the accuracy of its interpretation of its oral pathology cases for one of one year reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Pathologist Assessment by Second Review (PASR), approved 09/04/2022, under 2 SCOPE stated, "This policy applies to all Anatomic Pathologists that perform examinations on tissue biopsies, dermatopathology specimens, non-gynecological and selected gynecological cytology in Quest Diagnostic laboratories." The policy did not include the subspecialty of oral pathology. B. Review of the CMS form 116 showed an annual test volume of 3 cases in the subspecialty of oral pathology. C. Review of the Quarterly Summary of Pathologists Second Review and Quality Assurance for Q1 2021, Q2 2021, and Q3 2021 (and to date in Q1 2022 and Q2 2022) showed no subspecialty for oral pathology. D. Peer reviews for the subspecialty of oral pathology were requested on October 5, 2022, at 1500 hours. Interview with the QA Manager on October 5, 2022, at 1500 hours acknowledged oral pathology was not addressed in the policy and peer reviews not distinguished from other specialties, so she didn't know if any peer reviews had been performed.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, pre-survey paperwork, competency evaluations and interview, the technical supervisor failed to ensure competency evaluations were performed for six of seven testing personnel performing a combination of histopathology, cytology, oral pathology, and hematopathology interpretations for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Competency Assessment, approved 2/01 /2022, stated under 2. SCOPE, "This policy and process applies to departments with personnel involved in any phase of the testing process (pre-analytic, analytic, and post-analytic). This includes: All testing departments..." Under 4. DEFINITIONS for term "Competency assessment" stated, "Definition An objective evaluation that helps ensure a person continues to perform testing accurately, proficiently, and according to established processes and procedures"... and for "Test System" stated, "The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A Test System may be manual, automated, multi-channel or single-use and can include reagents, components, equipment or instruments required to produce results." Under 5.2 Competency assessment frequency stated, "During the first year of an individual's duties, competency must be assessed at least semiannually. When an individual has completed the first 2 semi-annual assessments, performance must be assessed at least annually (per calendar year), thereafter." At "6.0 PROCESS 6.1 General Competency Assessment Requirements 6.1.1 Elements for Evaluating Testing Personnel For each Test System, evaluate all six CLIA required elements for competency assessment. The six elements are as follows: 1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation, and specimen collection, handling, processing, and testing. 2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results. 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 6. Evaluation of problem-solving skills." B. Review of the CMS form 209 showed seven testing personnel, including the Laboratory Director. C. Attempted review of competency evaluations showed none available for review. Competency evaluations were requested on October 5, 2022, at 1500 hours. D. Interview with the QA Manager on October 5, 2022, at 1500 hours confirmed there were no competency evaluations performed for pathologists for the position of testing personnel.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed

	specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, peer reviews, and interview, the technical supervisor failed to ensure peer reviews were performed for four of five testing personnel performing cytology interpretations for one of one years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Competency Assessment, approved 2/01/2022, stated under 2. SCOPE, "This policy and process applies to departments with personnel involved in any phase of the testing process (pre-analytic, analytic, and post-analytic). This includes: All testing departments..." Under 4. DEFINITIONS for term "Competency assessment" stated, "Definition An objective evaluation that helps ensure a person continues to perform testing accurately, proficiently, and according to established processes and procedures"... and for "Test System" stated, "The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A Test System may be manual, automated, multi-channel or single-use and can include reagents, components, equipment or instruments required to produce results." At "6.0 PROCESS 6.1 General Competency Assessment Requirements 6.1.1 Elements for Evaluating Testing Personnel For each Test System, evaluate all six CLIA required elements for competency assessment. The six elements are as follows: ... 5. Assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples." B. Review of the laboratory's policy and procedure titled Pathologist Assessment by Second Review (PASR), approved 09/04/2022, under 1 PURPOSE stated, "Pathologists that perform gross and microscopic examinations on tissue biopsies, dermatopathology specimens, non-gynecological or gynecological cytology will have a portion of their work evaluated by peer review to determine the need for an increase in the review rate, directed continuing education or other corrective action. Peer review of a portion of a physician's current work is one measure of assessing diagnostic accuracy and can indicate the need for more intensive review and possible corrective action or progressive disciplinary action." 2 SCOPE stated, "This policy applies to all Anatomic Pathologists that perform examinations on tissue biopsies, dermatopathology specimens, non-gynecological and selected gynecological cytology in Quest Diagnostic laboratories." Under 5. POLICY AND PROCEDURE stated, "1. Set the Pathologist's Current Minimum Review Rate a) each Medical Director will establish and document a Minimum Review Rate for each Pathologist that is applicable to the mix of patient and specimen types: for pathologists reviewing predominately outpatient biopsies from varying organs, suggest minimum of 5% total second reviews of which a minimum 2% should be Level 2 Targeted and Random Cases (Section 7)." Step 7 stated, "Annual Performance Development Review The accumulated Second Review data, corrective action plans and results are reviewed as part of the Annual Performance Development and Review." The policy is not clear as to the requirement of peer reviews for each subspecialty for each pathologist. C. Review of peer reviews from 2021 (and to date in 2022) showed none in the subspecialty of cytology for testing personnel #3, 4, 6, and 7 as listed on the CMS form 209. D. Interview with the Laboratory Director on October 5, 2022, at 1450 hours confirmed there were no PASRs for the testing personnel except for his in cytology.