Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0671108	04/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Appalachian State University	614 Howard Street, Boone, NC	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the laboratory manager 4/3/19, the laboratory failed to establish and follow policies and procedures for monitoring the competency of the TC (technical consultant). Review of the laboratory's policies and procedures revealed the laboratory had a policy for conducting testing personnel competency evaluations, but did not have a policy for evaluating the competency of the TC. Review of personnel records revealed the TC was evaluated in May 2017 and May 2018 by the laboratory director. The evaluation included routine testing personnel duties, and included the following statement: "The Technical Consultant follows CLIA Regulations in the performance of assigned duties." The duties were not listed on the evaluation form. During interview at approximately 2:15 p.m., the laboratory manager confirmed that the laboratory did not have a policy for evaluating the competency of the TC.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review and review of a random patient test report (ID #900619184) 4/3/19, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual included a procedure for critical/alert value reporting, but did not include a list of critical/alert values. The "Laboratory Alert Value Reporting" procedure states "... Protocol The laboratory will immediately notify the appropriate clinician of critical / alert values obtained on any patient to ensure timely treatment and/or intervention. ..." There were no critical/alert values listed in the procedure. 2. The procedure manual did not include the laboratory's criteria for interpreting the results of the urine microscopic test (1+/2+ /3+; few/moderate/many, etc.). The "Procedure for Routine Urine Microscopic Examination" states "...Reporting Results: ... Type in the results of the test. (Each area has to have an answer- Example- WBC= none, RBC=none, and so forth). ..." Review of a random patient urine microscopic test report (ID #900619184) revealed white blood cells, red blood cells, and epithelial cells were reported as the number seen per high power field.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of two random patient test reports (ID #900642179, #900739462) and interview with the laboratory manager 4/3/19, the laboratory's wet prep and KOH (potassium hydroxide) test reports did not include reference ranges for the elements identified. Review of a random patient wet prep test report (ID #900642179) revealed the test report did not include reference ranges for the white blood cells, bacteria, epithelial cells, and clue cells listed in the saline portion of the report. In addition, the test report did not include reference ranges for the spores, buds, or hyphae listed in the KOH portion of the report. Review of a random patient KOH test report (ID #900739462) revealed the test report did not include a reference range. During interview at approximately 3:10 p.m., the laboratory manager confirmed the test reports did not include reference ranges.