Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0922674	02/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Healthcare Urgent Care	700 Sullivan Road, Statesville, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of 2019, 2020, and 2021 API PT(proficiency testing) records and absence of documentation 2/25/22, the laboratory failed to document evaluation and corrective action of all proficiency testing results received. Findings: The laboratory's " Quality Review of Proficiency Testing" procedure states, "Graded PT results are reviewed and signed by the testing personnel, Technical Consultant, and laboratory Director. Any grade of 80% or below must be investigated and remedial action taken. All efforts to explain incorrect results must be made including clerical, QC checks, maintenance record checks, and any other checks deemed necessary by the Technical consultant and /or laboratory director. After all checks have been performed, there must be documentation of all steps performed to identify and resolve the incorrect results." Review of 2019, 2020, and 2021 API PT records revealed the laboratory failed to document evaluation and corrective action of all unacceptable PT results. Examples: 1. 2020 3rd Hematology event: 80% score for HCT(hematocrit), platelet, MCV(mean corpuscular volume), and RDW(Red cell distribution width) with no corrective action documented; 2. 2020 3rd Chemistry Core event: 80% score for CKMB(creatine kinase-isoenzyme) with no corrective action documented other than "checked for clerical error"; 3. 2021 1st Hematology event: samples were tested and self-graded due to failure to submit on time. Self-grade revealed a 80% score for HCT, MCV, MCHC(Mean corpuscular hemoglobin concentration), RDW, plt, and MPV(mean platelet volume) with no corrective action documented.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(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 laboratory procedures, review of personnel records, the absence of documentation, and interview with the TC(technical consultant) 2/25/22, the TC failed to perform and document the competency evaluations for 6 of 12 TP(testing personnel) in 2019, 2020, and 2021. Findings: The laboratory's "Competency Evaluations and Assessments" procedure states, "Personnel Evaluations are performed yearly by the Laboratory consultant. Competency assessments are performed semi-annually the first year and annually thereafter and should be observed in intervals throughout each year by the Laboratory consultant. Evaluations and assessments are documented and kept in each employees's file." Review of personnel records revealed: 1. Training for TP #3 was completed in December 2019, completed for TP #4 in October 2019, and completed for TP #11 in January 2021. There was no documentation indicating the semiannual competency evaluations were performed for TP #3, TP #4, or TP #11 during the first year of testing patient specimens. 2. There was no documentation indicating the annual competency evaluations were performed for TP #2 and TP #12 in 2019, and for TP #2, TP #3, TP #4, TP #6, TP #12 in 2020 and 2021. At approximately 10 a.m., the TC confirmed the competency evaluations were not performed when they were due.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records 2/25/22 and the deficiency cited at D6065, the laboratory failed to verify that 1 of 12 testing personnel (TP # 11) met the minimum education requirements for performing moderate complexity testing.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	This STANDARD is not met as evidenced by: Based on review of personnel records and absence of documentation 2/25/22, the laboratory failed to verify that 1 of 12 testing personnel (TP # 11) met the minimum education requirements for performing moderate complexity testing. Findings: Review of personnel records revealed TP #11 had a School of Nursing Certificate on file. There was no additional evidence to show the TP had earned an Associate's or Bachelor's degree in a chemical, physical or biological science or medical lab technology/clinical lab science from an accredited institution. There was no other education documentation on file for TP#11.