

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442444	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Piedmont Family Clinic	Street Address, City, State #1 Hals Plaza Drive, Piedmont, MO	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018, 2019 proficiency testing (PT) and interview with the technical consultant the laboratory failed to verify accuracy for one of thirteen urine drug screen analytes in 2018. Findings: 1. Review of 2018 PT for urine barbiturates showed the laboratory failed to verify accuracy twice annually. 2. Interview with the technical consultant on November 5, 2019 at 2:00 PM confirmed the laboratory failed to verify accuracy for urine barbiturates twice annually in 2018.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018, 2019 instrument comparison documentation and interview with the technical consultant, the laboratory failed to perform instrument comparisons for two medtox instruments two times a year. Findings: 1. Review of two medtox instrument comparisons showed the laboratory failed to document comparisons for amphetamine, barbiturate, benzodiazepine, buprenorphine, cannabinoid, cocaine</p>

metabolites, methadone, methamphetamine, opiate, oxycodone, phencyclidine, propoxyphene and TCA two times a year for 2018 and 2019. 2. Interview with the technical consultant on November 5, 2019 at 2:00 PM confirmed, the laboratory failed to perform instrument comparisons for two medtox instruments two times a year for 2018 and to date 2019.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) for 2018, 2019 and interview with the technical consultant, the laboratory director failed to ensure PT reports received are reviewed by the appropriate staff to evaluate the laboratory's performance. Findings: 1. Review of 2019 PT for urine sediment showed US-02 not graded and no documentation to evaluate the laboratory's performance to identify any problems that require corrective action. 2. Interview with the technical consultant on November 5, 2019 at 2:00 PM confirmed the laboratory director failed to ensure 2019 PT for urine sediment was not reviewed by the appropriate staff to evaluate the laboratory's performance.