

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520334	(X3) Date Survey Completed 04/10/2018
Name of Provider or Supplier Family Practice Group, Pa	Street Address, City, State 1951 Bench Rd #B, Pocatello, ID	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory supervisor, the laboratory director failed to sign the attestation statements from the American Proficiency Institute (API) for the urine sediment analysis for 2017 events 2 and 3. Findings: 1. An API PT document review, revealed the laboratory director failed to sign the attestation statements for the urine sediment analysis for the 2017 events 2 and 3. 2. An interview on April 10, 2018 at 11:50 AM, with the laboratory supervisor, confirmed the laboratory director failed to sign the PT attestation statements in 2017.</p>
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>

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the laboratory supervisor, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) and semen analysis at least twice annually since the last survey on September 8, 2016. Findings: 1. A record review revealed the laboratory failed to document the accuracy of KOH and semen analysis at least twice annually since the last survey. 2. An interview on April 10, 2018 at 11:45 AM, with the laboratory supervisor, confirmed the laboratory failed to document the accuracy of KOH and semen analysis at least twice annually since the last survey.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a record review of final patient reports and an interview with the laboratory supervisor, the laboratory failed to indicate the name and the address of the reference laboratory where laboratory tests were reported on patients for the period reviewed between February 2018 through March 2018. Findings: 1. A review of patient laboratory test reports, revealed the name and address of the reference laboratory where tests were performed failed to be included on the patient's test reports. 2. An interview on April 11, 2018, at 12:15 PM, with the laboratory supervisor, confirmed the name and address of the reference laboratory failed to be indicated on patient laboratory reports.

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 a records review and an interview with the laboratory supervisor, the technical consultant failed to evaluate the competency assessments of the 5 testing personnel performing urine sediment exams, potassium hydroxide (KOH), and semen analysis since the last survey on September 8, 2016. Findings: 1. A review of personnel records revealed the technical consultant failed to evaluate the competency assessments on the 5 testing personnel listed on the CMS-209 Personnel Report form. 2. An interview on April 10, 2018 at 11:45 AM, with the laboratory supervisor, confirmed the technical consultant failed to perform the competency assessments on the testing personnel.