Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0935096	04/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Primary Care Specialists	110 Vista Dr, 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
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 a record review of personnel competency assessments and an interview with the lead laboratory technician, the laboratory failed to establish and follow procedures to assess the competency of testing personnel since the last survey on September 7, 2016. Findings: 1. A review of personnel documents and laboratory procedures and policies, revealed the laboratory failed to establish a policy in writing and assess the competency for 3 mid-level practitioners performing potassium hydroxide/wet mounts exams and 3 testing personnel performing urine microscopic exams since the last survey. 2. An interview on April 11, 2018, at 11:15 AM, with the lead laboratory technician, confirmed the laboratory failed to establish in writing and document the competency for the practitioners and testing personnel.
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 a record review and an interview with the laboratory manager, the laboratory failed to verify the accuracy of potassium hydroxide (KOH)/wet mounts and urine microscopic exams at least twice annually since the last survey on

	September 7, 2016. Findings: 1. A record review revealed the laboratory failed to document the accuracy of KOH/wet mounts and urine microscopic, at least twice annually since the last survey. 2. An interview on April 11, 2018 at 11:40 AM, with the laboratory manager, confirmed the laboratory failed to document the accuracy of KOH/wet mounts and urine microscopic exams at least twice annually.
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 a procedure review and an interview with the lead laboratory technician, the laboratory failed to include the requirements for specimen collection, processing, storage, preservation, transportation, specimen acceptability, and rejection to the urine microscopic and potassium hydroxide (KOH)/wet mount procedures since the last survey on September 7, 2016. Findings: 1. A record review of the procedures for KOH and urine microscopic examinations, revealed the laboratory failed to include the required elements for the procedures performed by the testing personnel since the last survey. 2. An interview on April 11, 2018 at 12:40 PM, with the lead laboratory technician, confirmed the laboratory failed to include all required procedure elements.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by:

	Based on a record review and an interview with the lead laboratory technician, the laboratory failed to verify the accuracy of a potassium hydroxide (KOH) result entered manually for a patient reviewed on March 16, 2018. Findings: 1. A review of a patient record from March 16, 2018, revealed the patient final report reports failed to indicate a test result for a KOH performed on the patient. 2. An interview on April 11, 2018 at 12:50 PM, with the lead laboratory technician, confirmed the laboratory failed to verify the test result for KOH was entered into the patient's electronic medical record.
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 lead laboratory technician, the laboratory failed to indicate the name and the address of the reference laboratory where laboratory tests were performed, and failed to indicate the result for potassium hydroxide (KOH) exam from the period reviewed between February 2018 through March 2018. Findings: 1. A review of patient laboratory test reports revealed the name and the address of the reference laboratory, where tests were performed, failed to be included on the patient's test reports. 2. A review of patient's KOH test reports on March 16, 2018, revealed the laboratory failed to indicate the result of a KOH performed on 1 out of 4 patient records. 3. An interview on April 11, 2018, at 12:15 PM, with the lead laboratory technician, confirmed the name and address of the reference laboratory failed to be indicated on patient laboratory reports, and confirmed that a KOH was not reported on a patient from March 16, 2018.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a records review and an interview with the lead laboratory technician, the laboratory director failed to ensure the quality assessment program for the urine sediment and potassium hydroxide (KOH) exams meets the CLIA requirements since the last survey on September 7, 2016. Refer to D5217, D5801, and D5805. Findings:

	1. A policy review revealed the laboratory failed to establish a quality assessment procedure to identify and correct problems in the pre-analytic, analytic, and post-analytic systems. 2. An interview on April 11, 2018, at 1:15 PM, with the lead laboratory technician, confirmed the laboratory failed to establish and document the quality assessment activities for the all phases of testing for the urine sediment and KOH exams.