Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0698151	01/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Boise Family Medicine Llc	10798 W Overland Rd, Boise, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and an interview with the laboratory manager, the laboratory director and the testing personnel failed to retain the American Association of Bioanalysts (AAB) test reports used to grade the PT events and failed to sign the attestation statements since the last survey on March 1, 2016. Findings: 1. A record review of PT documents from AAB revealed the laboratory failed to retain the AAB PT test result reports for urine sediment examination since the last survey on March 1, 2016. 2. A record review of PT documents from AAB revealed the laboratory director and the testing personnel failed to sign the attestation statements for urine sediments since the last survey on March 1, 2016. 3. A record review of PT documents from AAB revealed the laboratory failed to make available urine sediment PT records for 2016. 4. An interview on January 26, 2018 at 10:00 AM, with the laboratory manager, confirmed the laboratory failed to retain PT result reports or sign the attestation statements.
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 an observation, a procedure manual review, and an interview with the laboratory manager, the laboratory's procedure for urine sediment examination failed to include the centrifuge speed and time required for processing patient's urine specimen since the last survey March 1, 2016. Findings: 1. An observation on January 26, 2018 at 10:10 AM, of the laboratory's centrifuge used to spin down urine sediment, was set for 3 minutes at 3290 revolutions per minute (RPM). 2. A record review showed that the laboratory's written procedure failed to indicate the RPM and time for urine sediment processing. 3. An interview on January 26, 2018 at 10:00 AM, with the laboratory manager, confirmed the lab testing personnel use Sister Laurine Graff's A Handbook of Routine Urinalysis as the lab reference manual. The book references 2000 RPM for 5 minutes to process urine for microscopic evaluation.
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 patient records review and an interview with the laboratory manager, the laboratory testing person failed to document the results of a urine sediment examination for one out of three patient reports reviewed between January 22, 2018 and January 25, 2018. Findings: 1. An electronic medical record review of a urine sediment performed by medical assistant A, on patient D.R., January 24, 2018, failed

	to indicate the results of the urine sediment examination. 2. An interview on January 26, 2018 at 11:15 AM, with the laboratory manager, confirmed the patient's medical record failed to show the results of the urine sediment examination.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on personnel record review and an interview with the laboratory manager, the laboratory director failed to document training of the 4 testing personnel performing urine sediment evaluations since the last survey on March 1, 2016. Findings: 1. A record review of 4 out of 4 testing personnel listed on the CMS-209 form revealed there was no training documented for urine sediment examinations. 2. An interview on January 26, 2018 at 9:45 AM, with the laboratory manager, confirmed training of urine sediment microscopic exams was not documented.