Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0971391	05/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mcmillan Medical Center Physicians Clinic Pllc	4750 N Five Mile 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory testing person, the laboratory failed to test the Medical Laboratory Evaluation (MLE) proficiency testing (PT) samples for complete blood counts (CBCs) by the same personnel who perform patient testing during 2017. Findings: 1. A MLE PT record review revealed the laboratory failed to test the CBC PT samples by the same testing personnel who performed patient testing during the 2017 events 1 and 2. 2. An interview on April 9, 2018 at 10:30 AM, with the laboratory testing person, confirmed the laboratory failed to test the CBC proficiency samples from MLE by personnel who routinely test patient CBCs since the last survey.
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 record review and an interview with the laboratory testing person, the laboratory failed to have a written procedure manual to include all requirements of the pre-analytic, analytic, and post-analytic activities that include patient preparation, specimen collection and labeling, panic values, and corrective actions for complete blood counts (CBCs) tested on the Beckman Coulter AcT Diff 2 analyzer from July 6, 2016 through May 2017. Findings: 1. A review of the laboratory's procedure manual revealed the laboratory failed to establish a written procedure for the pre-analytic, analytic, and post-analytic phases of CBC testing since the last survey. 2. An interview on May 9, 2018 at 1:45 PM, with the laboratory testing person, confirmed the laboratory failed to establish a procedure manual for the testing of CBCs.
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 personnel record reviews and an interview with the laboratory testing person, the technical consultant failed to evaluate the competency of the testing personnel performing complete blood counts (CBCs) in 2016 and 2017. Findings: 1. A record review of personnel records revealed the technical consultant failed to document the competency of two testing personnel listed on the CMS-209 Personnel Report form during 2016 and 2017. 2. An interview on May 9, 2018 at 1:15 PM, with the laboratory testing person, confirmed the laboratory failed to document competency assessments on the testing personnel performing CBCs.