Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0986799	10/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Summit Memorial Medical Group Llc	6500 E 2nd St, Suite 200, Casper, WY	

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**
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 procedure manual review, patient test reports review, and interview with the laboratory staff, the laboratory procedure manual failed to include a procedure for staff to follow for complete blood count tests with flagged test results for 4 of 12 test reports reviewed. Findings include: 1. The laboratory procedure manual failed to include a step by step process for testing personnel to follow when the laboratory AcT Diff II instrument flagged the test results with error codes "*, M, 1, 2, or 3". 2, Patient test reports review for patient 821742 on 12/20/2017 included an error code flag "3" for Moncyte and Granulocyte percentages; for patient 01514852 on 01/15/2019 for a

	white blood cell (WBC) count of 7.8 included an error code flag "*"; for patient 01532335 on 03/07/2019 for Moncyte percentage (%) of 6.1 that included an error code flag of "3"; and for patient 05999702 on 10/15/2019 for a WBC count of 11.3 including an "*" code and code "1" for Lymphocytes of 24.6% , Granulocyte's of 63.5%, and Moncyte of 11.9%. 3. In an interview with staff on 10/22/2019 at approximately 12:50 P.M. and with the director at approximately 1:45 P.M. they confirmed the laboratory did not have a procedure for testing personnel to follow for coded results and that the results were reported with the flagged results.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, laboratory instrument maintenance records review, lack of documentation, and interview with staff, the laboratory failed to record the lot numbers and expiration dates of complete blood count (CBC) diluent, lyse, and cleaner reagents to document reagents were not used past their expiration dates for two years of testing reviewed from October 2017 to October 2019. Findings include: 1. The surveyor observed on 10/22/2019 at approximately 8:30 A.M. the laboratory used Coulter instrument diluent, red blood cell lysing reagent, and instrument cleaner to perform CBC tests. 2. Instrument records review failed to include documentation of the lot numbers and expiration dates of the reagents in use between October 2017 and October 2019. To document testing was not performed on expired reagents. 3. In an interview conducted on 10/22/2019 at approximately 1:15 P.M. staff stated they did not have an instrument reagent log for the AcT Diff II and the director confirmed the laboratory did not record lot numbers and expiration dates for CBC reagents at approximately 1:50 P.M.
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 test reports review and confirmation by staff, the laboratory test report failed to include the name and address where testing is performed for 7 of 13 complete blood count (CBC) reports reviewed for testing performed between 12/20 /2017 and 10/15/2019 . Findings include: 1. Patient test reports reviewed for CBC's reported on 10/05/2018, 01/15/2019, 03/07/3019, 05/09/2019, 07/08/2019, 09/13 /2019, and 10/15/2019 included: CSL laboratories 1900 E 1st Street, Casper, WY. as

	the location where tests were performed. The laboratory is located at 6500 East Second Street, Casper, WY. 2. In an interview conducted on 10/22/2019 at approximately 1:45 P.M. the director stated the incorrect street address belongs to a location where specimens are only collected and was substituted for the testing address during a software update and was not successfully corrected as they had been previously told.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on education records review, lack of documentation and interview with the director, the laboratory failed to have a technical consultant meeting qualification requirements. (See D6035)
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity

	testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on technical consultant qualification documentation review, lack of documentation, and interview with the laboratory director, the technical consultant failed to qualify for the position. Findings include: 1. Qualification records review failed to include documentation they held a Doctorate, Master's or Bachelors Degree in a chemical, physical, or biological science or medical technology or a Wyoming licensed physician. 2. In an interview conducted on 10/22/2019 at approximately 1:45 P.M. the director confirmed the technical consultant's degree was not in a chemical, physical, or biological science or medical technology nor were they a Wyoming licensed physician.