Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0986799	10/21/2021
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the CMS-116 form, procedure manual review, and staff interview, the current laboratory director failed to sign, and date as approved, the laboratory procedure manual for chemistry and hematology. The findings were: 1. Review of the CMS-116 form showed a change of ownership and laboratory director, effective 12/7 /20, was approved on 12/11/20. 2. Review of the hematology and chemistry procedure manuals failed to include the current director's signature and date of approval. 3. Interview with the laboratory director on 10/21/21 at 3 PM confirmed she had not reviewed and approved the procedure manuals.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

	range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for the CHEM8+ test cartridge (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, total carbon dioxide, hematocrit, and hemoglobin) and the CREA (creatinine) test cartridge analyzed on the Abbott i-STAT instrument for 1 year of testing (11/2/20 through 10/21/21) reviewed. The laboratory performed approximately 137 CHEM8+ and 19 CREA tests per year. The findings were: 1. Review of the laboratory's records showed no documentation the reportable range of the analytes on the Abbott i-STAT instrument had been verified. 2. Interview with the laboratory supervisor on 10/21/21 at 2:45 PM confirmed the calibration verification had not been completed.