Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0515585	01/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Middle Park Health - Kremmling	214 S 4th St, Kremmling, CO	

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 review of the laboratory's policies and procedures manual, and an interview with General Supervisor (GS), the laboratory failed to assess the competency of, or establish a written policy or procedure for assessing the competency of personnel in the positions of Clinical Consultant (CC), Technical Supervisor (TS), and General Supervisor (GS) since the laboratory's last survey on 8/11/2021. The laboratory conducts a total of approximately 30,750 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that the laboratory failed to assess the competency of, or establish a written policy or procedure for assessing the competency for the CC, the TS, or for the GS listed on CMS Form-209. The laboratory conducts a total of approximately 30,750 tests annually. 2. Based on an interview with the GS on January 4, 2024, at approximately 11:30 AM, confirmed that the laboratory failed to assess the competency of or establish a written policy or procedure for assessing the competency of personnel in the positions of CC, TS, and GS.
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 laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory director (LD) failed to ensure that the laboratory's policies and procedures manual for quality assurance, chemistry, hematology, and microbiology had been approved, signed, and dated by the current LD before use since the laboratory's last survey on 8/11/2021. The laboratory conducts a total of approximately 30,750 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual for quality assurance, chemistry, hematology, and microbiology revealed that the current LD had not approved, signed, or dated the laboratory's policies and procedures prior to their use in the laboratory. 2. Based on an interview with the GS on January 4, 2024, at approximately 11:00 AM, confirmed that the current LD had not reviewed, signed, and dated the laboratory's policies and procedures manual for quality assurance, chemistry, hematology, and microbiology prior to their use in the laboratory.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on an observation, and an interview with the general supervisor (GS), the laboratory failed to follow the manufacturer's instructions for testing coagulation specimens on the Sysmex CA600 since the last recertification survey on 8/11/2021. The laboratory conducts approximately 300 coagulation tests annually. Findings include: 1. An observation on January 4, 2024, at approximately 10:00 AM, revealed the laboratory failed to input the current lot number of the Innovin reagent (Lot #564616A, expiration date: 03/10/2025) into the Sysmex CA600 coagulation analyzer. 2. Based on an interview with the GS on January 4, 2024, at approximately 10:05 AM, confirmed that that laboratory failed to input the current lot number of Innovin reagent (see above) into the Sysmex CA600 coagulation analyzer.