

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0983756	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier South Routt Medical Center	Street Address, City, State 300 Main St, Oak Creek, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, a record review, and an interview with testing personnel #3 (TP #3), the laboratory failed to write a policy or procedure for, or perform competency assessment for the position of clinical consultant (CC), and technical consultant (TC) for one out of one CC, and for one out of one of TC listed on the CMS-209 form since the laboratory's last survey on 8/12/2021. Findings include: 1. A review of the laboratory's policies and procedures manual, the laboratory failed to have a written policy or procedure to assess the competency of the CC or TC. 2. A review of personnel records revealed the laboratory failed to perform competency assessment for the position of clinical consultant on one out of one CC listed on the CMS-209 form. 3. A review of personnel records revealed the laboratory failed to perform competency assessment for the position of technical consultant on one out of one TC listed on the CMS-209 form. 4. Based on an interview with TP #3, on February 15, 2024, at approximately 9:45 PM, confirmed the laboratory failed to have a written policy or procedure for, or performed competency assessments for the position of CC and TC at the laboratory.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures manual, and an interview with testing personnel #3 (TP #3), 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 8/12/2021. The laboratory conducts a total of approximately 192 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 TP #3 on February 15, 2024, at approximately 09:30 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.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on an onsite records review, and an interview with testing personnel #3 (TP #3) the laboratory failed to document instrument maintenance for their Beckman Coulter DxH 500 hematology analyzer as specified by the manufacturer since 2022. The laboratory performs approximately 192 hematology tests annually. Findings include: 1. Based on an onsite records review, it was revealed that the laboratory failed to document the instrument maintenance for their Beckman Coulter DxH 500 hematology analyzer as specified by the manufacturer since 2022. 2. Based on an interview with TP #3, on February 15, 2024, at approximately 10:45 AM, confirmed that the laboratory failed to document the instrument maintenance for their Beckman Coulter DxH 500 hematology analyzer as specified by the manufacturer since 2022.