

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409901	(X3) Date Survey Completed 03/17/2021
Name of Provider or Supplier Rosebud Healthcare Center	Street Address, City, State 383 North 17th Avenue, Forsyth, MT	
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 review of personnel files, Quality Assurance Plan policy, and communication with the general supervisor (GS)#1, the laboratory failed to perform annual competency assessments for the technical supervisor and testing personnel for years 2019 and 2020. Findings include: 1. Review of personnel files for 2019 and 2020 revealed the laboratory failed to perform annual competency for the technical supervisor and testing personnel. 2. Review of Quality Assurance Plan, Policy #018 states "Employee competency will be assessed at initial training, six months after hire, and yearly." 3. Interview with General Supervisor (GS) #1 on 3/17/2021 at 9:00 AM, confirmed the laboratory failed to perform annual competency assessment for 2019 and 2020.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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)</p>

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 review of the laboratory procedures, reports and interview with general supervisor (GS) #1, the laboratory failed to have a step by step procedure for microscopic urinalysis; failed to include in their procedure manuals the reference intervals (normal values) for microscopic urinalysis; and failed to include the normal reference range in the patient result reports. Findings: 1. No procedure for microscopic urinalysis was available for review 2. No reference intervals (normal values) were available in the laboratory procedure manual for microscopic urinalysis. 3. The laboratory patient results report lacked normal reference ranges for microscopic urinalysis. 4. Interview with the GS #1 on 3/17/2021 at 9:50 AM confirmed, the laboratory failed to have a step-by-step procedure of microscopic urinalysis and failed to include normal values for microscopic urinalysis in their reports and procedure manual.