

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385667	(X3) Date Survey Completed 12/13/2023
Name of Provider or Supplier Mccrary Rost Clinic - Lake View	Street Address, City, State 1160 Third Street, Lake View, IA	
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 11:09 am on 12/13/23, the laboratory failed to retain the proficiency testing attestation statements for three out of six proficiency testing events from 1/1/2022 - 12/13/2023. The findings include: 1. For 2023 event 1, the laboratory did not have the attestation statements for the hematology/coagulation/urinalysis or the microbiology events. 2. For 2023 event 2, the laboratory did not have the attestation statements for the hematology/coagulation /urinalysis or the microbiology events. 3. For 2023 event 3, the laboratory did not have the attestations statements for the microbiology event. 4. At the time of the survey, the laboratory did not have the above attestation statements.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on lack of quality assessment audits, review of the Quality Management Plan</p>

/Quality Assurance Plan and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 11:57 am on 12/13/23, the laboratory director failed to ensure the laboratory performed twice annual audits for four out of four time periods from 1/1/2022 - 12/13/2023. The findings include: 1. The Quality Management Plan/Quality Assurance Plan stated, ""McCrary-Rost clinic laboratories will be visited twice per year by a hospital lab employee and ensure quality using a quality assurance check off sheet". 2. At the time of the survey, the laboratory did not have documentation of any quality assurance checks.