

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407513	(X3) Date Survey Completed 05/02/2024
Name of Provider or Supplier Huron Regional Medical Center	Street Address, City, State 172 Fourth Street Se, Huron, SD	
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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 5/2/24. Huron Regional Medical Center laboratory was found not in compliance with the following requirements: D6107.
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to specify in writing the duties delegated to two of two technical supervisors (A, B), and one previous technical supervisor (C), including the performing of competency assessment for testing personnel. Findings include: 1. Review of the 2024 laboratory competency assessments revealed the following competencies had been completed and signed by technical supervisor A for: *Technical supervisor B on 4/6/24 *Testing personnel D on 2/7/24 *Testing personnel E on 2/7/24 *Testing personnel F on 2/7/24 *Testing personnel G on 2/14/24 Review of the 2024 laboratory competency assessments revealed the competency for technical supervisor A had been completed and signed by technical supervisor C on 2/7/24. On 5/1/24 the surveyor requested a copy from the laboratory supervisor of the laboratory director's designation of duties for technical supervisor A, B and C. No documentation was provided during the survey. Interview on 5/1/24 at 1:30 p.m. with the laboratory supervisor revealed she confirmed the laboratory did not have a written delegation of duties for technical supervisor A, B or</p>

C. She was unaware this delegation of duties was needed for these supervisors to perform employee competencies. The laboratory director was unavailable for interview at the time of the survey.