

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0407531	<b>(X3) Date Survey Completed</b> 06/07/2022
<b>Name of Provider or Supplier</b> Avera Hand County Memorial Hospital	<b>Street Address, City, State</b> 300 West 5th Street, Miller, SD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 6/7/22. The Avera Hand County Memorial Hospital laboratory was found not in compliance with the following requirements: D6028.
<b>D6028</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(10)</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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure competency evaluations for one of seven laboratory staff (A) were completed by qualified personnel (their credentials had not been reviewed to determine if they were qualified to serve as technical consultant) for the nonwaived test methods they had been performing under the laboratory's certificate. Findings include: 1.Review of the personnel file for laboratory staff A revealed his competency assessment was performed on 6/3/21 by laboratory staff B. There was no indication the laboratory director was involved in the competency assessment process. Review of the Center for Medicare and Medicaid Services 209 Laboratory Personnel Report form signed by the laboratory director on 6/2/22 revealed that employee C was listed as a technical consultant. Laboratory staff B was listed only as testing personnel. Review of the laboratory's yearly competency assessment policy stated that "A technologist will complete an evaluation/competency form for the laboratory manager, which will be</p>

reviewed and signed by the laboratory director." Review of education records for laboratory staff B revealed she had an associates degree. There was no documentation that a higher degree had been obtained. Interview with laboratory staff A on 6/7/22 at 10:30 a.m. revealed: \*He confirmed that laboratory staff B had completed his competency assessment. \*He was unaware that his competency assessment needed to be completed by personnel who qualified to serve as a technical consultant. \*He confirmed that laboratory personnel B had an associates degree for her highest level of education. The laboratory director was unavailable for interview at the time of the survey.