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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 43D0407531 | (X3) Date Survey Completed 09/21/2020 |
| Name of Provider or Supplier Avera Hand County Memorial Hospital | Street Address, City, State 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. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D2016 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory supervisor, the laboratory failed to achieve successful participation for the compatibility test method. Unsatisfactory results had been received in two of three American Proficiency Testing Institute PT events (1st and 2nd 2020 Immunology /Immunohematology testing events) resulting in unsuccessful PT participation. Refer to D2181.</p> |
| D2181 | <p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> |

Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of CASPER Reports and interview with the laboratory supervisor, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the compatibility test method in two out of three events American Proficiency Institute (API) events (1st and 2nd Immunology/Immunochemistry testing events).

1. Review of the laboratory's CASPER Reports 153D and 155D revealed the API PT scores for the compatibility test method were less than the 100% required to pass the compatibility test per CLIA requirements found at CFR 493.861(a): a. 2020 Immunology/Immunochemistry 1st event compatibility score = 80% (SER-01 was graded as unacceptable). b. 2020 Immunology/Immunochemistry 2nd event compatibility score = 80% (SER-08 was graded as unacceptable). Interview with the laboratory supervisor on 9/10/20 and 9/14/20 confirmed the failure. She stated she had investigated the unsatisfactory results. In both testing events the samples (SER-01 and SER-08) had a positive antibody screen. Laboratory staff did not perform the IgG phase of compatibility testing which was required when a specimen had a positive antibody screen. Laboratory staff performed only an immediate spin compatibility test and reported the result as compatible.