| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 43D0407804 | 08/02/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Winner Regional Healthcare Center | 745 East 8th Street, Winner, 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** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on proficiency testing (PT) record review and interview, the laboratory failed to achieve successful participation for the ABO blood typing test method. Unsatisfactory results had been received in two of three PT events (Nonchemistry Q1 and Q2 2021) resulting in unsuccessful PT participation. Refer to D2162. |
| **D2162** | ABO GROUP AND D(RHO) TYPING<br>CFR(s): 493.859(f)<br><br>Failure to achieve satisfactory performance for the same analyte in two consecutive |

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| | testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of CASPER Reports and interview, the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the ABO blood typing test method in two out of three American Association of Bioanalysts (AAB) events (Nonchemistry Q1 and Q2 testing events). 1. Review of the laboratory's CASPER Reports 153D and 155D revealed the AAB PT scores for the ABO blood typing test method were less than the 100% required to pass the ABO blood typing test per Clinical Laboratory Improvement Amendments of 1988 requirements found at CFR 493.861(a): a. 2021 Nonchemistry Q1 event ABO score = 80% (ABO Group specimen 3 was graded as unacceptable). b. 202I Nonchemistry Q2 event ABO score = 0% (AAB reported laboratory failed to participate). Interview with the laboratory supervisor on 6/15/21 confirmed the failure. She stated she had investigated the initial unsatisfactory result. The individual processing the PT survey documented the incorrect interpretation of the ABO blood test results for specimen 3. The laboratory was unable to participate in the Q2 event due to an issue with late payment for the PT survey. |