| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 03D0533657 | 06/17/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| White Mountain Regional Medical Center | 118 S Mountain Ave, Springerville, AZ | |

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 review of Proficiency Testing (PT) reports for 2019 and 2020 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the (A) sub-specialty, ABO Group and Rh Group; (B) regulated test, ABO, and (C) the regulated test, Compatibility Testing, under the specialty of Immunohematology. Findings include: A1. The laboratory's PT performance was unsatisfactory for the 3rd event of 2019 for the sub-specialty, ABO Group and Rh Group, with a score of 0%. A2. The laboratory's PT performance was unsatisfactory for the 1st event of 2020 for the sub-specialty, ABO Group and Rh Group, with a score of 90%. B1. The laboratory's PT performance was unsatisfactory for the 3rd |

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| | event of 2019 for the regulated test, ABO, with a score of 0%. B2. The laboratory's PT performance was unsatisfactory for the 1st event of 2020 for the regulated test, ABO, with a score of 80%. C1. The laboratory's PT performance was unsatisfactory for the 3rd event of 2019 for the regulated test, Compatibility Testing, with a score of 0%. C2. The laboratory's PT performance was unsatisfactory for the 1st event of 2020 for the regulated test, Compatibility Testing, with a score of 80%. |
| **D2160** | ABO GROUP AND D(RHO) TYPING<br>CFR(s): 493.859(e)<br><br>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on information the Proficiency Testing (PT) provider furnishes to the State Agency for 2019 and 2020, it could not be determined if the laboratory underwent training and technical assistance and if remedial action was taken to correct the PT failures for the regulated tests, ABO and Compatibility Testing, and for the sub-specialty, ABO Group and Rh Group. See D2016 for findings. |
| **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 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 Proficiency Testing (PT) reports for 2019 and 2020 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the regulated tests, ABO and Compatibility Testing, resulting in unsuccessful PT performance. See D2016 for findings. |
| **D2163** | ABO GROUP AND D(RHO) TYPING<br>CFR(s): 493.859(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve an overall testing event score of satisfactory performance for the sub-specialty of ABO Group and Rh Group for the 3rd event of 2019 and 1st event of 2020, resulting in unsuccessful PT performance. See D2016 for findings. |

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| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6089 - ensuring that proficiency testing samples are tested as required under Subpart H. |
| **D6089** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(i)<br><br>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated tests, ABO and Compatibility Testing and for the sub-specialty, ABO Group and Rh Group. See D2016 for findings. |