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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 32D0675807 | (X3) Date Survey Completed 05/11/2018 |
| Name of Provider or Supplier Tohatchi Health Center Laboratory | Street Address, City, State Choos Gai Drive, Tohatchi, NM | |
| 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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| D0000 | Federal Complaint Survey The Federal Complaint Survey was unsubstantiated with standard level deficiencies cited. |
| D1001 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's package insert, patient test charts, and interview, the laboratories failed to adhere to the Coaguchek XS manufacturer's instructions by testing patients that were not on Coumadin therapy as evidenced by: 1. In review of the manufacturer's instructions for the Coaguchek XS PT states, "The Coaguchek XS system is intended for use by professional healthcare providers for quantitative prothrombin time testing for monitoring warfarin therapy." 2. In review of the patient charts on May 9th @1352, the following patients were not on Coumadin: a. patient #131801 tested 1/6/17 INR results 1.0, patient was not on Coumadin after chart review with the Laboratory Director b patient #18349 tested 1/9/18 INR results 1.0, patient was not on Coumadin after chart review with the Laboratory Director 3. In interview with the Laboratory manager on May 9th @1348 she stated that if any of the doctors in the facility order a prothombrin time they will just run it. She stated that they do not check to see if the patient are already on Coumadin.</p> |