| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>13D1081070 | **(X3) Date Survey Completed**<br><br>09/29/2021 |
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| **Name of Provider or Supplier**<br><br>Saint Alphonsus Anticoagulation Clinic-Nampa | **Street Address, City, State**<br><br>4424 E Flamingo Ste 300, Nampa, ID | |
| 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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| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a record review of Quality Control (QC) documentation, the Individual Quality Control Plan (IQCP) for the CoaguChek XS Pro and an interview with the laboratory director on 9/29/2021, the laboratory failed to successfully perform two levels of QC monthly for Prothrombin Time/ International Normalized Ratio (INR) testing. The findings include: 1. A review of the IQCP for Prothrombin time/ INR testing on the two CoaguChek XS Pro analyzers identified that the laboratory would perform QC monthly and per new lot/shipment. The laboratory failed to perform QC monthly for 2020 and 2021. Unit one failed to have QC performed in March, May, August, September and November of 2020 and February, May and July of 2021. Unit two failed to have QC Performed in March, May, August, September and November of 2020 and February, May and July of 2021. 2. An interview with the laboratory director on 9/29/2021 at 1:08 pm confirmed that the laboratory had failed to perform QC for each month of testing. 3. The laboratory reports performing 5,000 Prothrombin Time/ INR tests annually. |