| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 16D0385384 | 02/07/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sanford Sheldon Medical Center | 118 North Seventh Avenue, Sheldon, IA | |

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 |
|---|---|
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Stago coagulation test system records and confirmed by laboratory personnel identifiers #2 and #3 (refer to the Laboratory Personnel Report) at approximately 12:45 pm on 02/07/2023, the laboratory failed to verify the manual calculation of the international normalized ratio (INR) for one out of one lot number of prothrombin time reagent (259495, expiration 06/30/2023). The findings include: 1. At the time of the survey, the laboratory had in use prothrombin time reagent lot number 259495 (expiration 06/30/2023). 2. The coagulation reagent verification records for prothrombin time reagent lot number 259495 did not include verification of the accuracy of the INR calculation from the instrument. 3. Personnel identifiers #2 and #3 confirmed that the laboratory did not verify the accuracy of the INR calculation from the instrument. |