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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 43D0407358 | (X3) Date Survey Completed 04/25/2018 |
| Name of Provider or Supplier Avera De Smet Memorial Hospital | Street Address, City, State 306 Prairie Ave Sw, De Smet, 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 |
|---------------------------|---|
| D0000 | A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 4/25/18. The Avera De Smet Memorial Hospital laboratory was found not in compliance with the following requirement: D5411. |
| D5411 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the thromboplastin package insert, observation, interview with laboratory personnel A, and review of the annual test volume form the laboratory, failed to enter the correct International Sensitivity Index (ISI) value in the Sysmex CA-560 coagulation analyzer to determine an accurate International Normalized Ration (INR) patient results. The laboratory reported 1293 patient INR test results during 2017. Findings include: 1. Observations of the CA-560 coagulation analyzer at 11:35 a.m. on 4/25/18 and review of the thromboplastin package insert revealed the following: *The ISI value documented in the thromboplastin reagent package insert for lot # 539378 expiration date 1/21/19 was 0.97. *The ISI value entered in the Sysmex CA-560 coagulation analyzer for thromboplastin lot #539378 expiration date 1/29/18 was 0.98. Interview with laboratory personnel A at the same time of the observation revealed laboratory staff had been unaware of the discrepant ISI values. In addition there was no documentation as to when the lot # of reagent had been changed and the ISI value had been entered into the Sysmex CA-560 coagulation analyzer.</p> |