| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>16D0648020 | (X3) Date Survey Completed<br><br>01/26/2018 |
|---|---|---|
| **Name of Provider or Supplier**<br><br>Siouxland District Health Department | **Street Address, City, State**<br><br>1014 Nebraska Street, Sioux City, 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 |
|---|---|
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of procedure manuals, lack of centrifuge speed and timer checks, and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 10:00 am on 01/26/2018, the laboratory failed to define a function check protocol for performing centrifuge speed and timer checks. In addition, the laboratory failed to perform speed and timer checks on two out of two centrifuges (International Cent centrifuge and the IEC Central 4-B centrifuge) in 2016 and 2017. The findings include: 1. At the time of the survey, the laboratory did not have a function check protocol defining the frequency for performing centrifuge speed and timer checks on the centrifuges. 2. The laboratory did not perform speed and timer checks on either of their centrifuges (International Cent centrifuge and the IEC Central 4-B centrifuge) in 2016 or 2017. |