| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 17D0452463 | 06/09/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Herington Hospital, Inc | 100 E Helen St, Herington, KS | |

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 |
|---|---|
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of documentation of performance verifications, non-waived test list, and interview with the Laboratory Director (LD) and Laboratory Manager, the laboratory failed to perform a validation/verification on Quidel's Solana analyzer performance specifications prior to reporting patient test results. Findings: 1. Request was made to review the performance verifications of two of two Quidel's Solana analyzer analytes; serial number (S/N) 20022051. No documentation of verification of the manufacturer's performance characteristics for accuracy, precision, reportable range, and normal values appropriate for the laboratory's patient population were made available for two of two analytes performed on the analyzer at the time of survey. 2. Non waived analytes performed were: Group B Screen (GBS) and Clostridioides difficile (C.diff). Laboratory Manager stated the laboratory began reporting patient test results on the analyzer as of 10/21/21. 3. Patient results were released for 12 tests on 12 patients from 10/21/21 to date of survey. 4. Interview with the LD and the Laboratory Manager on 6/6/22 at 10:34 p.m. confirmed, the laboratory failed to perform a verification/validation for Quidel's Solana analyzer performance specifications prior to reporting patient test results. |