| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 17D0046990 | 11/20/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Hospital District No 6 Of Harper County | 485 N Ks Hwy 2, Anthony, 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 |
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| **D5393** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(b)(c)<br><br>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of specimen rejection logs and interview, the laboratory failed to perform a review of the effectiveness of preanalytical systems quality assessment. Findings: 1. Review of the specimen rejection log showed regular entries of unacceptable specimens for laboratory analysis, including the date, patient name, sample type and reason for the rejection. No review documentation was found for July 22, 2019 through to date of survey November 20, 2019. 2. When General Supervisor (GS) #1 was asked how the specimen rejection rates were reviewed to determine if corrective action was needed, she stated the specimen rejection log was not reviewed. 3. Interview of GS #1 on November 20, 2019 at 10 a.m. confirmed, the laboratory failed to perform a review of the effectiveness of preanalytical systems quality assessment. |
| **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) |

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| | 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>1. Review of the laboratory's method validation documentation for the new Sysmex XN-550 analyzer found the laboratory performed and collected data on the precision, accuracy, reportable range, and reference intervals of the new analyzer. No documentation demonstrating evaluation, review, or approval of the data collected was present for reference ranges of analytes: WBC,RBC,HGB,HCT,PLT, MCV, MCHC, MPV and auto WBC differerials. 2. GS #1 confirmed the laboratory and/or laboratory director had not documented the evaluation of the reference ranges before using the analyzer for patient testing. The interview occurred 11/20/2019 at 1254 PM. |