

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453076	(X3) Date Survey Completed 11/10/2021
Name of Provider or Supplier Gove County Medical Center	Street Address, City, State 520 W 5th Street, Quinter, 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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Chemistry "Assay Problem Log" from 1/5/21 to date of survey, the "Remedial action when QC results are not acceptable:" work guide, and interview with the general supervisor #2 (GS #2), the laboratory failed to evaluate patient test results since the last acceptable quality control (QC) test run to determine if patient results have been adversely affected and may require corrective action. Findings: 1. Review of the Chemistry "Assay Problem Log" revealed: a. on 9/14/21--BNP QC failure: "CA1 out of range. Reran. Recal". No documentation of prior patient results evaluation. b. on 9/28/21--Lipase QC failure: "MAS3 out of range. Reran. Recal". No documentation of prior patient results evaluation. c. on 9/28/21--BNP QC failure: "CA1 and CA3 out of range. Reran. Recal". No documentation of prior patient results evaluation. 2. Review of the Chemistry "Remedial action when QC results are not acceptable:" work guide revealed no patient remediation process when QC is not acceptable, and calibration is required to attain acceptable QC results. 3. A request was made to review patient remediation data for the QC failures noted in Findings 1. a, b, and c. No documentation was made available at the time of survey. 4. Interview with GS #2 11/10/21 at 4:20 p.m. confirmed, the laboratory failed to evaluate patient test results since the last acceptable test run to determine if patient results have been adversely affected and may require corrective action.</p>

D6118

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(5)

The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:

Based on a review of "Blood Bank Compatibility and Transfusion Review Form" documents from 8/13/2020 to date of survey and interview with GS #2, the Technical Supervisor (TS) for immunohematology failed to ensure remedial actions were taken whenever documented performance deviated from established procedures. Findings:

1. Review of the "Blood Bank Compatibility and Transfusion Review Form" detailing deviations from transfusion protocols revealed documentation of review by the TS for immunohematology was not present for: a. Transfusion not completed within 4 hours for one unit on 8/13/2020. b. Documentation missing for bedside check completed by two licensed personnel for one unit on 11/18/2020, one unit on 9/14/21, and one unit on 9/15/21. c. Transfusion completion time not documented for 2 units given on 2/5/21, one unit on 6/10/21, and one unit on 9/10/21. d. No documentation of pretransfusion vitals for one unit on 7/24/21, and one unit on 8/26/21.
2. Interview with GS #2 on 11/10/21 at 2:45 p.m. confirmed, the TS for immunohematology failed to ensure remedial actions were taken whenever documented performance deviated from established procedures for 10 of 74 transfusion reviews from 8/13/2020 to date of survey.