

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0047372	(X3) Date Survey Completed 05/19/2021
Name of Provider or Supplier Stevens County Hospital	Street Address, City, State 1006 S Jackson St, Hugoton, 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
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Review of quality control and patient test records from 4/1/2019 to 4/30/2021 and interview revealed the Technical Consultant (TC) failed to ensure acceptable levels of analytic performance were maintained for the OPTI-CCA-TS2. Findings: 1. Examination of the OPTI-CCA-TS2 quality control and patient test records revealed no review documentation by the TC from 4/1/2019 to 4/30/2021. 2. Interview with Testing Personell #4 on 5/19/21 at 10:55 a.m. confirmed, the TC failed to ensure acceptable levels of analytic performance were maintained for the OPTI-CCA-TS2.</p>
D6108	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: The Technical Supervisor (TS) of immunohematology failed to provide supervision in accordance with 493.1451. See D6117, D6118, D6119 and D6123.</p>

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of 4/2/19 to 5/19/21 patient testing logs and interview, the TS for immunohematology failed to ensure analytical performance was maintained at acceptable levels. Findings: 1. No documentation of review by the TS for immunohematology of patient testing logs with test reactions and interpretation were available for 4/2/19 to 5/19/21. This included 89 type and screens, 111 crossmatches, and transfusion of 94 red cell products to 56 patients. 2. Phone interview with TS #2 on 5/19/21 at 1:30 p.m. confirmed, the TS for immunohematology failed to ensure analytical performance was maintained at acceptable levels.

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 review of 4/2/19 to 5/19/21 patient testing logs and interview, the TS for immunohematology failed to ensure remedial actions were taken whenever testing deviated from established performance. Findings: 1. No documentation of review by the TS for immunohematology of patient testing logs with test reactions and interpretation were available for 4/2/19 to 5/19/21. 2. Phone interview with TS #2 on 5/19/21 at 1:30 p.m. confirmed, the TS for immunohematology failed to ensure remedial actions were taken whenever testing deviated from established performance.

D6119

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(6)

The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.

This STANDARD is not met as evidenced by:

Based on review of 4/2/19 to 5/19/21 patient testing logs and interview, the TS for immunohematology failed to ensure that patient results are not reported until all corrective actions are taken. Findings: 1. No documentation of review by the TS for immunohematology of patient testing logs with test reactions and interpretation were available for 4/2/19 to 5/19/21. 2. Phone interview with TS #2 on 5/19/21 at 1:30 p.m. confirmed, the TS for immunohematology failed to ensure that patient results are not reported until all corrective actions are taken.

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of 4/2/19 to 5/19/21 patient testing logs and interview, the TS for immunohematology failed to review intermediate test results for the competency evaluation for 3 of 3 high complexity test personnel performing immunohematology patient testing. Findings: 1. No documentation of review by the TS for immunohematology of patient testing logs with test reactions and interpretation were available for 4/2/19 to 5/19/21. 2. Phone interview with TS #2 on 5/19/21 at 1:30 p.m. confirmed, the TS for immunohematology failed to review intermediate test results for the competency evaluation for 3 of 3 high complexity test personnel performing immunohematology patient testing.