

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453221	(X3) Date Survey Completed 10/07/2020
Name of Provider or Supplier Hodgeman County Health Center	Street Address, City, State 809 West Bramley St, Jetmore, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's method verification documentation, non-waived test list, and interview, the laboratory failed to verify that the reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results. Findings: 1. Review of the method verification of the Dimension EXL, Serial # DR271912 revealed the laboratory performed an instrument verification in July 2019. The exact date the laboratory started reporting patient test results was not available at the time of survey. 2. The non-waived test list provided at the time of survey, listed 38 analytes as performed on the Dimension EXL. 3. No documentation for verification of the manufacturer's normal values were available for 38 of 38 analytes at the time of survey. 4. Interview with the General Supervisor (GS) on October 7, 2020 at 12:50 p.m. confirmed, the laboratory failed to verify that the reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
The laboratory director fails to provide overall management and direction in accordance with 493.1445. See D6086, D6089, and D6092.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on a review of verification procedures for the chemistry analyzer, the immunohematology (blood bank) gel testing system and interview, the Laboratory Director (LD) failed to ensure the verification procedures were adequate. Findings: 1. Review of the verification procedures for the Siemens Dimension EXLS/N DR27191 showed the analyzer was put into use in July 2019. No specific date was available at the time of survey. a. No documentation of a normal range study for 38 of 38 analytes was available at the time of survey. b. No documentation of when patient testing began was available at the time of survey. c. No documentation of the LD review and approval for use in patient testing was available at the time of survey. 2. Review of the verification procedures for the Grifols immunohematology gel testing system DG Therm S/N 319005643 and DG Spin S/n 320-0006707 showed the system was put into use on November 12, 2019 for patient testing. a. No documentation of a comparison study with the previous Ortho gel blood bank system was available at the time of survey. b. No documentation of the LD review and approval for use in patient testing was available at the time of survey. 3. Interview with the GS on October 7, 2020 at 12:50 p.m.confirmed, the laboratory director failed to ensure the verification procedures were adequate for both the chemistry analyzer and the immunohematology (blood bank) gel testing system.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on a review of proficiency testing (PT) documents from American Proficiency Institute (API) for attestation statements and interview, the LD failed to ensure that PT samples are tested as required for participation in PT testing for laboratories performing non-waived testing. Findings: 1. Review of PT attestation pages for 2019 and 2020 revealed seven attestation pages signed by LD after the submission period had passed and contained no signatures from the testing personnel (TP) as required. a. 2019 Hematology/Coagulation 1st Event-submission deadline 3/29/2019, signed by LD 4/16/2019-no TP signatures. b. 2019 Microbiology 1st Event-submission deadline 3/1/2019, signed by LD 4/16/2019-no TP signatures. c. 2019 Immunohematology 1st

Event-submission deadline 4/12/2019, signed by LD 4/16/2019-no TP signatures. d. 2020 Chemistry Core 1st Event-submission deadline 1/31/2020, signed by LD 8/22/2020-no TP signatures. e. 2020 Hematology/Coagulation 1st Event-submission deadline 3/27/2020, signed by LD 8/22/2020-no TP signatures. f. 2020 Hematology/Coagulation 2nd Event-submission deadline 7/29/2020, signed by LD 8/22/2020-no TP signatures. g. 2020 Microbiology 2nd Event-submission deadline 7/6/2020, signed by LD 8/22/2020-no TP signatures. 2. Interview with GS on October 7, 2020 at 1:30 p. m. confirmed, the LD failed to ensure that PT samples are tested as required for participation in PT testing for laboratories performing non-waived testing.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Review of 2019 PT performance evaluation records, chemistry procedure manual, and interview revealed that the laboratory director failed to ensure corrective action was performed in response to incorrect PT responses. Findings: 1. The laboratory received the unacceptable score of 67% for microalbumin and urine creatinine testing on the 1st Event Chemistry Miscellaneous from API. 2. Correct Action (CA) listed on the performance evaluation page states, "Laboratory personnel have been advised to be more careful and proficiency testings will now be supervised by 2 individuals to prevent errors like this in the future." 3. LD signature is present with a date of 7/16/2019. 4. No documentation of updated procedures for the chemistry manual requiring 2 individuals for PT or patient testing were available at the time of survey. 5. No documentation of 2 individuals performing PT sample testing or patient testing was available at the time of survey. 6. No documentation of corrective action including retraining of testing personnel to utilize this CA was available at the time of survey. 7. Interview with GS on October 7, 2020 at 11:30 a.m. confirmed, the laboratory director failed to ensure corrective action was performed in response to incorrect PT responses.