

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0920006	(X3) Date Survey Completed 05/02/2018
Name of Provider or Supplier Konza Prairie Community Health Center, Inc	Street Address, City, State 361 Grant Avenue, Junction City, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documents and interview at 09:00 hrs on 05/02/2018, the laboratory failed to have and follow policies and procedures to monitor, assess, and when indicated correct problems in: the establishment and following of written policies and procedures to assess proficiency testing .failures. Finding were as follows: a. Based upon a review of American Proficiency Institute (API) 2018 Microbiology 1 1st event C. Trichomatis specimen CGC-01 Unacceptable, N.gonnorrhoeae specimen CGC-01 Unacceptable. At the time of the survey the laboratory failed to produce documentation of corrective action for the unacceptable results. This was confirmed by the Laboratory Director from the CMS form 209 on 05/02/2018 at 09:30 hrs</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
A review of temperature logs and interview with staff revealed the laboratory failed to document the room temperature for the laboratory storage room.. Findings were as follows: a. Based upon review of temperature logs the laboratory failed to document the room temperature for the laboratory storage room storing BD VACUETTE tubes. The manufacture's instructions state the tubes need to be stored 4 degrees C to 25 degrees C. b. At the time of the survey 05/02/2018 the laboratory failed to produce documentation of the laboratory supply storage room. This was confirmed by the Technical Consultant from the CMS 209 form on 05/02/2018 at 10:45 a.m.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
A review of calibration verification records for the ACE Alera, and interview with staff. A review of revealed that the laboratory failed to calibration verification once every six months for 2016 and 2017. Finding were as follows a. Based upon a review of the ACE Alera calibration verification documentation revealed the laboratory failed to perform at least once every six months that was due in 2016 and 2017. This was confirmed in interview with Laboratory Director 05/02/2018 at 10:00 hrs.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(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.

This STANDARD is not met as evidenced by:
A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results. Findings were as follows a. Interview with Technical Consultant from the CMS 209 05 /02/2018 at 09:20 a.m. confirmed the laboratory failed to have the policy, (All patients 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).

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
A review of quality control records and interview with staff revealed the laboratory policy failed to have a method to monitor, review, and provide documentation for quality controls failures, shifts or trends. Findings 1. Based upon interview with the Technical Consultant on 5/2/2018 at 10:10 a.m., the laboratory failed to produce documentation of monitoring and review of quality control failures, shifts, and trends for the Ace Alera chemistry analyzer.