

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0984309	(X3) Date Survey Completed 09/10/2018
Name of Provider or Supplier Univ Of Ks Health System - Great Bend Campus, The	Street Address, City, State 514 Cleveland, Great Bend, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with General Supervisor (GS) #1, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings Include: 1. Review of the laboratory's policies and procedures failed to find a competency assessment policy and procedure. 2. GS #1 confirmed the laboratory did not have policy or procedure for assessing employee competency. The interview occurred 09/10/2018 at 8:41 AM.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and interview with General Supervisor (GS) #1, the</p>

laboratory failed to verify the accuracy of any analyte assigned a proficiency testing score that did not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part). Findings Include: 1. Review of the laboratory's API PT documentation found the following analytes that received a PT of "Not Graded": Hematology / Coagulation 2018 - 2nd Testing Event Blood Cell ID (Educational) BCI-13 BCI-14 Blood Cell Identification BCI-10 2018 - 1st Testing Event Blood Cell ID (Educational) BCI-06 BCI-07 Blood Cell Identification BCI-01 Cell Count (Manual) PMN (CSF/Body Fluid) % BFL-01 BFL-02 Microbiology 2018 - 2nd Testing Event Blood Culture BL-01 Educational Culture ID ES-02 Educational Susceptibility ES-02 BioFire FilmArray RP / Influenza A RSP-10 MIC Testing / Piperacillin/Tazobactam UR-06 Immunology / Immunohematology 2018 - 2nd Testing Event C-Reactive Protein (quan) QCP-03 ABO Group (Educational) EDU-03 Antibody Screen (EDU) EDU-03 D Type (Rho) (Educational) EDU-03 Chemistry / Miscellaneous 2018 - 1st Testing Event UDS Opiates (qual) UDS-02 No documentation of a self-assessment or evaluation of the "Not Graded" samples above was present. 2. GS #1 confirmed the laboratory had not documented self-assessments or evaluations of the "Not Graded" PT samples. The interview occurred 09/10/2018 at 10:14 AM.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and interview with General Supervisor (GS) #1, the laboratory failed to document all proficiency testing evaluation and verification activities. Findings Include: 1. Review of the laboratory's API PT documentation found the laboratory's received a score of "Unacceptable" on the follow PT samples: Microbiology 2018 - 2nd Testing Event Gram Stain Morphology GS-10 No documentation of corrective actions for the "Unacceptable" sample were present. Immunology / Immunohematology 2017 - 3rd Testing Event Fetal Screen FET-06 Hemoglobin F, quantitative % FET-06 On the date of survey, GS #1 was unable to locate corrective action documentation for the "Unacceptable" samples. 2. GS #1 confirmed no documentation of corrective actions were present or were able to located for the "Unacceptable" samples noted above. The interview occurred 09/10/2018 at 10:14 AM.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
 Based on direct observation, review of the manufacturer's reference guide, and interview with General Supervisor (GS) #1, the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer for the Ortho Workstation test system, which is not subject to FDA clearance or approval, before reporting patient test results. Findings Include: 1. Direct observation on the date of survey at 11:50 AM found an Ortho Workstation with the serial number (SN) of 51001873 in the immunohematology department. 2. GS #1 stated the Ortho Workstation was new as of December 2016. The interview occurred 09/10/2018 at 11:50 AM. 3. Review of the Ortho Workstation for use with ID-MTS Gel Cards Reference Guide, provided by GS #1, found the following handwritten documentation: Received and put into service on 11/21/2016. Returned on 12/12/2016 due to unit giving several latch sensor errors. Received new workstation on 12/12/2016 and put into service. SN # 51001873 In Section 7 - Qualification Procedures of the reference guide, the following performance specifications were listed: Speed Verification OCD recommends that calibration checks be performed with 10 cards. - Cycle Speed: 1032 rpm +/- 10 rpm. Centrifuge Timing Verification - Cycle timing: 10 minutes +/- 10 secs. (including ramp up time) NOTE: The centrifuge must not be used if the timer is out of specification. Incubator Temperature Verification NOTE: Fluid temperature measurements should be made with an unused card and a calibrated, thin wire digital temperature meter. Temperature must read 37 degrees Celsius (C) +/- 2 degrees C. Incubator Timing Verification NOTE: The incubator must not be used if the timer is out of specification. 4. GS #1 stated the laboratory did not perform method verifications or validations prior to putting the Ortho Workstation into use for patient testing. The interview occurred 09/10/2018 at 11:57 AM.

D5435

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
 Based on direct observation, review of the laboratory's function check documentation, and interview with General Supervisor (GS) #1, the laboratory failed to document Ortho Workstation function checks, and demonstrate the results were within the laboratory's established limits before patient testing is conducted. Findings Include: 1. Direct observation on the date of survey at 11:50 AM found an Ortho Workstation with the serial number (SN) of 51001873 in the immunohematology department. The Ortho Workstation had a service sticker dated 2018 present on its side. 2. Review of the function check documentation for the Ortho Workstation, provided by GS #1, found the laboratory had documentation that the workstation had been serviced but it failed to indicate the performance or results of the function and/or calibration checks performed for the thermometer, centrifuge, and timer. 3. GS #1 confirmed the

documentation failed to demonstrate the results of the function checks for the Ortho Workstation. The interview occurred 09/10/2018 at 11:53 AM.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Food and Drug Administration (FDA) CLIA complexity website, Individualized Quality Control Plan (IQCP) documentation, manufacturer's package insert instructions, and interview with General Supervisor (GS) #1, the laboratory failed to perform control procedures, to include a negative and positive control, each day of use for the qualitative procedure MedTox Urine Drug Screens (UDS). Findings Include: 1. On the date of survey, GS #1 stated the laboratory performed UDS testing using a MedTox UDS test kit. The interview occurred 09/10/2018 at 11:05 AM. 2. Review of the FDA CLIA complexity website found the MedTox Profile-II ER test kit was classified as moderate complexity. 3. GS #1 stated the laboratory was under the impression the test was classified as waived complexity. GS #1 stated the laboratory performed external positive and negative controls on each new box, lot, and shipment of the MedTox UDS test kit. GS #1 stated the laboratory had not performed a positive and negative control on the MedTox UDS test kits each day of use in 2016, 2017, and 2018. The interview occurred 09/10/2018 at 11:13 AM. 4. Review of the laboratory's IQCPs failed to find an IQCP for the MedTox UDS test kit. GS #1 confirmed the laboratory did not have an IQCP for the MedTox UDS test kits.

D5507

BACTERIOLOGY
CFR(s): 493.1261(b)(c)

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, individualized quality control plans (IQCP), and interview with General Supervisor (GS) #2, the laboratory failed to use appropriate control organism(s) to check the antimicrobial susceptibility tests novobiocin disk and optochin sensitivity with Taxo P disc procedures each day tests are performed. Findings Include: 1. Review of the laboratory's policies and procedures found two procedures titled "Novobiocin Disk Test" and "Optochin Sensitivity Test with Taxo P Discs" which stated: Novobiocin Disk Test Quality

Control: Run with each new lot or shipment Optochin Sensitivity Test with Taxo P Discs Quality Control: Run with each new lot or shipment 2. Review of the laboratory's IQCPs failed to find an IQCP for the novobiocin disk and optochin sensitivity with Taxo P disc tests. 3. GS #2 stated the laboratory did not have IQCPs for the bacteriology confirmation or peripheral tests. The interview occurred 09/10/2018 at 11:13 AM.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's competency assessment documentation and interview with General Supervisor (GS) #1, the Technical Supervisors (TS) failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings Include: 1. GS #1 stated Testing Personnel (TP) # 10, 12, 13, and 14 were new since the previous survey. GS #1 provided the following dates when TP # 10, 12, 13, and 14 began patient testing: TP #10: September 2016 TP #12: April 2018 TP #13: January 2018 TP #14: June 2018 GS #1 also stated that TP #8 left the laboratory in January 2016 and then returned to the laboratory as a TP in March 2017. The interview occurred 09/10/2018 at 8:35 AM. 2. Review of the laboratory's competency assessment documentation for TP #8, 10, 12, 13, and 14 found the following competency assessment documentation: TP #8 March 2017 (Initial) - NONE September 2017 (6 month) - NONE 03/28/2018 (1 year) TP #10: September 2016 (Initial) - NONE 03/14/2017 (6 month) 08/22/2017 (1 year) TP #12: April 2018 (Initial) - NONE 08/03/2018 (6 month) TP #13: January 2018 (Initial) - NONE June 2018 (6 month) - NONE TP #14: June 2018 (Initial) - NONE 3. GS #1 confirmed initial and 6 month competency assessments were missing for TP #8, 10, 12, 13, and 14. The interview occurred 09/10/2018 at 9:06 AM.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's competency assessment documentation and interview with General Supervisor (GS) #1, the Technical Supervisors (TS) failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually during the first year the individual tests patient specimens. Findings Include: 1. Review of the laboratory's competency assessment documentation for 2016, 2017, and 2018 found the TS failed to assess and document testing personnel (TP) competency as follows: TP #6: No competency assessment for

2016. TP #7: No competency assessment for 2016. TP #11: No competency assessment for 2016. Only chemistry competency assessment for 2017. 2. GS #1 confirmed the laboratory did not have 2016 competency assessment documentation for TP #6, 7, and 11 and only had a chemistry competency assessment for TP #11 in 2017. The interview occurred 09/10/2018 at 8:55 AM.