

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453227	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier Kearny County Hospital	Street Address, City, State 500 E Thorpe Street, Lakin, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's individualized quality control plan (IQCP), and quality control documentation, the laboratory failed to ensure the quality control testing for the OPTI-CCA blood gas analyzer was performed according to the IQCP requirements at time of survey. Findings: 1. Review of the laboratory's IQCP documentation titled "AVL OPTI 1" included a section for two external quality control (QC) frequency as "Two levels of external controls (OPTI Check) shall be performed each day of use." 2. Review of the "ABG LOG SHEET QC LOG" included: a. QC performed on September 1, 2022, October 1, 2022, and October 31, 2022. b. Patient and Proficiency testing done without QC performed weekly as required occurred on: September 8, 2022, September 15, 2022, September 22, 2022, October 3, 2022, October 10, 2022, October 17, 2022 and October 24, 2022. 3. Interview with the Chief Executive Officer (CEO) and Laboratory Director on November 30, 2022 at 3:00 p.m.confirmed, the laboratory failed to ensure the quality control testing for the OPTI-CCA blood gas analyzer was performed according to the IQCP requirements.</p>
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(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 the laboratory's quality control documentation and interview, the technical consultant (TC) failed to ensure the quality control (QC) was reviewed regularly on fifty-one analytes for seven months for shifts, trends and outliers to maintain consistency of QC results on the Siemens Dimension EXL (s/n: DR252105) chemistry instrument at time of survey. Findings: 1. Review of the October 2022 Unity World Wide Reports showed no evidence that the TC performed a review on any of the fifty-one analytes on the Siemens Dimension EXL chemistry analyzer. 2. Interview with an external consultant, Chief Executive Officer (CEO) and laboratory director (LD) could not verify or confirm the TC performed a review of any of the QC for the Dimension EXL chemistry analyzer for the months of April, May, June, July, August, September and October of 2022. 3. Interview with the Chief Executive Officer (CEO) and Laboratory Director on November 30, 2022 at 1:15 p.m. confirmed the technical consultant (TC) failed to ensure the quality control (QC) was reviewed regularly for shifts, trends and outliers to maintain consistency of QC results on the Siemens Dimension EXL chemistry instrument.

D6073

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(4)

Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.

This STANDARD is not met as evidenced by:

Review of Kearny County Hospital quality control (QC) Levy-Jennings (L-J) chart and interview with staff reveals that testing personnel failed to perform corrective action when the QC does not perform as required on the Siemens Dimension EXL (s/n: DR252015) and Siemens 600 Coagulation for the month of November 2022 at time of survey. Findings: 1. Review of November control Bio-Rad Cardiac Markers Plus (Lot #67643) for CKMB found the following failed corrective actions for QC when out of range (51.97-66.61): a. 11/12/2022 - Result: 50.2 b. 11/16/2022 - Result: 47.9, repeat 50.3 c. 11/19/2022 - Result: 50.8 d. 11/20/2022 - Result: 50.4 e. 11/22/2022 - Result: 51.7 f. 11/26/2022 - Result: 50.3 2. Review of November controls Bio-Rad Urine Chemistry L1 (Lot #88131) and Urine Chemistry L2 (88132) for Urine Microalbumin found the following failed corrective actions for QC when out of range: L1 (8.2-14.6); L2 (48.4-56.4) a. 11/1/2022 - Level 2 >3 standard deviation (SD), repeat >2SD b. 11/6/2022 - Level 1 >3SD; Level 2 QC >3SD c. 11/7/2022 - Level 1 >3SD, repeat >2SD, repeat >2SD d. 11/7/2022 - Level 2 >3SD, repeat >2SD, repeat >2SD e. 11/12/2022 - Level 1 >2SD f. 11/25/2022 - Level 1 >2SD 3. Review of November control Bio-Rad MultiQual L1 (Lot #45931) for Phosphorus found the following failed corrective actions for QC when out of range (1.64-2.16): a. 11/25/2022 - Result: 2.2, repeat 2.2 b. 11/26/2022 - Result: 2.2, repeat 2.2 c. 11/27/2022 - Result: 2.2, repeat 2.2 4. Review of November control Bio-Rad MultiQual L3 (Lot #45933) for Bilirubin Direct found the following failed corrective actions for QC

when out of range (1.73-2.29): a. 11/3/2022 - Result: 1.7 b. 11/12/2022 - Result: 1.9 c. 11/23/2022 - Result: >2SD d. 11/24/2022 - Result: >2SD e. 11/25/2022 - Result: >2SD f. 11/27/2022 - Result: >2SD g. 11/28/2022 - Result: >2SD 5. Review of November controls Bio-Rad MultiQual L1 (Lot #45931) and Bio-Rad MultiQual L3 (Lot #45933) for Lactic Acid found the following failed corrective actions for QC when out of range: L1 (1.11-1.75); L3 (5.38-6.42): a. 11/1/2022 - Level 3 - Result: 4.6 b. 11/2/2022 - Level 1 - Result: 1.1; Level 3 - Result: 4.4 6. Review of November control Bio-Rad MultiQual L3 (Lot #45933) for LDH found the following failed corrective actions for QC when out of range: L3 (383-443): a. 11/25/2022 - Level 3 - >2SD 7. Review of November controls Bio-Rad MultiQual L1 (Lot #45931) and Bio-Rad MultiQual L3 (Lot #45933) for Transferrin found the following failed corrective actions for QC when out of range: L1 (135.84-153.16); L3 (223.02-256.58): a. 11/10/2022 - Level 3 >2SD b. 11/14/2022 - Level 1 >3SD, repeat >2SD c. 11/21/2022 - Level 1 >2SD; Level 3 >3SD 8. Review of November controls Bio-Rad MultiQual L1 (Lot #45931) and Bio-Rad MultiQual L3 (Lot #45933) for Lipase found the following failed corrective actions for QC when out of range: L1 (19.22-24.42); L3 (146.02-167.78): a. 11/19/2022 - Level 1 - Result: 19; Level 3 - Result: 144 9. Review of November control CITROL L1 (Lot #564855) and CITROL L3 (Lot#556556) for Protine found the following failed corrective actions for QC when out of range: L1 (8.95-11.95); L3 (41.65-51.65): a. 11/22/2022 - Level 1 - Result: 15.0, repeat - 14.7, repeat - 14.7 b. 11/22/2022 - Level 3 - Result: 39.1, repeat - 39.3, repeat - 40.1 10. Interview with the Chief Executive Officer (CEO) and Laboratory Director on November 30, 2022 at 1:15 p.m.confirmed, the laboratory personnel failed to perform corrective action when the QC does not perform as required on the Siemens Dimension EXL (s/n; DR252015) and Siemens 600 Coagulation for the month of November 2022 at time of survey.