

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 37D0997934 | (X3) Date Survey Completed 02/10/2020 |
| Name of Provider or Supplier Lake Pointe Medical Center | Street Address, City, State 20912 Se 29th Street, Harrah, OK | |
| 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 |
|---------------------------|---|
| D0000 | The recertification survey was performed 02/10/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with testing person #1 at the conclusion of the survey. |
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to thoroughly review the results of proficiency testing performed in 2 of 6 Hematology events to identify the cause of failures. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor, the laboratory performed Hemogram testing, which included the analytes, RBC (Red Blood Count), Hct (Hematocrit), etc., using the Beckman Coulter AcT diff 2 analyzer; (2) The surveyor reviewed 2018 and 2019 proficiency testing records and identified the following: (i) First 2018 event: (a) RBC: Sample HD-4: The laboratory failed the result and obtained a score of 80%; (b) Hct: Sample HD-4: The laboratory failed the result and obtained a score of 80%. (ii) Second 2018 event: (a) RBC: Sample HD-11: The laboratory failed the result and obtained a score of 80%; (b) Hct: Sample HD-11: The laboratory failed the result and obtained a score of 80%. (3) There was no documentation the laboratory investigated (i.e., reviewed quality control, maintenance records, testing technique, etc.) the failures to determine the cause of the failures, or to determine if a systematic failure had occurred; (4) The surveyor reviewed the findings with testing person #1 who stated to the surveyor, the failures had not been thoroughly reviewed to determine the cause, or to ensure a systematic failure had not occurred.</p> |
| D5417 | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT |

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with testing person #1, the laboratory failed to ensure quality control materials were not used beyond the expiration date for 3 of 27 lot numbers. Findings include: (1) At the beginning of the survey, testing person #1 stated the following to the surveyor: (a) The laboratory performed Hemogram testing (WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), RDW (Red Cell Distribution Width), and Platelet Count) using the Beckman Coulter AcT diff 2 analyzer; (b) Three levels (Low, Normal, High) of Coulter 4C-ES Cell Control QC (Quality Control) materials were tested each day of patient testing. (2) The surveyor reviewed QC records from 03/01/18 through 01/31/20 and identified the laboratory utilized 27 lot numbers of QC materials. Of the 27 lot numbers utilized, 3 lot numbers (in use from 09/24/19 through 12/20/19), with the expiration date of 12/16/19, had been used on 12/17/19, 12/18/19, and 12/19/19, as follows: (a) Low Level - Lot #068300 (b) Normal Level - Lot #078300 (c) High Level - Lot #088300 (3) The surveyor reviewed the records with testing person #1 who stated the 3 lot number of QC materials listed above, had been used beyond the expiration date; (4) The following were examples of patient Hemogram testing performed when the laboratory used expired QC materials to assess the acceptable performance of the analyzer: (a) 12/17/19: (i) Patient #4014: Testing performed at 09:02 AM (ii) Patient #5492: Testing performed at 09:13 AM (iii) Patient #14884: Testing performed at 10:21 AM (iv) Patient #16365: Testing performed at 10:23 AM (v) Patient #12200: Testing performed at 10:42 AM (vi) Patient #3427: Testing performed at 10:52 AM (vii) Patient #14878: Testing performed at 11:41 AM (viii) Patient #6858: Testing performed at 01:35 PM (b) 12/18/19: (i) Patient #6844: Testing performed at 10:11 AM (ii) Patient #11886: Testing performed at 10:13 AM (iii) Patient #12536: Testing performed at 10:15 AM (iv) Patient #16622: Testing performed at 10:16 AM (v) Patient #14672: Testing performed at 10:18 AM (vi) Patient #8256: Testing performed at 10:50 AM (vii) Patient #12378: Testing performed at 10:54 AM (viii) Patient #6349: Testing performed at 10:56 AM (ix) Patient #9089: Testing performed at 3:02 PM (c) 12/19/19: (i) Patient #4446: Testing performed at 09:52 AM (ii) Patient #5435: Testing performed at 09:54 AM (iii) Patient #15458: Testing performed at 09:55 AM

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with testing person #1, the laboratory failed to have control procedures that monitored over time the accuracy and precision of test performance that may be influenced by changes in test system performance, environmental conditions, and variance in operator performance. Findings include: (1) At the beginning of the survey, testing person #1 stated the following to the surveyor: (a) The laboratory performed Hemogram testing (WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), RDW (Red Cell Distribution Width), and Platelet Count) using the Beckman Coulter AcT diff 2 analyzer; (b) Three levels (Low, Normal, High) of Coulter 4C-ES Cell Control QC (Quality Control) materials were tested each day of patient testing. (3) The surveyor reviewed QC (Quality Control) records from 03/01/18 through 01/31/20 and identified the laboratory used 27 lot numbers of QC materials during the review period, as follows: (a) Used from 03/01/18-03/31/18: (i) Low Control: Lot #068800 (ii) Normal Control: Lot #078800 (iii) High Control: Lot #088800 (b) Used from 04/02/18-07/02/18: (i) Low Control: Lot #0694000 (ii) Normal Control: Lot #079400 (iii) High Control: Lot #089400 (c) Used from 07/03/18-09/21/18 (i) Low Control: Lot #067500 (ii) Normal Control: Lot #077500 (iii) High Control: Lot #087500 (d) Used from 09/24/18-12/31/18: (i) Low Control: Lot #068200 (ii) Normal Control: Lot #0782000 (iii) High Control: Lot #088200 (e) Used from 01/02/19-03/29/19: (i) Low Control: Lot #068900 (ii) Normal Control: Lot #078900 (iii) High Control: Lot #088900 (f) Used from 04/0/19-06/28/19: (i) Low Control: Lot #069500 (ii) Normal Control: Lot #079500 (iii) High Control: Lot #089500 (g) Used from 07/01/19-09/19/19: (i) Low Control: Lot #067700 (ii) Normal Control: Lot #077700 (iii) High Control: Lot #087700 (h) Used from 09/24/19-12/20/19: (i) Low Control: Lot #068300 (ii) Normal Control: Lot #078300 (iii) High Control: Lot #088300 (i) Used from 12/20/19 and in use on the day of the survey: (i) Low Control: Lot #069000 (ii) Normal Control: Lot #079000 (iii) High Control: Lot #089000 (4) For 27 of the 27 lot numbers listed above, there were no records (i.e., Levey-Jennings data, statistical data, etc.) proving the control results had been monitored for variances; (5) The surveyor asked testing person #1 to explain how the lot numbers listed above had been monitored for variances. Testing person #1 explained each day the results of the three levels of QC were printed and reviewed for acceptability, but QC results were not reviewed for variances over time; (6) The surveyor reviewed the findings with testing person #1 and explained the laboratory must have a method to review QC results to monitor over time the accuracy and precision of testing that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of records, and interview with testing person #1, the laboratory failed to ensure normal reference intervals appropriate for the patient population serviced by the laboratory, were made available to the provider responsible for using the test results. Findings include: GENDER SPECIFIC NORMAL REFERENCE INTERVALS (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed Hemogram testing (i.e., WBC-White Blood Count; RBC-Red Blood Count; Hgb-Hemoglobin, Hct-Hematocrit, MCV-Mean Corpuscular Volume, MCH-Mean Corpuscular Hemoglobin; MCHC-Mean Corpuscular Hemoglobin Concentration; Platelet Count, and RDW-Red Cell Distribution Width) using the Beckman Coulter AcT Diff 2 analyzer; (2) The surveyor reviewed 2 patient test reports as follows: (a) Patient #312: Adult female. Testing performed on 03/29/19 (b) Patient #802: Adult male. Testing performed 01/08/20 (3) The two test reports included the same reference intervals for the following analytes: (a) WBC: 4.1-10.9 (b) RBC: 4.2-6.3 (c) Hgb: 12.0-18.0 (d) Hct: 37.0-51.0 (e) MCV: 80-97 (f) MCH: 26-32 (g) MCHC: 31-36 (h) RDW: 11.6-14.8 (4) The surveyor reviewed the findings with testing person #1 and asked if the laboratory had gender specific normal Hemogram reference intervals. The laboratory manager stated to the surveyor, the laboratory had gender specific reference intervals for the Hemogram analytes listed above but the ranges had not been included on the patient test reports. NOTE: Routinely, female reference intervals for analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals. PEDIATRIC NORMAL REFERENCE INTERVALS (1) At the beginning of the survey, the surveyor asked testing person #1 if the laboratory performed Hemogram testing on pediatric patients (less than 18 years of age). Testing person #1 stated to the surveyor on a rare occasion, the laboratory had performed Hemogram testing on pediatric patients when requested by the provider; (2) The surveyor asked testing person #1 for a Hemogram test result report for a pediatric patient (Patient #10351: Hemogram testing performed on a 9 year old female patient on 09/09/19). The surveyor reviewed the test report and identified the normal reference ranges on the pediatric patient's test report were the same reference ranges as provided for adult female and male patients: (a) WBC: 4.1-10.9 (b) RBC: 4.2-6.3 (c) Hgb: 12.0-18.0 (d) Hct: 37.0-51.0 (e) MCV: 80-97 (f) MCH: 26-32 (g) MCHC: 31-36 (h) RDW: 11.6-14.8 (3) The surveyor asked testing person #1 if the laboratory had normal reference intervals specific for pediatric patients. Testing person #1 stated to the surveyor the laboratory did not have normal reference intervals specific for pediatric patients.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

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

This STANDARD is not met as evidenced by:

Based on a review of records and interview with testing person #1, the technical consultant failed to ensure a testing person performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed Hemogram testing (i.e., WBC-White Blood Count; RBC-Red Blood Count; Hemoglobin, Hematocrit, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin; Mean Corpuscular Hemoglobin Concentration; Platelet Count, and Red Cell Distribution Width) using the Beckman Coulter AcT Diff 2 analyzer; (2) The

surveyor reviewed personnel records for the 2 individuals (testing person #1 and testing person #2) who performed the moderate complexity testing. The surveyor identified the semiannual competency assessment had not been performed for testing person #2, hired after the previous recertification survey performed on 02/20/18: (a) The initial training had been completed on 02/01/19; (b) The annual competency assessment had been completed on 01/02/20; (c) There was no evidence a semiannual evaluation had been performed. (3) The surveyor reviewed the records with testing person #1, who stated there was no documentation a competency assessment had been performed for testing person #2 during the first year of testing.