Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0476010	(X3) Date Survey Completed 10/04/2019
Name of Provider or Supplier Eastern Oklahoma Medical Center	**Street Address, City, State** 105 Wall Street, Poteau, 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	A recertification survey was performed on 10/01/19 through 10/04/19. The findings were reviewed with chief operating officer, chief financial officer, chief nursing officer and the laboratory manager/technical consultant during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager/technical consultant, it was determined the laboratory failed to maintain patient records for at least 2 years for 3 of 8 months. Findings include: (1) On the second day of the survey, the laboratory manager/technical consultant stated CBC (Complete Blood Count) testing was performed using the Sysmex 4000 analyzer; (2) Later during the survey, the surveyor requested analyzer printouts from testing performed from 01/01/2019 through 03/16 /19, which would include morphology flags (printouts would include the following if morphology flags were present: RBC Abn Distribution, Hypochromia, Macrocytosis, NRBC, Blasts). The laboratory manager/technical consultant explained since patient information was transferred to their LIS (Laboratory Information System), the instrument printouts were not maintained before 08/30/19; (3) The surveyor then asked the laboratory manager/technical consultant how morphology flags were verified. The supervisor explained: (a) The specimen would be retested; (b) If the flags were still present, a manual differential or morphology would be performed

	according to manufacturer's instructions. (4) Since the laboratory did not maintain instrument printouts, the surveyor could not determine if morphology flags had been verified as required between 01/01/19 through 03/19/19.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant, the laboratory failed to review and evaluate proficiency testing results for 1 of 27 events. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2019 Chemistry Core Event (i) Troponin - 3 of 5 results exhibited a positive bias (aa) CM-06 - SDI of 2.9 (bb) CM-07 - SDI of 2.7 (cc) CM-10 - SDI of 2.7 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the laboratory manager/technical consultant, and asked if the biases had been addressed. The laboratory manager stated the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 1 of 27 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2018 First Event (aa) Blood Cell Identification BC-01 (bb) Blood Cell Identification BC-06 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the laboratory manager/technical consultant if the results had been documented as evaluated. The laboratory manager/technical consultant reviewed the records and stated the non-graded results had not been documented as reviewed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records, written procedure, and interview with laboratory manager/technical consultant, the laboratory failed to demonstrate the performance specifications for a new test method. Findings include: (1) On the second day of the survey, the laboratory manager/technical consultant stated to the surveyor the laboratory began using the K-check Tablets to perform serum Ketone patient testing on 09/06/17; (2) The surveyor requested documentation from the technical consultant to substantiate the performance specifications (i.e., accuracy) had been demonstrated for the test kit before it had been put into use; (3) The laboratory manager/technical consultant stated to the surveyor, the performance specifications had not been demonstrated for the test kit.
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 the laboratory manager/technical consultant, the laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process for Vitamin B12 for 7 of 7 months. Findings include: (1) On the second day of the survey, the laboratory manager /technical consultant stated the following to the surveyor: (a) Vitamin B12 testing was performed using the OrthoVitros 5600 analyzer; (b) Two levels (Level 1 and Level 3) of Bio Rad control materials were performed each day of patient testing. (2) The surveyor reviewed quality control records for testing performed between 01/01/19 through 07/31/19. A bias was identified as follows: (a) Vitamin B 12 (level 3 lot#40973) - 140 out of 161 control results were consistently above the established mean. (3) There was no evidence in the records the control biases had been identified and addressed; (4) The surveyor reviewed the records with the laboratory manager /technical consultant and asked if there was documentation to prove the bias had been identified and addressed. The laboratory manager/technical consultant stated the bias had not been addressed; (5) Since the above bias had not been identified and addressed, the surveyor determined the laboratory failed to have control procedures that monitored the accuracy of testing for the above analyte.

D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that 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 records and interview with the laboratory manager/technical consultant, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 3 of 27 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records. It was identified for 3 of 27 events, the attestation statements had been signed approximately 2-4 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Hematology/Coagulation second event of 2018 - The samples had been tested on 07/17/18 and the attestation statement had not been signed by the laboratory director until 12/13/18; (b) Immunohematology second event of 2018 - The samples had been tested on 08/14/18 and the attestation statement had not been signed by the laboratory director until 12/13/18; (c) Chemistry Miscellaneous first event of 2018 - The samples had been tested on 10/25/18 and the attestation statement had not been signed by the laboratory director until 12/13/18; (2) The surveyor reviewed the findings with the laboratory manager/technical consultant and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 7 of 7 testing persons. Findings include: (1) On the second day of the survey, the laboratory manager/technical consultant stated to the surveyor serum Ketone analysis was performed using the K-Check Tablets in the laboratory: (2) The surveyor then reviewed personnel records for 7 persons performing serum ketone analysis in the laboratory. The records verified that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 01 /30/18 and 01/29/19 (b) Testing Person #2 - Performed on 01/30/18 and 01/29/19 (c) Testing Person #3 - Performed on 01/30/18 and 01/29/19 (d) Testing Person #4 - Performed on 01/30/18 and 01/29/19 (e) Testing Person #5 - Performed on 01/30/18 and 01/29/19 (f) Testing Person #6 - Performed on 01/30/18 and 01/29/19 (g) Testing

	Person #7 - Performed on 01/30/18 and 01/29/19 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of serum Ketone analysis; (4) The surveyor reviewed the findings with the laboratory manager /technical consultant, who stated the above evaluations did not include serum Ketone analysis.