

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0969327	(X3) Date Survey Completed 04/19/2018
Name of Provider or Supplier Clinic At Central Oklahoma Family Medical Ctr, The	Street Address, City, State 2403 W Wrangler Blvd, Seminole, 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 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 and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2016 and 2017 proficiency testing records and identified the following failures, in which corrective action documentation could not be located: (a) Third 2017 Hematology Event (i) RDW (Red Cell Distribution Width) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (2) The surveyor asked testing person #1 if corrective action had been taken for the failure. After reviewing the records, testing person #1 stated corrective action had not been taken to determine the cause of the failure.</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>

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with testing person #1, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2016 and 2017 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Chemistry Group 2 (i) 2016 third event (aa) Cholesterol, HDL (High Density Lipoprotein) - LIP-14 (b) Hematology (i) 2016 third event (aa) Blood Cell Identification - BCI- 13 and BCI-14 (ii) 2017 second event (aa) Blood Cell Identification - BCI - 13 and BCI - 14 (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 testing person #1 if the results had been documented as evaluated. Testing person #1 reviewed the records and stated the non-graded results had not been documented as reviewed.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with testing person #1, the laboratory failed to verify the accuracy of wet prep testing at least twice annually. Findings include: (1) On the first day of the survey, testing person #1 stated the following to the surveyor: (a) The laboratory performed wet prep testing; (2) The surveyor reviewed 2016, 2017, and 2018 records which indicated the following: (a) No documentation to prove wet prep analysis had been verified for accuracy between 05/20/17 through the first day of the survey (04/18/18). (2) The surveyor reviewed the findings with testing person #1 who stated there was no documentation to prove wet prep analysis had not been verified for accuracy at least twice annually as indicated above.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to ensure equipment maintenance was performed as required by the manufacturer. Findings include: (1) On the first day of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed on the Cell Dyn Emerald analyzer; (2) The surveyor reviewed 2016 and 2017 (24 months) manufacturer's maintenance logs for the analyzer with the following identified: (a) Monthly - Bleaching (i) The monthly maintenance procedure had not been documented as performed during: (aa) August 2016 (bb) December 2016 (cc) December 2017 (3) The surveyor reviewed the records with testing person #1 who stated there was no evidence the above maintenance had been performed as required.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to perform calibration procedures as required by the manufacturer. Findings include: (1) On the first day of the survey, testing person #1 stated the laboratory performs CBC (Complete Blood Count) testing using the Cell Dyn Emerald analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions (contained in the Operation Manual) for performing calibration procedures. The manufacturer required calibrations be performed at least every 6 months; (3) The surveyor reviewed 2016 and 2017 records for calibration procedures and identified the following: (a) Calibration had not been performed between 10/25/16 and 07/24/17 (4) The surveyor reviewed the findings with testing person #1 who stated the calibration procedure had not been performed as indicated above.

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 reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell Dyn Emerald analyzer; (2) On the second day of the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 04/19/18 at 11:48 am; the second report was for an adult female patient with the testing performed on 04/19/18 at 11:47 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit, which were: (a) RBC - 4.20 - 6.30 10^{12} /L (b) Hemoglobin - 12.0 - 18.0 g/dL (c) Hematocrit - 37 - 51% (3) The surveyor viewed the findings with testing person #1 who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.