Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0969327	01/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Clinic At Central Oklahoma Family Medical Ctr, The	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 recertification survey was performed on 01/07/2020. The laboratory was found out of compliance with the following CLIA regulation: 493.1421: D6063: Condition: Testing Personnel, Moderate Complexity The findings were reviewed with the laboratory manager at the conclusion of the survey.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the laboratory manager, the laboratory failed to retain proficiency testing records for at least 2 years for 1 of 10 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed Hematology and Chemistry proficiency testing records from 2018 and 2019. The attestation statement for 1 of the 10 events reviewed (Chemistry 2nd 2019 Event) could not be located; (2) The surveyor asked the laboratory manager if the attestation statement for the event was available. The laboratory manager stated to the surveyor the laboratory failed to maintain the attestation statement; (3) The surveyor explained to the laboratory manager that all proficiency testing records must be retained for at least 2 years.
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, the laboratory failed to verify the accuracy of testing when the proficiency testing program had not evaluated submitted results for 3 of 10 events. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed the following testing: (a) Microscopic urine sediment examination (b) Blood smear examinations, which included WBC (White Blood Cell) differentials (i.e., Lymphocytes, Neutrophils, Monocytes, Eosinophils, Basophils) and RBC (Red Blood Cell) morphology. (2) The surveyor reviewed proficiency testing records from 2018 and 2019 and identified the proficiency testing program had not evaluated the laboratory's results, as follows: (a) Second 2018 Hematology Event: Blood Cell Identification (i.e. WBC differential): (i) Although the laboratory obtained a score of 100%, the result of 1 of the laboratory's 5 results (BCI-10) had not been evaluated by the proficiency testing program, due to "No Consensus"; (ii) In addition, the laboratory's result was "Neutrophil, hypersegmented." The proficiency testing program's expected result was "see Data Summary"; (iii) There was no documentation located in the records which verified the laboratory obtained the Data Summary and performed a self-evaluation of their result to verify the accuracy of the result. (b) Third 2018 Hematology Event: Blood Cell Identification (Educational): (i) The result of 1 of the laboratory's 2 results (BCI-20) had not been evaluated by the proficiency testing program due to it being an "Educational Sample"; (ii) In addition, the laboratory's result was "Schistocyte." The proficiency testing program's expected result was "Echinocyte (Burr, crenated)"; (iii) There was no documentation located in the records which verified the laboratory obtained the Data Summary and performed a self-evaluation of their result to verify the accuracy of the result. (c) 2019 First Hematology Event: Microscopic urine sediment examination: (i) Although the laboratory obtained a score of 100%, the result of 1 of the laboratory's 2 results (US-02) had not been evaluated by the proficiency testing program, due to "No Consensus"; (ii) In addition, the laboratory's response was "Mucous thread." The proficiency testing program's expected result was "see Data Summary"; (iii) There was no documentation located in the records which verified the laboratory obtained the Data Summary and performed a self-evaluation of their result. (3) The surveyor then reviewed the proficiency testing program's "Performance Evaluation Sheet," which stated that, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded."; (4) The surveyor asked the laboratory manager if the laboratory had performed a self-evaluation of the non-graded results listed above to verify the accuracy of the testing. The laboratory manager stated to the surveyor the laboratory had not obtained the Data Summary, and had not performed a self-evaluation of their results. NOTE: D5215 was cited at the previous recertification survey on 04/19/18.
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, and interview with the laboratory manager, the laboratory failed to ensure reference intervals used with a new analyzer, had been determined as acceptable for the patient population it serviced. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory began patient CBC (Complete Blood Count) (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Sysmex XP-300 analyzer on 09/12/19. In addition, the laboratory manager stated to the surveyor the laboratory performed CBC testing on pediatric patients (less than 18 years of age); (2) Later during the survey, the surveyor reviewed the laboratory's implementation records for the analyzer. There was no evidence in the records the laboratory had established or verified reference intervals (normal ranges) for pediatric patients; (3) The surveyor asked the laboratory manager if the laboratory had established or verified pediatric reference intervals for the pediatric patient population it serviced. The laboratory manager explained the laboratory used the adult normal reference intervals for pediatric patient CBC's and had not established its own pediatric reference intervals or verified reference intervals for pediatric patients; (4) The surveyor then reviewed 7 CBC (6 adult patients and 1 pediatric patients) test reports of testing performed between 12/31/18 and the 01/07/20. For 1 of the 1 pediatric CBC test reports (Patient #119, 2 year-old female, testing performed on 01 /07/20) reviewed, the laboratory failed to have reference intervals specific for pediatric patients. Examples follow: (a) Normal reference ranges for Adult Females were included on the test report: (i) WBC: 4.1-10.9 (ii) RBC: 4.2-6.3 (iii) Hemoglobin: 12.0-18.0 (iv) Hematocrit: 37.0-51.0 (v) Platelet: 140-440 (vi) Lymphocyte %: 10.0-58.5 (vii) Neutrophil %: 37.0-92.0 (5) The surveyor explained to the laboratory manager, the laboratory must verify the reference intervals the laboratory utilizes for CBC testing are appropriate for the patient population it services. NOTE: The Interpretive Guidelines for 493.1253(b)(1) state, "The laboratory may use the manufacturer's reference range provided it is appropriate for the laboratory's patient population (i.e., a normal range that reflects the type of specimen and demographic variables such as age and sex, as applicable). If the manufacturer has not provided reference ranges appropriate for the laboratory's patient population, the laboratory may use published reference range(s). The laboratory must evaluate an appropriate number of specimens to verify the manufacturer's claims for normal values or, as applicable, the published reference ranges."
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 the laboratory manager, 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: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory began using the Sysmex XP-300 analyzer to perform CBC (Complete Blood Count) (i.e., RBC-Red Blood Count, Hgb-Hemoglobin, Hct-Hematocrit, etc.) on 09/12/19; (2) The surveyor reviewed 6 patient CBC reports as follows: (a) Patient #098: Adult female. Testing performed on 01/07/20 (b) Patient #100: Adult male. Testing performed on 01/07/20 (c) Patient #101: Adult male. Testing performed 01/07/20 (d) Patient #103: Adult female. Testing performed on 01/07/20 (3) The four test reports included the same reference intervals for the following CBC analytes: (a) RBC: 4.2-6.3 (b) Hgb: 12.0-18.0 (c) Hct: 37.0-51.0 (4) The surveyor reviewed the findings with the laboratory manager and asked if the laboratory had gender specific normal CBC reference intervals. The laboratory manager stated to the surveyor, the laboratory had gender specific reference intervals for the CBC 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. NOTE: D5215 was cited at the previous recertification survey on 04/19/18.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure an individual who performed moderate complexity testing met the educational qualification requirements as listed in 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of testing performed. Findings include: (1) The laboratory failed to ensure a testing person met the educational qualifications. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure a testing person met the required educational qualifications

	to perform moderate complexity testing. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed the following moderate complexity testing: (a) CBC (Complete Blood Count) testing using the Sysmex XP-300 hematology analyzer (b) Manual WBC (White Blood Cell) differentials (c) Vaginal Wet Prep examinations (d) Microscopic urinalysis examinations (e) Qualitative Serum HCG using the Consult Diagnostics HCG Combo test kit (2) The surveyor reviewed the Laboratory Personnel Report (CMS Form-209) completed by the laboratory prior to the survey. The form listed 4 testing persons who performed the moderate complexity testing (Laboratory manager, testing person #1, testing person #2, and testing person #3); (3) The surveyor reviewed testing personnel records and identified an employee (testing person #4) hired after the previous recertification survey performed on 04/19/18 had performed the moderate complexity patient testing until testing person #4 ended employment on 11/10/19. The surveyor could not locate educational documents (a minimum of a high school diploma /transcript or equivalent - GED) for the individual; (4) The surveyor asked the laboratory manager if testing person #4 had performed moderate complexity testing. The laboratory manager stated to the surveyor, testing person #4 had been trained and had performed moderate complexity testing while employed; (5) The surveyor reviewed the findings with the laboratory manager and asked if educational documents were available for testing person #4. The laboratory manager stated to the surveyor the laboratory was unable to obtain the educational documents for testing person #4.