Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0969327	03/23/2022
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 03/23/2022 The laboratory was found out of compliance with the following CLIA regulations: 493.1210; D5016: Routine Chemistry 493.1403; D6000: Laboratory Director The findings were reviewed with the laboratory supervisor at the conclusion of the survey.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory suprvisor, the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry testing for one of one analyzer. Findings include: (1) The laboratory failed to perform function checks as defined by the manufacturer for one of one analyzer. Refer to D5431; (2) The laboratory failed to perform two levels of quality control materials 47 of 49 days of patient Chem 8+ testing reviewed. Refer to D5447; (4) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to perform function checks as defined by the manufacturer for one of one analyzer. Findings include: (1) On 03/23/2022 at 10: 30 am, the laboratory supervisor stated to the surveyor the laboratory performed BUN, Chloride, CO2, Creatinine, Ionized Calcium, Glucose, Potassium, and Sodium testing using the Chem 8+ cartridge and iSTAT 1 analyzer; (2) The surveyor reviewed the manufacturer's instructions contained in the operator's manual regarding the performance of the thermal probe check. Under the heading "Checking the Thermal Probes in the i-STAT Analyzers" on page 14-17 the instructions stated, "External Electronic Simulator used routinely, results not transmitted to a Central Data Station: Use the procedure below to check the thermal probes on each analyzer twice a year"; (3) The surveyor asked the laboratory supervisor if the thermal probe checks had been performed during the review period of January 2021 through the current date. The laboratory supervisor stated on 03/23/2022 at 12:40 pm the thermal probe checks had not been performed; (4) Refer to D5447 for examples of patient testing.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory supervisor, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly one of two function checks performed. Findings include: (1) On 03/23/2022 at 10:15 am, the laboratory supervisor stated the following to the surveyor: (a) The laboratory performed urine microscopic testing; (b) The urine specimens were processed at a speed of 2000 rpm (revolutions per minute) for five minutes using the Unico Select Medical PSS 602 centrifuge. (2) The surveyor reviewed the function check policy for the urine centrifuge, which required the speed and timer checks be performed annually; (3) The surveyor reviewed the centrifuge records from 2020 through 2021 with the following identified for one of two checks performed: (a) 06/21/2020 - Although the speed check had been performed, there was no documentation the timer check had been performed. (3) The surveyor reviewed the findings with the laboratory supervisor who stated on 03/23/2022 at 12:45 pm, there was no documentation to prove the timer had been checked as shown above.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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--

	At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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 supervisor, the laboratory failed to perform two levels of quality control materials 47 of 49 days of patient Chem 8+ testing reviewed. Findings include: (1) On 03/23/2022 at 10:30 am, the laboratory supervisor stated to the surveyor the laboratory performed BUN, Chloride, CO2, Creatinine, Ionized Calcium, Glucose, Potassium, and Sodium testing using the Chem 8+ cartridge and iSTAT 1 analyzer; (2) The surveyor asked the laboratory supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory supervisor stated on 03/23/2022 at 10:45 am, the laboratory had not developed an IQCP. Therefore, the surveyor determined two levels of QC (quality control) materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records from January 2021 through the current date and identified that two levels of QC materials had not been performed 47 of 49 days of testing reviewed; (4) The surveyor reviewed the records with the laboratory supevisor who stated on 03/23/2022 at 11:30 am, two levels of QC materials had not been performed each day of patient Chem 8+ testing: (5) The following were examples of patient BUN, Chloride, CO2, Creatinine, Ionized Calcium, Glucose, Potassium, and Sodium testing performed when two levels of QC materials had not been performed: (a) Patient #1- Testing performed on 01/04/2021 (b) Patient #2 - Testing performed on 01/15/2021 (c) Patient #3 - Testing performed on 02/02/2021 (d) Patient #4 - Testing performed on 02/07/2021 (e) Patient #5 - Testing performed on 02/16/2021 (f) Patient #6 - Testing performed on 02/26/2021 (g) Patient #7 - Testing performed on 03/03/2021 (h) Patient #8 - Testing performed on 03/17/2021 (i) Patient #9 - Testing performed on 03/31/2021 (j) Patient #10 - Testing performed on 04/01/2021 (k) Patient #11 - Testing performed on 04/15/2021 (l) Patient #12 - Testing performed on 04/30/2021 (m) Patient #13 - Testing performed on 05/03/2021 (n) Patient #14 - Testing performed on 05/17/2021 (o) Patient #15 - Testing performed on 06/01/2021 (p) Patient #16 - Testing performed on 06/15/2021 (q) Patient #17 - Testing performed on 06/30/2021 (r) Patient #18 - Testing performed on 07/01/2021 (s) Patient #19 - Testing performed on 07/16/2021 (t) Patient #20 - Testing performed on 07/30/2021 (u) Patient #21 - Testing performed on 08/02/2021 and 12/02/2021 (v) Patient #22 - Testing performed on 08/12/2021 (w) Patient #23 - Testing performed on 08/16/2021 (x) Patient #24 - Testing performed on 08/31/2021 (y) Patient #25- Testing performed on 09/01/2021 (z) Patient #26 - Testing performed on 09/03/2021 (aa) Patient #27 - Testing performed on 09/30/2021 (bb) Patient #28 - Testing performed on 10/01/2021 (cc) Patient #29 - Testing performed on 10/14/2021 (dd) Patient #30 - Testing performed on 10/29/2021 and 03 /04/2022 (ee) Patient #31 - Testing performed on 11/01/2021 (ff) Patient #32 - Testing performed on 11/18/2021 (gg) Patient #33 - Testing performed on 12/02/2021 (hh) Patient #34 - Testing performed on 12/14/2021 (ii) Patient #35 - Testing performed on 12/30/2021 and 01/08/2022 (jj) Patient #36 - Testing performed on 01/03/2022 (kk) Patient #37 - Testing performed on 01/14/2022 (ll) Patient #38 - Testing performed on 01/31/2022 (mm) Patient #39 - Testing performed on 02/01/2022 (nn) Patient #40 - Testing performed on 02/14/2022 (oo) Patient #41- Testing performed on 02/28/2022 (pp) Patient #42 - Testing performed on 03/03/2022 (qq) Patient #43 - Testing performed on 03/10/2022 (rr) Patient #44 - Testing performed on 03/22/2022
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to perform function checks as defined by the manufacturer for one of one analyzer. Refer to D5431; (b) The laboratory failed to perform two levels of quality control materials 44 of 49 days of patient Chem 8+ testing reviewed. Refer to D5447.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure that laboratory personnel were performing the test methods as required for accurate and reliable results. Refer to D6014; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory director failed to ensure laboratory personnel

	were performing test methods as required for accurate and reliable results. Findings include: (1) The laboratory director failed to ensure function checks had been performed as defined by the manufacturer. Refer to D5431.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure two levels of quality control materials had been performed each day of patient testing on the iSTAT 1 analyzer. Refer to D5447.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.