Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2257432	(X3) Date Survey Completed 03/15/2024
Name of Provider or Supplier Council Oak Comprehensive Healthcare	**Street Address, City, State** 10109 E 79th St, Tulsa, 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 initial survey was performed on 03/12,13,14,15/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief operating officer, administrative director of hospital services, quality improvement, technical consultant #2, technical consultant #3, laboratory lead, and blood bank lead during an exit conference performed at the conclusion of the survey.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with technical consultant #2, the laboratory failed to follow the manufacturer's instructions for storing a patient specimen prior to Transferrin testing for one of one patient specimen. Findings include: (1) On 03/12/2024 at 11:50 am, technical consultant #2 stated Transferrin testing was performed using the Abbott Architect Plus ci4100 analyzer weekly (each Thursday) and aliquoted serum samples (pending tests) were stored in the chemistry refrigerator; (2) A review of the manufacturer's product inserts for Transferrin, under the section "Specimen Storage" stated serum /plasma can be stored at 2 to 8 degrees Centigrade for a maximum of 3 days; (3) Observation of the chemistry refrigerator on 03/12/2024 at 04:30 pm identified a patient specimen (ID #24C-068C0016.1) that had been collected from 03/08/2024

	awaiting testing (specimen was beyond the stability for testing the analyte); (4) The findings were reviewed with technical consultant #2 who stated on 03/12/2024 at 04: 45 pm, the laboratory had not followed the specimen storage requirement.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with technical consultant #2, the laboratory failed to have a written procedure for Transferrin testing. Findings include: (1) On 03/12/2024 at 11:50 am, technical consultant #2 stated the laboratory performed Transferrin testing using the Abbott Architect Plus ci4100 analyzer; (2) A review of the test volume list completed for the survey identified the laboratory performed approximately 466 Transferrin tests annually; (3) A review of the laboratory policy and procedure manual identified no evidence of a written procedure for Transferrin testing; (4) The findings were reviewed with technical consultant #2 who stated on 03/13/2024 at 9:00 am, the laboratory did not have a written procedure for performing the test.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with technical consultant #2, the laboratory failed to ensure materials were stored as required during the review period of January through February 2024. Findings include: (1) On 03/14/2024 at 02: 55 pm, observation of the contents of the Sanyo Biomedical freezer identified the following materials with storage requirements (as stated on the boxes) of -25 to -10 degrees C (Centigrade): (a) One box of Validate LP Test Set, lot #10679084 (b) One box of Validate TDM Test Set, lot #10678765 (c) One box of Validate GC3 Test Set, lot #10662819 (d) One box of Validate GCV1 Test Set, lot #10666295 (2) A review of temperature records for two months (January through February 2024) identified documented temperatures colder than -25 degrees C for two of two months as follows: (a) January 2024 - 28 of 31 temperatures were documented as colder than -25 degrees C; (b) February 2024 - 28 of 29 temperatures were documented as colder than -25 degrees C. (3) The records were reviewed with technical consultant #2 who stated on 0503/14/2024 at 03:00 pm the materials were not being stored as required by the manufacturer.

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 technical consultant #2, and testing person #1, the laboratory failed to ensure the manufacturer's instructions were followed for performing quarterly maintenance procedures on one of two Abbott Architect Plus ci4100 analyzers during the review period of January 2023 through February 2024. Findings include: (1) On 03/12/2024 at 11:37 am, technical consultant #2 and testing person#1 stated routine chemistry and immunoassay tests were performed using two Abbott Architect ci4100 analyzers denoted by the laboratory as "Dr. Bunsen" and "Beaker"; (2) A review of the onboard manufacturer's instruction manual stated the following required quarterly maintenance procedures: (a) "1003 Change Lamp"; (b) "6011 Clean Reagent Supply Centers (c8000 /c16000)"; (c) "6013 Clean Sample Carousel/Area (c8000/c16000)"; (d) "6301 Sample Syringe Maintenance"; (e) "6302 Wash Syringe Maintenance"; (f) "6303 Reagent Syringe Maintenance"; (g) "6304 Change I mL Syringes"; (h) "6305 Change ICT Asp Check Valve"; (i) "6306 Check ICT Ref Check Valves." (3) A review of maintenance logs from January 2023 through February 2024 for "Dr. Bunsen" identified no documentation quarterly maintenance had been performed between: (a) 09/19/2023 and 01/15/2024. (4) The records were reviewed with technical consultant #2 who stated on 02/13/2024 at 01:20 pm, the quarterly maintenance had not been documented as performed as shown above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2 and testing person #1, the laboratory failed to perform calibration verification procedures at least once every six months for seven of seven analytes reviewed using the Abbott Architect Plus ci4100 analyzers. Findings include: (1) On 03/12/2024 at 11:37 am, technical consultant #2 and testing person #1 stated Acetaminophen, Albumin, Ammonia, Glucose, Magnesium, HDL (High Density Lipoprotein), and HgbA1c (Hemoglobin A1c) were performed using two Abbott Architect Plus ci4100 analyzers denoted by the laboratory as "Dr. Bunsen" and "Beaker"; (2) A review of calibration records for 2023 identified the calibration procedures for the above analytes were performed with less than three levels of calibrators. Therefore, calibration verification procedures using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of records for both analyzers from 07/14/2023 through the current date identified calibration verification had not been performed at least once every six months as follows: (a) Acetaminophen, Albumin, Ammonia, Glucose, Magnesium, and HDL (High Density Lipoprotein) - Not performed after 07/27/2024 (Due 01/2024); (b) HgbA1c (Hemoglobin A1c) - Not performed after 07/14/2024 (Due 01/2024). (4) The records were reviewed with technical consultant #2 who stated on 03/14/2024 at 11:21 am, calibration verification procedures had not been performed every six months.
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, QC (quality control) package inserts, and interview with technical consultant #2, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for CBC (Complete Blood Count) testing for five of five months reviewed from June through October 2023. Findings include: (1) On 03/12/2024 at 11:50 am, technical consultant #2 stated the following: (a) The laboratory performed CBC testing using two Cell Dyn Ruby analyzers (Ruby #2 was used as the primary analyzer and Ruby #1 was used as the back up analyzer); (b) Three levels of Cell Dyn 26 Plus Control materials were performed each day of patient testing on both analyzers; (c) When new lot numbers of control materials were put into use, the laboratory established means and utilized historic SD (Standard Deviation) ranges for each analyte. (2) On 03/15/2024 a review of the manufacturer's instruction (package insert) for the control materials identified the listed ranges were to be used as a guide when implementing new lot numbers of control materials (not to be used for QC limits of acceptability) and stated, "The mean range does not represent standard deviations (SD)"; (3) A review of QC records for

three lot numbers of control materials used during the review period of June through October 2023 identified the laboratory had used either used the package insert guideline ranges or ranges wider than the package insert ranges for four of four analytes reviewed as follows: (a) Ruby #1 (i) Level 3135 (low, normal, and high) were used from 06/13/2023 through 07/20/2023 (aa) WBC (White Blood Cell) Count Low Level - The laboratory was using the package insert range of 3.7-4.5; (bb) Hemoglobin Low Level - The laboratory was using the package insert range of 6.8-7.6; (cc) Hematocrit Low Level - The laboratory was using the package insert range of 18.8-21.8 (dd) Platelet Low Level - The package insert range was 60-100 and the laboratory was using a range of 0.0-88; (ee) WBC Normal Level - The laboratory was using the package insert range of 6.4-7.8; (ff) Hemoglobin Normal Level - The laboratory was using the package insert range of 11.2-12.4; (gg) Hematocrit Normal Level - The laboratory was using the package insert range of 29.4-34.4; (hh) Platelet Normal Level - The laboratory was using the package insert range of 199-259; (ii) WBC High Level - The laboratory was using the package insert range of 13.7-18.7; (jj) Hemoglobin High Level - The laboratory was using the package insert range of 15.1-16.7; (kk) Hematocrit High Level - The laboratory was using the package insert range of 38.9-45.9; (ll) Platelet High Level - The laboratory was using the package insert range of 483-603. (ii) Level 3191 (low, normal, and high) were used from 07/21/2023 through 07/31/2023 (aa) WBC Low Level - The package insert range was 3.2-4.0 and the laboratory was using a range of 2.09-5.39; (bb) Hemoglobin Low Level - The package insert range was 6.5-7.3 and the laboratory was using a range of 3.87-9.73; (cc) Platelet Low Level - The package insert range was 54-94 and the laboratory was using a range of 42.1-107; (dd) WBC Normal Level - The package insert range was 6.0-7.4 and the laboratory was using a range of 3.89-9.67; (ff) Hemoglobin Normal Level - The package insert range was 10.6-11.8 and the laboratory was using a range of 6.20-15.4; (gg) Hematocrit Normal Level - The package insert range was 28.6-33.6 and the laboratory was using a range of 16.3-42.7; (hh) Platelet Normal Level - The package insert range was 197-257 and the laboratory was using a range of 113-303; (ii) WBC High Level - The package insert range was 12.7-17.7 and the laboratory was using a range of 6.25-23.4; (jj) Hemoglobin High Level - The package insert range was 14.4-16.0 and the laboratory was using a range of 6.11-22.5; (kk) Hematocrit High Level - The package insert range was 37.8-44.8 and the laboratory was using a range of 16.6-61.4; (ll) Platelet High Level - The package insert range was 471-591 and the laboratory was using a range of 195-767. (iii) Level 3247 (low, normal, and high) were used from 09/12/2023 through 10/31/2023 (aa) WBC Low Level - The package insert range was 3.5-4.3 and the laboratory was using a range of 2.05-5.83; (bb) Hemoglobin Low Level - The package insert range was 6.6-7.4 and the laboratory was using a range of 3.13-10.0; (cc) Platelet Low Level - The package insert range was 55-95 and the laboratory was using a range of 39.9-119; (dd) Hemoglobin Normal Level - The package insert range was 10.9-12.5 and the laboratory was using a range of 7.75-14.3; (ee) WBC High Level - The package insert range was 12.9-17.9 and the laboratory was using a range of 7.45-22.8; (ff) Hemoglobin High Level - The package insert range was 14.5-16.1 and the laboratory was using a range of 6.31-22.5; (gg) Platelet High Level - The package insert range was 482-612 and the laboratory was using a range of 276-848. (b) Ruby #2 (i) Level 3135 (low, normal, and high) were used from 06/03/2023 through 07/20/2023 (aa) WBC Low Level - The laboratory was using the package insert range of 3.7-4.5; (bb) Hemoglobin Low Level - The laboratory was using the package insert range of 6.8-7.6; (cc) Hematocrit Low Level - The laboratory was using the package insert range of 18.8-21.8; (dd) Platelet Low Level - The laboratory was using the package insert range of 60-100; (ee) WBC Normal Level - The laboratory was using the package insert range of 6.4-7.8; (ff) Hemoglobin Normal Level - The laboratory was using the

	package insert range of 11.2-12.4); (gg) Hematocrit Normal Level - The laboratory was using the package insert range of 29.4-34.4; (hh) Platelet Normal Level - The laboratory was using the package insert range of 199-259; (ii) WBC High Level - The laboratory was using the package insert range of 13.7-18.7; (jj) Hemoglobin High Level - The laboratory was using the package insert range of 15.1-16.7; (kk) Hematocrit High Level - The laboratory was using the package insert range of 38.9-45.9; (ll) Platelet High Level - The laboratory was using the package insert range of 483-603. (ii) Level 3191 (low, normal, and high) were used from 07/21/2023 through 08/31/2023 (aa) WBC Low Level - The laboratory was using the package insert range of 3.2-4.0; (bb) Hemoglobin Low Level - The laboratory was using the package insert range of 6.5-7.3; (cc) Hematocrit Low Level - The laboratory was using the package insert range of 18.2-21.2; (dd) Platelet Low Level - The laboratory was using the package insert range of 54-94; (ee) WBC Normal Level - The laboratory was using the package insert range of 6.0-7.4; (ff) Hemoglobin Normal Level - The laboratory was using the package insert range of 10.6-11.8; (gg) Hematocrit Normal Level - The laboratory was using the package insert range of 28.6-33.6; (hh) Platelet Normal Level - The laboratory was using the package insert range of 197-257; (ii) WBC High Level - The laboratory was using the package insert range of 12.7-17.7; (jj) Hemoglobin High Level The laboratory was using the package insert range of 14.4-16.0; (kk) Hematocrit High Level - The laboratory was using the package insert range of 37.8-44.8; (ll) Platelet High Level - The laboratory was using the package insert range of 471-591. (iii) Level 3247 (low, normal, and high) were used from 09/12/2023 through 10/31/2023 (aa) WBC Low Level - The package insert range was 3.5-4.3 and the laboratory was using a range of 1.99-5.91; (bb) Hemoglobin Low Level - The package insert range was 6.6-7.4 and the laboratory was using a range of 3.48-10.3; (cc) Platelet Low Level - The package insert range was 55-95 and the laboratory was using a range of 38.2-118; (dd) WBC Normal Level - The package insert range was 6.1-7.5 and the laboratory was using a ranage of 1.26-12.2; (ee) Hemoglobin Normal Level - The package insert range was 10.9-12.5 and the laboratory was using a range of 2.17-20.6; (ff) Platelet Normal Level - The package insert range was 194-254 and the laboratory was using a range of 41.0-407; (gg) WBC High Level - The package insert range was 12.9-17.9 and the laboratory was using a range of 4.90-25.9; (hh) Hemoglobin High Level - The package insert range was 14.5-16.1 and the laboratory was using a range of 4.90-26.1; (ii) Hematocrit High Level - The package insert range was 37.7-44.7 and the laboratory was using a range of 21.1-62.9; (jj) Platelet High Level - The package insert range was 482-612 and the laboratory was using a range of 176-948. (4) The records were reviewed with technical consultant #2 who stated on 03/15/2024 at 10:54 am, the laboratory had used ranges that would not detect immediate error.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 technical consultant #2 and technical consultant #3, the laboratory failed to perform QC (quality control) as stated in the IQCP (Individualized Quality Control Plans) for i-STAT 1 test system for one of 12 months reviewed. Findings include: (1) On 03/12/2024 at 11:30 am, technical consultant #2 and technical consultant #3 stated the following: (a) The laboratory performed pH, PCO2, PO2, HCO3, Sodium, Potassium, Ionized Calcium, Glucose, Hematocrit, and Hemoglobin testing using the CG8+ Cartridge and i-Stat 1 analyzer (SN #431327) in the ICU Room; (b) Two levels of QC (quality control) materials were tested monthly according to the IQCP (Individualized Quality Control Plan). (2) A review of QC records from January 2023 through December 2023 identified no documentation to prove QC had been performed as stated in the QCP (Quality Control Plan) between 07/31/2023 and 09/02/2023; (3) The records were reviewed with technical consultant #2 who stated on 03/14/2024 at 02:45 pm, QC had not been performed as shown 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 a patient report and interview with technical consultant #2, the laboratory failed to provide therapeutic reference intervals for INR test results for one of one report reviewed. Findings include: (1) On 03/13/2024 at 01:15 pm, technical consultant #2 stated INR-International Normalized Ratio testing was performed using the ACL TOP 350 analyzer; (2) A review of one patient report with INR results for a patient tested on 03/05/2024 identified the report did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (3) The report was reviewed with technical consultant #2 who stated on 03/14/2024 at 12:35 pm, the patient report did not include a therapeutic range for INR.