Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2257432	01/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Council Oak Comprehensive Healthcare	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 recertification survey was performed on 01/13/2026 through 01/16/2026. The laboratory was found in compliance with standard-level deficiencies cited.
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. 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 follow control procedures that monitored the accuracy and precision of the testing process; and detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for three of three analytes reviewed for the Abbott Architect #1 chemistry analyzer from 06/26/2025 through 08/27/2025. Findings include: (1) On 01/14/2026 at 10:30 am, technical consultant #2 stated the following: (a) Total Bilirubin (TBIL), Direct Bilirubin (DBIL), and High Density Lipoprotein Cholesterol (HDL) testing were performed using the Abbott Architect #1 analyzer; (b) Two levels of Bio-Rad Liquid Assayed Multiqual control materials were performed each day of patient testing; (c) When new lot numbers of control materials were put into use, the laboratory calculated their own mean and SD (standard deviation), based on the initial workup of a lot number of QC and the historical data of that lot number. (2) On 01/15

	/2026 a review of the manufacturer's instructions (package insert) for the control materials stated, "The mean and corresponding +/- 3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish it's own acceptable ranges and use those provided only as guides"; (3) A review of QC records for two lot numbers of control materials used during the review period of 06 /26/2025 through 08/27/2025 identified the following: (a) Level one lot # 46031 and level three lot#46303 were in use - The laboratory was using package insert guideline ranges, instead of the laboratory's calculated ranges as follows: (i) Total bilirubin (TBIL) (aa) Level One - The laboratory was using the package insert guideline range of 0.293 - 0.627 mg/dL. (bb) Level Three - The laboratory was using the package insert guideline range of 5.35 - 7.01 mg/dL. (ii) Direct bilirubin (DBIL) (aa) Level One - The laboratory was using the package insert guideline range of 0.234 - 0.366 mg /dL. (bb) Level Three - The laboratory was the package insert guideline range of 2.56 - 3.19 mg/dL. (iii) High density lipoprotein cholesterol (HDL) (aa) Level One - The laboratory was using the package insert guideline range of 20.9 - 28.5 mg/dL. (bb) Level Three - The laboratory was using the package insert guideline range of 59.5 - 79.1 mg/dL. (4) The records were reviewed with technical consultant #2, who stated on 01/15/2026 at 1:30 pm, the laboratory had used the package insert guideline ranges as shown above.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interviews with Technical Supervisor #2 and Technical Supervisor #4, the laboratory failed to ensure that blood products were stored under appropriate conditions for two of sixteen alarm checks reviewed between January 2024 through December 2025. Findings include: I. BLOOD BANK REFRIGERATOR (1) On 01/14/2026 at 03:30 pm, Technical Supervisor #4 stated PRBC (Packed Red Blood Cells) were stored in the blood banking refrigerator for patient transfusions; (2) A review of the alarm check policy required the low and high alarm system to be tested quarterly; (3) A review of alarm check records between January 2024 through December 2025 identified no evidence an alarm check was performed between 01/31/2025 and 07/17/2025; (4) The findings were reviewed with Technical Supervisor #2 and Technical Supervisor #4, who stated on 01/15/2026 at 11:44 am, the low and high alarm check had not been documented as performed. II. BLOOD BANK FREEZER (1) On 01/14/2026 at 03:25 pm, Technical Supervisor #4 stated FFP (Fresh Frozen Plasma) was stored in the blood banking freezer for patient transfusions; (2) A review of the alarm check policy required the high alarm system to be tested quarterly; (3) A review of alarm check records between January 2024 through December 2025 identified no evidence of an alarm check was performed between 01/31/2025 and 07/17/2025; (4) The findings were reviewed with

	Technical Supervisor #2 and Technical Supervisor #4, who stated on 01/15/2026 at 11: 44 am, the high alarm check had not been documented as performed.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with Technical Supervisor #2 and Technical Supervisor #3, the Technical Supervisors failed to ensure competency evaluations for high complexity testing had been performed at least two times (semiannually) during the first year of testing for two of three testing persons reviewed. Findings include: (1) On 01/13/2026 a review of personnel records for two of three testing persons performing high complexity testing identified the following: (a) Testing person #3 - The initial training was completed on 03/27/2024 and the first competency evaluation was completed on 08/27/2024. The second competency evaluation was not performed until 10/21/2025; (b) Testing person #6 - The initial training was completed on 07/26/2024 and the first competency evaluation was completed on 03/28/2025. The second competency evaluation was not performed until 10/05/2025. (2) The records were reviewed with Technical Supervisor #2 and Technical Supervisor #3 who stated on 01/15/2026 at 04:00 pm, the semiannual competency evaluations had not been performed. Note: High complexity testing included ABO/Rh typing, Antibody Screen, and Compatibility testing.