Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1089529	09/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ccso	2465 N Whisenant Dr, Duncan, 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 validation survey was performed on 09/04/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and testing person #1 at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the technical consultant, the written competency assessment policy did not define the frequency of the assessments for the technical consultant based on the position responsibilities for one of one technical consultant. Findings include: (1) A review of the competency assessment policy titled, "Technical Consultant Job Description" identified it did not define the frequency of the assessments; (2) Interview with the technical supervisor on 09/04/2025 at 10:39 am confirmed that although the competencies based on the position responsibilities of the technical consultant had been performed annually, the policy did not define the frequency of the assessments.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by:

	Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results for one of five Hematology Proficiency testing events reviewed in 2024 and 2025. Findings include: (1) A review of Hematology Proficiency testing records for five events (First 2024, Second 2024, Third 2024, First 2025, and Second 2025) identified the following failure with no evidence that corrective action had been documented as performed: (a) Third 2024 Event - The laboratory attained a score of 80% for MCH (Hem-3) Sample Hem -14. (2) Interview with the technical consultant on 09/04/2025 at 12:20 pm confirmed corrective action had not been taken and documented for the failure.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with testing person #1, the laboratory failed to ensure an expired material was not available for use. Findings include: (1) Observation of the refrigerator in the storage room on 09/04/2025 at 09:50 am, identified one vial of Mindray SC-CAL PLUS calibrator - lot #PLUS0725 with an expiration date of 08/05/2025; (2) Interview with testing person #1 on 09/04/2025 at 10:13 am confirmed the expired material was available for use.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory director failed to perform onsite visits at least once every six months during the review period of January 2025 through the current date. Findings include: (1) On 09/14/2025 at 12:10 pm, the technical consultant and testing person #1 stated the laboratory director was not housed on-site; (2) A review of records and interview with the technical consultant and testing person #1 on 09/04/2025 at 12:35 pm confirmed the laboratory director had not performed on-site laboratory visits during the review period as stated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for two of five proficiency testing events reviewed in 2024 and 2025. Findings include: (1) On 09/04/2025 at 11:30 am, a review of 2024 and 2025 proficiency testing events identified attestation statements had been signed after the graded evaluations were completed by the proficiency testing program for two of five events reviewed: (a) Third event 2024 Hematology/Coagulation - The graded evaluation was completed on 12/09/2024 and the attestation statement had not been signed by the laboratory director until 12/19/2024; (b) First event 2025 Hematology /Coagulation - The graded evaluation was completed on 04/16/2025 and the attestation statement had not been signed by the laboratory director until 05/05/2025. (2) The records were reviewed with the technical consultant who stated on 09/04/2025 at 12:20 pm the attestation statements had not been signed timely as stated above.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure proficiency testing reports were reviewed for one of five Hematology events reviewed in 2024 and 2025. Findings include: (1) A review of 2024 and 2025 Hematology proficiency testing events identified the "Performance Evaluations" included a space for the laboratory director or designee signature and date (indicating review of the graded evaluation). The following was identified for one of five events: (a) API Third event of 2024 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee. (2) The records were reviewed with the technical consultant who stated on 09/04/2025 at 11:48 am, the graded evaluation had not been signed and dated as reviewed by the laboratory director or designee.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for two of two testing persons during the review period of March 2023 through the current date. Findings include: (1) On 09/04/2025, a review of personnel records for two persons performing moderate complexity testing from March 2023 through the current date identified no evidence an annual competency evaluation had been performed for two of two testing persons as follows: (a) Testing Person #1 - not performed between 09/12/2023 and 03/03/2025 (b) Testing

	Person #2 - not performed prior to 03/05/2025 (2) The records were reviewed with the technical consultant who stated on 09/04/2025 at 11:02 am, the annual evaluations had not been documented as performed as stated above.