# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 38D2157177	**(X3) Date Survey Completed** 03/17/2026
Name of Provider or Supplier Central Oregon Surgical Institute	**Street Address, City, State** 1550 Ne 27th St Suite 110, Bend, OR	
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
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 review of laboratory's policies and procedures and interview with the office administrator, the laboratory failed to have a written policy to assess laboratory personnel competency. Findings include: 1. Upon requesting the laboratory's procedure for assessing laboratory personnel, none could be produced. 2. Interview with the office administrator at 2:00pm on 03/17/2026 confirmed there was no policy for assessing laboratory personnel. 3. The laboratory performs 100 moderate complexity tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 review of the maintenance records for the Abbott iSTAT analyzer, review of the Abbott iSTAT procedure and interview with testing personnel (TP), the laboratory failed to ensure manufacturer's guidelines for semi-annual maintenance was being performed and documented. Findings include: 1. Upon request for the iSTAT semi-annual maintenance documentation none could be produced. 2. Review of the laboratory's iSTAT procedure lacked any instruction on performing the required semi-

	annual thermal probe check maintenance. 3. Interview with TP #1 at 1:30pm on 03/17/2026 confirmed findings.
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 review of Quality Control (QC) records, review of the Individualized Quality Control Plan (IQCP) policy for the Abbott iSTAT analyzer and interview with testing personnel (TP), it was revealed that QC was not being performed and documented at the frequency established by the laboratory. Findings include: 1. Upon request for documentation of QC performed on the iSTAT analyzer, none could be produced. 2. Upon review of the laboratory's IQCP policy, the established QC frequency for the iSTAT analyzer was not being followed. 3. Interview with TP #1 at 1:30pm on 03/17/2026 confirmed the findings. 4. The laboratory performs 100 iSTAT tests annually.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of the 2025 Wisconsin State Laboratory of Hygiene (WSLH) proficiency test (PT) results and interview with the office administrator, the laboratory director (LD) failed to ensure complete corrective action (CA) was performed and documented for failed analytes. Findings include: 1. Upon review of the 2025 Wisconsin State Laboratory of Hygiene (WSLH) PT results, it was revealed that the laboratory failed to ensure complete CA was documented for event one (1) and event three (3) in 2025. a. 2025 Blood Gas event #1, incomplete CA documentation for failed analytes: Hematocrit - BGB-2 Hemoglobin - BGB-2 pO2 - BGB-1 b. 2025 Blood Gas event #3, incomplete CA documentation for failed analyte: pCO2 - BGB-6 2. Upon request for the laboratory's procedure for CA on unacceptable or failed PT results, none could be produced. 3. Interview with the office administrator at 2:45pm on 03/17/2026 confirmed the failure to document complete CA on failed or unacceptable PT results. 4. The laboratory performs 100 moderate complexity tests annually.