

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304589	(X3) Date Survey Completed 11/21/2025
Name of Provider or Supplier Oxford Family Practice	Street Address, City, State 6 Allen Pkwy, Oxford, AL	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Tosoh G8 Glycohemoglobin Laboratory Procedure Manual, the Tosoh G8 Glycohemoglobin analyzer maintenance records and interviews with the Laboratory Director (LD), who is also the Technical Consultant (TC), and Testing Personnel 1 (TP1), the laboratory failed to replace the filter as instructed by the manufacturer. The surveyor noted non-compliance with the manufacturer's instructions approximately for two and a half months out of the 10 months reviewed in 2025. The findings include: 1. A review of the Tosoh G8 Glycohemoglobin Laboratory Procedure Manual revealed on page 9-31 the following instructions. e. Replacing the Filter Element 1. Replace the filter element after 400 injections or when the pressure exceeds limits as indicated on the column inspection report plus 4 megapascal. 2. A review of the Tosoh G8 Glycohemoglobin analyzer maintenance logs revealed the filter was replaced on December 31, 2024. However, the next filter replacement was not performed until March 12, 2025, when the number of injections was recorded at 1186. 3. A further review of the maintenance log revealed the log did not indicate the acceptable pressure range after every column replacement. 4. The LD /TC and TP1 confirmed the above findings during the exit conference on 11-21-2025 at 1:57 PM.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(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)</p>

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 reviews of the 2025 Tosoh G8 Glycohemoglobin analyzer Calibration-Verification (C-V) records, the Tosoh G8 Glycohemoglobin analyzer procedure manual and an interview with the Laboratory Director (LD), who is also the Technical Consultant (TC), the laboratory failed to perform and document the C-V at least every six months as per laboratory procedure. The surveyor noted no documentation for one of the two Tosoh G8 C-V due in 2025. The findings include: 1. A review of the Tosoh G8 Glycohemoglobin analyzer records revealed no documentation of C-V for the first half of 2025. 2. A review of the Tosoh G8 Glycohemoglobin analyzer procedure manual revealed on page 15-16, the analyzer has a two-point calibration procedure with low and high calibrators. 3. During an interview on 11-21-2025 at approximately 11:57 PM, the LD/TC stated it is the laboratory's policy is to perform C-V on the Tosoh G8 analyzer at least every six months. However, the C-V due in February 2025 was missed because the Testing Personnel assumed the Tosoh service engineer had performed the C-V with the annual preventive maintenance completed that month. 4. The LD/TC confirmed the above findings during the exit conference on 11-21-2025 at 1:57 PM.