Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2058341	01/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Prescott Healthcare Solutions, Llc Dba	3151 N Windsong Dr, Prescott Valley, AZ	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 lack of calibration verification documentation for the Beckman DXC 700 and TOSOH G8 analyzers and interview with the General Supervisor (GS-1), the laboratory failed to perform and document calibration verification procedures at least once every 6 months during 2023 and 2024. Findings include: 1. The laboratory began performing A1C testing utilizing the TOSOH G8 analyzer in February 2023. 2. The laboratory began performing chemistry testing on patients utilizing the Beckman DXC 700 analyzer in September 2023. 3. No documentation was presented for review to indicate the laboratory performed a calibration verification on the Beckman DXC 700 analyzer at least once every six months during 2024, 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. 4. No documentation was presented for review to indicate the laboratory performed a calibration verification on the TOSOH G8 analyzer at least once every six months during 2023 and 2024, 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. 5. The GS-1 interviewed on 1/27/25 at 10:20 AM confirmed the laboratory failed to perform calibration verification procedures on the chemistry analyzers indicated above during 2023 and 2024. 6. The laboratory's reported annual test volume in the specialty of Chemistry is 1,024,414.