Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2297305	10/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Abo Plasma- West Valley City	3495 W 3500 S, West Valley City, UT	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: _ Based on record review and interview with the Quality Director, the laboratory failed to ensure verification of performance specifications of four of four Reichert digital refractometers before reporting patient test results. _ Findings include: 1. Record review on 10/22/2025 failed to demonstrate the accuracy, between day precision, and of the verification that the manufacturer's reference intervals are appropriate for the laboratory's patient population for four of four Reichert digital refractometers with the following identification numbers: 17920-1223, 17926-1223, 17927-1223, and 18039-0224 2. Interview with the Quality Director on 10/22/2025 at approximately 3:45 PM, confirmed the laboratory failed to verify the accuracy, between day precision, and of the verification that the manufacturer's reference intervals are appropriate for the laboratory's patient population for four of four Reichert digital refractometers before reporting patient test results. 3. The laboratory performed approximately 50,000 total protein tests annually. _
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy,

	precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: _ Based on record review and interview with the Quality Director, the laboratory director (LD) failed to ensure the verification procedures were adequate for four of four Reichert digital refractometers before reporting patient test results. _ Findings include: 1. Record review revealed the LD failed to sign and date the document "Equipment Qualification - Refractometer" as approved for use prior to reporting patient test results for four of four Reichert digital refractometers with the following identification numbers: 17920-1223, 17926-1223, 17927-1223, and 18039-0224 2. In an interview conducted on 10/22/2025 at approximately 4:15 PM the Quality Director confirmed the LD's approval signature was missing from the document "Equipment Qualification - Refractometer" for laboratory refractometers. 3. The laboratory performs approximately 50,000 total protein tests annually.