

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2093052	(X3) Date Survey Completed 07/29/2025
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 14088 Woodward Avenue, Highland Park, MI	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Assistant Manager of Quality (AMQ), the laboratory failed to ensure that quality control materials (1 of 10) were not used beyond their expiration dates. Findings include: 1. During a tour of the laboratory conducted on 07/29/2025 at 9:30 AM, the surveyor observed one unopened vial of Normal Level Refractol (Lot# K305912) with an expiration date of 11/30/2024. The expired vial was stored alongside nine unexpired vials of Normal Level Refractol (Lot# STI586N, expiration date 04/30/2026). 2. A review of the laboratory's policy titled Digital Refractometer Activities on page 3 of 3 revealed in the section titled Control Reading, "Inspect the control vial for suitability - Control is not expired ...". 3. A review of the laboratory's policy titled Reagent and Vaccine Check on page 1 of 2 revealed in the section titled Expired Reagents, Controls or Vaccines, "Discard any expired reagents and controls by placing them in a sharp's container.". 4. An interview was conducted on 07/29/2025 at 9:35 AM, with the AMQ who confirmed that an expired control was available for use to test patients.</p>