

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2189480	(X3) Date Survey Completed 02/03/2021
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 1417 Hanover Ave, Allentown, PA	
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>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 of the Laboratory area and interview with the Center Manger and Assistant Manager of Quality, the laboratory failed to ensure, 2 of 3 vials of Kova International Refactrol Serum Protein Reference Controls (High and Normal) used to analyze total protein, were not used beyond their expiration dates in 2020 and 2021. Findings Include: 1. The Opening a New Sub Lot standard operating procedure states, "For Digital Refractometer and Mircohematocrit controls: The expiration date is always 14 days after opening the vial to include the opening date as day one." 2. On the day of survey, 02/03/2021, observation of the laboratory area revealed, 2 of 3 vials of Kova International Refactrol Serum Protein Reference control materials (High and Normal) were used pass there expiration dates: a. 1 of 1 vial of Kova International Refactrol Serum Protein Reference Controls, High control. - Lot #: K303961, Sub Lot: 7, Open date: 10/7/2020, Expiration date: 10/20/2020. b. 1 of 1 vial of Kova International Refactrol Serum Protein Reference Controls, Normal control. - Lot #: K304604, Sub Lot:4, Open date: 12/09/2020, Expiration date: 12/22/2020. 3. From 10 /20/2020 to 02/03/2021, 2862 donors were tested for total protein. 4. From 12/22/2020 to 02/03/2021, 1464 donors were tested for total protein. 5. The Center Manger and Assistant Manager of Quality confirmed the findings above on 02/03/2021 around 1: 00 pm.</p>