

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2227274	(X3) Date Survey Completed 04/23/2025
Name of Provider or Supplier Kedplasma Llc	Street Address, City, State 1700 N. Zaragoza Rd. Suite 160, El Paso, TX	
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
D0000	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of validation survey completed April 23, 2025.
D6066	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii)</p> <p>(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has-</p> <p>(b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii) (B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii) (C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii) (E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b) (6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based upon review of the Laboratory Personnel Report, policies and procedures, and interview of facility personnel, the laboratory failed to have documentation of training for one of nineteen testing personnel performing total protein testing. The findings included: 1. Review of the Laboratory Personnel Report (dated 04/16/2025) found the laboratory defined nineteen testing personnel performing moderate complexity procedures. 2. Review of the laboratory's written policy TM-1.1 titled General Raining Instructions found on page 10 under the heading Total Protein/Hematocrit Test Assessment Certification: The specific training item used to document the</p>

Laboratory (CLIA) Director's assessment/approval of protein testing personnel. A certified Area Expert also documents the trainee's hematocrit test performance. This is completed initially, six months after the initial assessment/approval, one year after the initial assessment/approval, and annually thereafter." 3. Review of employee personnel records found no documentation of initial training for testing person nine (hire date 10/27/2022) listed on the Laboratory Personnel report. 4. During interview of the training coordinator conducted April 23, 2025 at 11:54 AM, she confirmed that initial training had not been completed at this facility. She went on to say that testing person nine had originally been trained at another location in a different city.