Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2144027	04/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kedplasma, Llc	8989 Forest Lane Suite 100, Dallas, 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 substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 review of laboratory policy, calibration verification records, and in staff interview, the laboratory failed to evaluate the calibration verification raw data to ensure the refractometers were acceptable for the total protein analyte at least once every six months in 2024 and 2025 for 11 of 11 calibration verification testing records for the 11 Reichert TS Meter -DSP Refractometers. Findings included: 1. Review of laboratory policy titled "Refractometer Calibration Verification" stated:

	"FREQUENCY Calibration Verification is required for each refractometer: Prior to first use At least every 6 months, thereafter Following major repair where there is a replacement of critical parts When control materials reflect an unusual trend or shift (i. e., if control readings are significantly different than other devices being checked at the same time) ... PROCEDURE 1. Follow these steps below to obtain Refractrol control readings and record data on the Refractometer Calibration Verification Spreadsheet (F5004). Step 1 Action Assemble and prepare the essential items. Step 2 Action From MasterControl access the Refractometer Calibration Verification (Excel Spreadsheet) (F5004) and enter the following information: Center ID Date Performed Refractrol Low (i.e. abnormal), Normal and High Control Lot Number, Expiry Date, and Low/High Limit to be used. If a vial has reached or exceeded the expiration date, obtain a new vial prior to continuing with this procedure. In the Equipment ID columns, record the Equipment# for each refractometer to be verified. Step 3 Action Follow the applicable steps and best practices for refractometer use and routine QC testing per SOP-21.3 Refractometer. Concurrently, record the results on F5004 for each refractometer: Obtain and record the ambient temperature. Obtain and record the distilled water reading. Obtain a reading for each of the low, normal and high Refractrol controls on one refractometer at a time until all refractometers have been tested ... Step 4 Action When all the control values are entered, F5004 will display a PASS or FAIL result for each refractometer in the Equip Interpretation section ... Step 5 Action The completed F5004 is printed and used to enter the calibration verification results in the DMS. Enter Pass/Fail in the DMS, as applicable, for the Calibration Verification on each refractometer and initial in the corresponding space on F5004. Sign / date in the spaces designated for the person completing the form. Attach copies of the manufacturer's assay sheets." 2. Review of the calibration verification activities performed 07/13/2024 discovered the laboratory used the following Kovatrol control testing each control once to verify the reportable range: Low Control: Lot# K306759, expiration date: 11/30/2026, acceptable range 3.9 - 4.7 g/dL Normal Control: Lot# K306166, expiration date: 02/28/2026 acceptable range 7.3 - 8.1 g/dL High Control, Lot# K306089, expiration date: 11/30/2025, acceptable range 9.8 - 10.6 g/dL. The following refractometers were tested by equipment number with the results of the Low (L), Normal (N) and High (H) Controls in g/dL: a. L2444: L 4.4, N 7.5, H 10.3 b. L2445: L 4.5, N 8.0, H 10.5 c. L2446: L 4.6, N 8.0, H 10.4 d. L2447: L 4.5, N 7.5, H 10.3 e. L2448: L 4.4, N 8.0, H 10.0 The equipment interpretation for each refractometer stated "PASS". The laboratory failed to evaluate the calibration verification data to ensure the refractometers were linear throughout the reportable range of the test system. 3. Review of the calibration verification activities performed 01/09/2025 discovered the laboratory used the following Kovatrol control testing each control once to verify the reportable range: Low Control: Lot# K306759, expiration date: 11/30/2026, acceptable range 3.9 - 4.7 g/dL Normal Control: Lot# K306161, expiration date: 03/31/2027 acceptable range 7.2 - 8.0 g/dL High Control, Lot# K306089, expiration date: 11/30/2025, acceptable range 9.8 - 10.6 g/dL The following refractometers were tested by equipment number with the results of the Low (L), Normal (N) and High (H) Controls in g/dL: a. E04336: L 4.6, N 8.0, H 10.4 b. E04337: L 4.5, N 7.9, H 10.4 c. E04338: L 4.5, N 7.8, H 10.4 d. E04340: L 4.3, N 7.7, H 10.1 e. E04339: L 4.4, N 7.5, H 10.2 f. E04329: L 4.6, N 8.0, H 10.4 The equipment interpretation for each refractometer stated "PASS". The laboratory failed to evaluate the calibration verification data to ensure the refractometers were linear throughout the reportable range of the test system. 4. During an interview in the conference room on 04/29/2025 at 11:26 a.m., the laboratory representatives after a review of the records, confirmed the laboratory failed to evaluate the calibration verification raw data to ensure the refractometers were acceptable for the total protein analyte at least once every six months in 2024 and 2025.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on the lack of laboratory policy, Reichert TS Meter -DSP Refractometer quality control (QC) records for total protein analyte, and staff interview, the laboratory failed to verify the criteria for acceptability of all control materials for four of four lot numbers in 2024. Findings included: 1. On 04/29/2025 at 11:43 a.m., the laboratory was asked to provide a policy for the verification of new quality control material. No policies were provided. 2. Random review of total protein QC records tested on the Reichert TS Meter -DSP Refractometer revealed the following QC lot numbers were placed into service and the laboratory failed to verify new quality control lot against the manufacturer's assay ranges for the low and high control levels in 2024: Low Control: Lot# K306759, expiration date: 11/30/2026; dates tested 06/2024 through 02 /2025 Normal Control: Lot# K306166, expiration date: 02/28/2026; dates tested 06 /2024 through 02/2025 On 04/29/2025 at 12:15 p.m., the laboratory was asked to provide the dates the above lot numbers were placed into use. The laboratory could not provide the dates. 3. During an interview in the conference room on 04/29/2025 at 11:43 a.m., the Center Manager stated the laboratory did not verify the acceptability criteria for QC before placing a new lot into use, confirming the above findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory personnel records, and confirmed in interview, the Laboratory Director failed to specify in writing the responsibilities and duties 17 of 17 Testing Persons (TP-1 through TP-17) performing moderate complexity testing. Findings included: 1. Review of the CMS 209 form listed TP-1 through TP-17 as testing personnel performing moderate complexity testing. 2. Review of personnel records for TP-1 through TP-17 revealed a delegation of "Medical Screener" that were signed by personnel who were NOT the laboratory director. The laboratory director did not specify, in writing, which procedures TP-1 through TP-17 were authorized to perform. 3. During an interview on 04/29/2025 at 9:

	57 a.m., the laboratory representatives confirmed the laboratory director failed to specify in writing the responsibilities and duties 17 of 17 Testing Persons (TP-1 through TP-17) performing moderate complexity testing. Word key: CMS: Centers for Medicare and Medicaid Services