Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2222655	06/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Kamada Plasma, Llc	85 N 23rd Street, Beaumont, 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 the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an recertification survey completed on June 24, 2026, and recertification is recommended. Standard level deficiencies were cited.
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 review of laboratory documentation, laboratory policy, laboratory verification studies, and confirmed in interview, the laboratory failed to ensure the manufacturer's reference intervals were appropriate for the laboratory's patient population for one of one Reichert clinical refractometers before it was put into use for patient testing on February 12, 2025. The findings included: 1. Review of laboratory documentation included the following Reicher clinical refractometer, used in the measurement of patient serum total protein, put into use February 6, 2025: SN: 17288-1122 2. Review of the laboratory's verification studies did not include the evaluation of patient normal values, reference intervals, approved before the instrument was put into use. Surveyor asked for documentation that the studies had been performed and none could be provided. 3. Review of the laboratory policy titled "Quality Assurance: Process Validation, Equipment and Reagent Validation" included the following instruction: " ... 4. Perform a donor population study (parallel testing)

	when a different manufacturer's reagent and/or piece of equipment replaces the one in use." 4. In an interview on 6/24/2026 at 10:00 hours, in the office, the quality manager confirmed the normal patient reference range studies had not been documented in the validation of the Reichert refractometer before it was put into use.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control documentation, laboratory policy, laboratory instrument validation records, and confirmed in interview, the laboratory failed to perform calibration verification, to verify the laboratory's reportable range, for one of one Reichert clinical refractometers since it was put into use for patient testing on February 6, 2025. The findings included: 1. Review of the laboratory policy titled "Quality Assurance: Process Validation, Equipment and Reagent Validation", section 5. "Determine linearity, if appropriate, as follows": "Perform initially, at a minimum of twice yearly and when an instrument has been repaired, changed or when controls demonstrate an unexpected result." 2. Review of laboratory daily quality control sheets included the daily calibration with distilled water, with an acceptability of 0.0 +/-0.01, to be performed prior to quality control and patient samples. 3. Review of the laboratory document titled "Validation of TS Meter-DSP Serum/Plasma Protein Refractometer" included the following reportable range: Total Protein: 0.0 to 15.1 g/mL 4. Surveyor asked for the laboratory's documentation of calibration verification records since it was put into use, and none could be provided. 5. In an interview on 6/24/2026 at 09:55, in the office, the laboratory quality manager and the Executive Director of the laboratory, confirmed calibration verification had not been performed since it had been put into use February 12, 2025.