Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0925340	12/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Jeffrey L Stein Md Pa	9291 Glades Rd Ste 306, Boca Raton, FL	

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	A recertification survey conducted, 12/21/2022 found the JEFFREY L STEIN MD PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have attestations signed by testing person (TP) and laboratory director (LD) for five out of six events for Hematology/Coagulation specialty, six out six events of Chemistry Core and four out of four events of Chemistry Miscellaneous and failed to have the LD to sign attestation for one out of six events in Hematology/Coagulation specialty for the last 2 years. Findings include: -Review of American Proficiency Institute (API) proficiency testing (PT) records for years 2021 and 2022 revealed that a) The laboratory failed to have attestation signed by the TP and LD in the following events: 1- Hematology /Coagulation first and third event 2021, first, second and third event 2022. 2- Chemistry Core for the first, second and third event of 2021 and 2022. 3- Chemistry Miscellaneous first and second event 2021 and 2022. b) The Laboratory failed to have attestation signed by LD for second event of 2021 for Hematology/Coagulation specialty. During an interview on 12/21/2022 at 1:30 PM, the laboratory consultant confirmed that the laboratory failed to have a signed attestation for the events of reference.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 record review and interview with Laboratory Consultant (LC), the laboratory failed to have documentation of the calibration verification for the Cell-Dyn 1800 complete blood analyzer at least every 6 months from 01/01/2021 to 12/21/2022. Findings include: -Review of the Cell-Dyn 1800 Analyzer revealed that the laboratory performed calibration on 10/28/2022. No other calibration records found. During an interview on 12/21/2022 at 12:00 PM, the LC explained that they cannot print from the CBC instrument and she was not able to provide any other documentation of previous calibrations verification performed in 2021 and first half of 2022.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory Quality Assessment (QA) failed to identify and correct the deficiency of incomplete documentation of required maintenance for the Cobas e411 and Cobas Integra 400 Analyzer in 2021 and 2022. The QA failed to correct the deficiency of not having records for calibration verification in 2021 and 2022. The QA failed to ensure the laboratory had records of the Annual Preventive Maintenance for the Cobas e411, Cell-Dyn 1800 and Cobas Integra analyzers for 2021 and 2022. The QA failed to identify the missing Room Temperature and Room Humidity record for March 2022. Findings include: -Review of Monthly QA policy checklist revealed that the Laboratory will review that all required temperatures will be taken. The QA checklist failed to include verification of

	instruments maintenance. -Review of maintenance logs for Cobas Integra 400 analyzer revealed that the monthly logs for February, May, July and September of 2021 failed to have the monthly maintenance action (clean waste box fitting and clean ISE tower manually) documented. No correction documented in QA. -Review of monthly maintenance log for Cobas e411 analyzer revealed that the following logs failed to have every 2 month maintenance action (replace pinch valve tubing) documented: Jan, May and November 2021 and March, May, July and September of 2022. No corrective action documented in the QA. -Review of maintenance logs for Cell-Dyn 1800 analyzer revealed that no monthly maintenance action (rinse lyse inlet line and rinse reagent inlet lines) documented for April 2021 and October 2022. . No records for maintenance for September 2022. No corrective action documented for the missing maintenance actions. -Review of temperature logs for 2021 and 2022 revealed that the record for March 2022 was missing. No corrective action documented for the missing record. -The laboratory had no records for anual preventive maintenance for the Cobas e411, Cell-Dyn 1800 and Cobas Integra analyzers for 2021 and 2022. No corrective action documented for the missing documentation for this deficiency. During an interview on 12/21/2022 at 1:30 PM, the laboratory consultant confirmed that the QA failed to correct the deficiencies listed above.