

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0925340	(X3) Date Survey Completed 04/18/2025
Name of Provider or Supplier Jeffrey L Stein Md Pa	Street Address, City, State 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	An announced CLIA recertification survey was conducted at Jeffrey L Stein MD PA on March 17, 2025 to April 18, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews, the laboratory failed to verify twice annual accuracy for Urinary Beta-Trace Protein (UIBC) testing in 2024. Findings Included: 1. Review of 2024 American Proficiency Institute Chemistry -Core revealed the following: 2nd event in 2024 for Urinary Beta-Trace Protein was 60%. 3rd event in 2024 for Urinary Beta-Trace Protein was 0%. There was no documentation of a rerun for Urinary Beta-Trace Protein failures. 2. Review of Policy: "Proficiency testing" signed by laboratory director read, "corrective action is to be taken on out of range results. This may include thawing and repeating specimen analysis or checking for clerical mistakes." 3. On 03/18/2025 at 4:59 PM, Testing Personnel confirmed the Laboratory failed to have verified twice annual accuracy for UIBC testing in 2024.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>

applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the Laboratory failed to store ISE Calibrator Indirect/Urine, ISE Calibrator direct and ISE Electrolytes reagent for Cobas integra instrument at manufacture's required temperature. Findings included: 1. On 03/18/2025 at 3:47 PM, ISE Calibrator Indirect/Urine, ISE Calibrator direct and ISE Electrolytes reagents were stored on top of the fridge with the air conditioner blowing on them with a temperature gauge. 2. a. Review of ISE Calibrator Indirect/Urine, ISE Calibrator bottle read store "15 to 25 Celsius (C)." b. Review of ISE Calibrator direct bottle read "15 to 25 C." c. Review of ISE Electrolytes direct bottle read "15 to 25 C." 3. Review of laboratory Policy Manual: "Room Temperature and Humidity" read, "if the temperature exceeds any of the established ranges listed below, testing is to be discontinued. The office is to be notified so that the appropriate corrective actions can be initiated. Room temperature: 20 to 26 C." 4. Review of March and February 2025 Room Temperature Logs revealed the following dates were above 25 degrees C: On 02/03/2025 the room temperature listed was 25.3 C On 02/04/2025 the room temperature listed was 26.3 C On 02/05/2025 room temperature listed was 27.1 C On 02/07/2025 room temperature was listed to be 25.3 C On 02/11/2025 room temperature listed was 26.8 On 02/13/2025 room temperature listed was 26.4 On 02/14/2025 room temperature listed was 25.1 On 02/19/2025 room temperature listed was 26.6 On 02/20/2025 room temperature listed was 28.1 On 02/26/2025 room temperature listed was 25.1 On 02/27/2025 room temperature listed was 26.3 On 02/28/2025 room temperature listed was 25.8 On 03/14/2025 the room temperature listed was 25.9 C. On 03/18/2025 room temperature listed was 27.1 C. 5. Interview on 03/18/2025 at 4:59 PM, Testing Personnel confirmed reagents were not stored at required temperatures.