

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0929531	(X3) Date Survey Completed 08/28/2025
Name of Provider or Supplier Boca Raton Physicians Pa	Street Address, City, State 1905 Clint Moore Rd Ste 201, 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 Boca Raton Physicians PA on June 09, 2025 to August 28, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory stored Linearity FD chemistry, Linearity FD bilirubin and Linearity FD Lipids for Roche systems outside of manufacturer's requirements. Findings Included: On 6/9/2025 at 3:42 PM, 2 Linearity FD chemistry, Linearity FD bilirubin and Linearity FD Lipids reagents were stored in freezer with a biohazard sticker. Each Linearity kit read, "store "2 to 8 Celsius (C)." Freezer's temperature gauge read, -17 C. Review of General Maintenance policy read, "Review all package inserts for information on required storage temperatures for reagents, calibrators, quality control and patient specimens. Verify that refrigerators and freezers within the laboratory meet these minimum requirements. Review of Temperature logs read, "Freezer temperature (-10) - (-25) Celsius(C)." On 6/9/2023 at 4:00 PM, the Office Manager and Technical Consultant confirmed the linearities were not stored based on manufacturer's guidelines.</p>

D5805**TEST REPORT**

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to identify the specimen source for 2 out of 2 patient reports reviewed. Findings Included: Review of patient reports revealed the following: 1. Patient #1 was collected on 7/10/2024 at 12:17 PM, and tested on 7/10/2024 at 4:01 PM, for complete blood count (CBC) with a specimen source listed as other. 2. Patient #2 was collected on 12/28/2023 at 11:05 AM, and tested on 12/28/2023 at 11:11 AM for CBC with specimen source listed as blank. Review of report policy revealed there was no policy on reports. On 6/9/2025 at 4:00 PM, the Office Manager and Technical Consultant confirmed 2 out of 2 lab reports did not have specimen identity.