

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0902966	(X3) Date Survey Completed 04/27/2023
Name of Provider or Supplier Premier Cardiology Of Boca Raton, Llp	Street Address, City, State 1000 Nw 9th Ct 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	A recertification survey conducted from 04/25/2023 to 04/27/2023 found the LEWIS GOTLIEB SALTZMAN EDEP & BRODSKY MD LLP clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5427	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c)</p> <p>(c) Documentation. The laboratory must document all activities specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have documentation that the laboratory director reviewed and approved the ABX Micros 60 Complete Blood Counter (CBC) analyzer verification on 04/27/2022. Findings included: - Review of the ABX Micros 60 CBC analyzer verification study performed on 04/27/2022 revealed that the study failed to have the acceptance signature of the laboratory director. The laboratory tested 2876 patients from 04/27/2023 to 04/25/2023. During an interview on 04/25/2020 at 12:30 PM, Testing Person # A confirmed that the laboratory failed to have documentation that the laboratory director reviewed and approved the ABX Micros 60 CBC analyzer verification study before patient testing.</p>