

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0219525	(X3) Date Survey Completed 02/15/2023
Name of Provider or Supplier David Oneil Md Pa	Street Address, City, State 17 Fontana Lane Suite 201, Baltimore, MD	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure that the PT samples were routinely performed with the laboratory's regular patient workload. Findings: 1. The blood banking PT records for 2021 and 2022 (six events) were reviewed. Two of six events showed that the PT samples were tested without patient and quality control (QC)specimens. 2. The five PT samples from the third event of 2022 were tested on 09 /16/2022. The patient logs show that no patients were tested that day and the QC logs show that no QC was tested that day. 3. The five PT samples from the first event of 2022 were tested on 02/03/2022. The patient logs show that no patients were tested that day and the QC logs show that no QC was tested that day. 4. During the survey on 02/15/2023 at 10:45 AM, the TC confirmed that the blood banking PT samples were not being routinely performed with the laboratory's regular patient workload along with the QC materials to ensure accurate and reliable test results.</p>