

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  08D1061103	<b>(X3) Date Survey Completed</b>  11/12/2025
<b>Name of Provider or Supplier</b>  Michael K Rosenthal, D O, P C	<b>Street Address, City, State</b>  2300 Pennsylvania Ave, Wilmington, DE	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification Survey was conducted on November 12, 2025 at approximately 2:30PM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
<b>D6093</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on document review, interview, and facility policy review, the Laboratory Director (LD) and/or an appropriate, designated staff member failed to review quality control (QC) records on a monthly basis and results of proficiency testing bi-annually for 2 (2024 and 2025) of 2 years reviewed. Findings included: An undated facility policy titled "Quality Assessment Procedures," revealed "All Quality Control (QC) records such as log sheets that have not been reviewed previously will be reviewed by the Laboratory Director or an appropriate, designated staff member on a monthly basis." The policy specified, "The programs and methods used for Proficiency Testing [PT] and results of this testing will be evaluated by the Laboratory Director or an appropriate, designated staff member bi-annually." The "Proficiency Testing (Method: Peer Review)" cases for MR24-0164 dated 01/31/2024, MR24-0155 dated 01/31/2024, MR24-1722 dated 10/22/2024, MR24-1711 dated 10/22/2024, MR25-0235 dated 02/27/2025, MR25-0558 dated 05/01/2025, MR25-1338 dated 09/04/2025, and MR25-1596 - 10/16/2025 revealed no evidence of review by the LD or an appropriate, designated staff member. The "H &amp; E [hematoxylin and eosin] Quality Control" records for 01/2024 - 11/2025 revealed no evidence of review by the LD or an appropriate, designated staff member. During an interview on 11/12/2025 at 3:40 PM,</p>

the LD was asked where the review of the PT was documented. The LD stated he reviewed the results, but did not document the review. Per the LD, he had not designated a staff member to perform the review. During a follow-up interview on 11/12/2025 at 3:50 PM, the LD was asked where the review of the QC results were documented. The LD stated he did not review the QC results and had not designated a staff member to perform the review.