

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D1061103	(X3) Date Survey Completed 05/11/2022
Name of Provider or Supplier Michael K Rosenthal, D O, P C	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification Survey was conducted on May 11, 2022 at approximately 2:30 pm at Michael K. Rosenthal, DO PC. The laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows:
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: lack of documentation and interview, the laboratory failed to perform competency assessment on testing personnel. The findings include: 1. At approximately 3:20 pm on May 11, 2022 during record review, no competency assessment policies or procedures were available for the Technical Consultant (TC). 2. During the interview at approximately 3:30 pm the Laboratory Director (LD) confirmed there was no Standard Operating Procedure (SOP) or documentation of competency assessment. No documents were provided at the conclusion of the survey at 3:45 pm.</p>