

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  08D2019169	<b>(X3) Date Survey Completed</b>  09/23/2022
<b>Name of Provider or Supplier</b>  Regional Medical Associates Pa	<b>Street Address, City, State</b>  240 Beiser Blvd, Suite 201, Dover, 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 at approximately 8:30 am on September 23, 2022 at Regional Medical Associates. The laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows:
<b>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 with the Laboratory Director (LD) and the Testing Personnel (TP). The laboratory failed to address any of the six elements of Competency Assessment(CA) of Testing Personnel. Additionally, there is no Standard Operating Procedure (SOP) addressing CA. Findings include: 1. At approximately 8: 30 am on September 23, 2022 during record review of CA, none was found for the the TP. 2. During the interview, the LD and TP stated that there was no CA for TP, and no SOP to specifically address the six minimal regulatory requirements for CA at all. 3. At the end of the interview at approximately 9:45 am, no documentation was provided that addressed Competency Assessment.</p>