

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  08D2019169	<b>(X3) Date Survey Completed</b>  06/05/2018
<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>D6094</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the 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 review of the Procedure Manual and interview with the General Supervisor it is determined that the Laboratory Director is not providing a Quality Assessment program to identify and communicate Quality Failures as they occur. Findings include: 1. In review of the Laboratory's Procedures no documents indicating a Quality Assessment Procedure or Program could be provided to the surveyor. 2. In interviewing the General Supervisor they confirmed that the Laboratory did not have a Quality Assessment or Quality Assurance program.</p>
<b>D6103</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must 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: Based on review of procedure manual, personnel files and interview with the General Supervisor it was determined that the Laboratory Director failed to ensure the</p>

competency of personnel performing preanalytical, analytical, and post analytical phases of testing. Findings include: 1. Review of Procedures, Policies, and Personnel files failed to reveal documented evidence of evaluation and documentation of the competency of personnel for 2016, 2017, and 2018 to present. 2. Interview with the General Supervisor confirmed that competency had not been documented. The only documentation available was prior to 2016.