

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0998945	<b>(X3) Date Survey Completed</b> 01/04/2024
<b>Name of Provider or Supplier</b> Reproductive Medicine Associates	<b>Street Address, City, State</b> 25 Rockwood Place, Englewood, NJ	
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>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Endocrinology tests performed on the Roche Cobas e411 analyzer from September 2021. The findings include: 1. The laboratory did not verify Patient Normal Range. 2. The laboratory did not verify the Laboratory Information system (LIS). 3. The laboratory did not perform linearity studies on Follicle-stimulating hormone (FSH), Luteinizing Hormone (LH), Progesterone (P4), Estradiol (E2), and Beta-Human Chorionic Gonadotropin (bHCG) 4. The GS confirmed on 1/4/2024 at 11:15 am that not all PS were adequate.</p>