

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2014945	<b>(X3) Date Survey Completed</b>  06/19/2024
<b>Name of Provider or Supplier</b>  Reproductive Medicine Associates	<b>Street Address, City, State</b>  2 Industrial Way West, Eatontown, 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>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with General Supervisor (GS) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 7/27/21 to the date of survey. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 2. The GS confirmed on 6/19/24 at 11:40 am that the laboratory failed to have a procedure to verify new lots of controls before they were put in use.</p>