

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0927210	<b>(X3) Date Survey Completed</b>  07/09/2025
<b>Name of Provider or Supplier</b>  Reproductive Management Services Inc	<b>Street Address, City, State</b>  7051 Southpoint Pkwy S Ste 200, Jacksonville, FL	
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 completed on July 9, 2025 at Reproductive Management Services Inc. The facility was not in compliance with 42 CFR 493, Requirements for CLIA.
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records and interview with the Laboratory Director, the laboratory failed to perform QC each day of patient testing for the analyte Estradiol for 1 day in May 2025. The findings include: The record review of QC documentation for the Beckman Coulter Access 2 used to perform Estradiol testing showed no QC was performed on 5/23/25. Twelve patients were tested. During the interview with the Laboratory Director on 7/9/25 at 11:10am, it was confirmed QC was not performed and 12 patients were tested on 5/23/25.</p>