

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0119398	(X3) Date Survey Completed 08/07/2024
Name of Provider or Supplier Center For Reproductive Medicine	Street Address, City, State 200 A Route 73, Voorhees, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with testing Personnel (TP), the laboratory failed to take corrective action when controls were out of range for Endocrinology Testing on the Tosho analyzer from March 2024 to the date of survey. The findings include: 1. A review of the QC records revealed: a. On 3/29/24 Estrodial (E2) was out of range on two out of three levels of controls. b. On 6/3/24, 6/6/24, 6/7/27, 6/10/24 6/13/24, 6/21/24, 6/25/24, 6/26/24, 7/1/24, 7/2/24, 7/2/24, 7/8/24, 7/19/24, 7/24/24 Progesterone (PRG) were out of range on two out of three levels of controls. c. On 7/9/247/18/24, 7/22/24 PRG were out for all three levels of controls. 2. Approximately 15 patients were run and reported each day of testing. 3. The TP confirmed on 8/7/24 at 11:00 am that corrective action on failed QC was not performed.</p>