

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0974286	(X3) Date Survey Completed 11/07/2022
Name of Provider or Supplier Reproductive Medicine Institute	Street Address, City, State 4709 Golf Rd - Ste 1000, Skokie, IL	
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
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, final patient reports, and interview with testing personnel 2 (TP); the laboratory failed to monitor and correct problems problems identified in reporting pH reference ranges for semen analysis on five of five final patient reports from dates 04/05/2021 to 07/11/2022. Findings Include: 1. Review of laboratory procedures manual and final reports of five patients (PT) from dates: 04/05/2021 (PT 1) 06/14/2021 (PT 2) 11/01/2021 (PT 3) 01/03/2022 (PT 4) 07/11/2022 (PT 5) 2. Surveyor review of five of five final reports reviewed, as identified in finding #1 indicated the pH reference range for semen analysis was 7.2 to 8.5. 3. Review of the reference ranges utilized for analysis of semen samples on page 9 of the Andrology Lab Policy & Procedure Manuel 2021 revealed: g. pH: i. Normal pH: 7.2 - 8.0 4. Review of quality assessment and preventative maintenance records revealed the laboratory failed to identify the discrepancy in pH reference ranges in the laboratory's procedure manual when compared to five of five patient reports reviewed. 5. On 11/07/2022 12:25 p.m., Testing Personnel 2 confirmed the above findings. *MACROSCOPIC OBSERVATIONS ** REFERENCE RANGE</p>