

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2286016	(X3) Date Survey Completed 04/29/2025
Name of Provider or Supplier Institute For Reproductive	Street Address, City, State Professional Center Ii, Princeton, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), the lack of Data Entry Verification Reports (DEV) and interview with the Laboratory Director (LD), the laboratory personnel failed to follow the PM for Data Entry Verification from 5/1/23 to 4/29/25. The findings include: 1. The PM states "verification of the manually entered results in the LIS is performed on a quarterly basis in accordance with the Data Entry Verification SOP. Results of these verification studies and corrective actions are reviewed by the laboratory director." 2. There were no DEV available for review. 3. The LD confirmed on 4/29/25 at 10:25 am, laboratory did not follow the PM for Data Entry Verification.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT 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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records, Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to follow their</p>

procedure to verify commercial QC material with each new lot and/or shipment of QC used for Semen Analysis tests from 10/12/24 to 4/29/25. The finding includes: 1. The PM states "Prior to the expiration or exhaustion of the current lot of accu-beads, a validation must be performed using the new lot to verify manufacturer ranges and/or establish laboratory ranges. 2. New lot Accubead numbers 241405351 and 240403181 were verified on 10/15/24, but the previous lot # 043-922 expired on 10/12/24. 3. The LD confirmed on 4/29/25 at 11:20 am, new lots of QC material were not verified before the expiration of the previous lot of QC material.