

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2110492	(X3) Date Survey Completed 07/18/2024
Name of Provider or Supplier Centers For Reproductive Medicine & Wellness	Street Address, City, State 6 Bronze Pointe S, Swansea, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory director (LD); the laboratory failed to attest to the routine integration of PT samples for 3 of 18 PT events reviewed from Event 2 of 2022 through Event 1 of 2024. Findings include: 1. Review of laboratory policy and procedure manuals identified the procedure, "Kindbody CAP Proficiency Testing" which stated, under section 2. I., "The Attestation Form will have the name printed, signed, and dated by personnel that performed PT (electronically entered or physically signed). The Lab Manager (or Director if indicated) will review all PT documents (data or worksheet calculation, report form, and final report print out) and will check if results correctly submitted. The Lab Manager or Director may perform a final review before submission. After PT has been approved, the Lab Manager or Director may sign the Attestation Form (electronically entered or physically signed)." 2. Review of 18 CAP PT attestation records, from Event 2 of 2022 through Event 1 of 2024, revealed no LD (or designee) signature on 3 of 18 attestation records. a. Endocrinology Event 2 on 08-09-2022 b. Immunology Event 2 on 08 -23-2022 c. Immunology Event 2 on 09- 05-2023 3. An interview with the LD at 02:30 PM, on 07/19/2024, confirmed the LD (or Designee) failed to attest to the routine integration of PT samples for the events listed above.</p>