

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2110492	(X3) Date Survey Completed 02/19/2026
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, Collage of American Pathologists (CAP) proficiency testing (PT) records and interview with technical consultant (TC) #2; the laboratory failed to have PT samples tested by four of five TP who perform testing in the specialty of chemistry for 11 of 11 events in 2024 through the on-site survey date, 02/19/2026. Findings include: 1. Review laboratory competency documents revealed five TP authorized to perform chemistry testing on the Beckman Coulter Access 2 immunoassay system. 2. Review of CAP PT attestation statements for 11 of 11 PT events from 06/11/2024, to the date of the on-site survey, 02/19/2026, revealed TP #3 performed all chemistry proficiency testing events for the site. Year: Event: TP: 2024 K-A Ligand 3 2024 Y-A Sex hormones 3 2024 K-B Ligand 3 2024 Y-B Sex Hormones 3 2024 K-C Ligand 3 2025 S-A hCG 3 2025 Y-A Sex Hormones 3 2025 S-B hCG 3 2025 Y-B Sex Hormones 3 2025 S-C hCG 3 2025 Y-C Sex Hormones 3 3. Interview with technical consultant #2 on 02/19/2026, at 12:01 pm, confirmed the laboratory failed to have PT samples tested by four of five TP authorized to perform testing in the specialty of chemistry.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the</p>

staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Review of policy and procedure, review of laboratory personnel records, lack of documentation, and interview with technical consultant (TC) #2 ; the TC failed to ensure competency evaluations were completed for two of five testing personnel (TP) that performed chemistry testing on the Beckman Coulter Access 2 immunoassay system. Findings Include: 1. Review of the laboratory policy and procedure revealed a document titled "Personnel Training Policy" that stated: "E. Employee competency assessment and performance review will be conducted six months post hire and annually thereafter" 2. Review of laboratory personnel records revealed the laboratory failed to have competency assessments for TP #5 and #6 at this laboratory for chemistry testing on the Beckman Coulter Access 2 immunoassay system. 3. On survey date 02/19/26, at 09:40 am, interview with TC #2 confirmed that the laboratory failed to perform competency assessments for two of five TP that perform chemistry testing on the Beckman Coulter Access 2 immunoassay system.