

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2065154	(X3) Date Survey Completed 05/30/2019
Name of Provider or Supplier Davies Fertility & I V F Specialist	Street Address, City, State 2640 Patriot Blvd, Ste 260, Glenview, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the AAB (American Association of Bioanalysts) proficiency testing (PT) reports, records, manuals, and an interview with the laboratory staff, the laboratory failed to verify the accuracy of the semen analysis test it performs in the laboratory. Findings include: 1. The AAB Semen analysis results for 2017 through 2019, procedures manual, and patients' final reports were reviewed. 2. The laboratory failed to receive 'Satisfactory performance' from the AAB-PT program, in which it participates for the analysis of sperm motility. The following scores were received: *Forward Progression - Scored 50%, Event 1 of 2017; *Forward Progression - Scored 50%, Event 2 of 2017; *Forward Progression - Scored 50%, Event 1 of 2018; *Scored "0%" in Sperm Motility for Events 1 & 2 of 2018. 3. The laboratory failed to follow its PT policy to investigate all PT failures. 4. The laboratory failed to establish another method to verify the accuracy it's analysis of Sperm forward progression and motility during the period it received failure scores from AAB. 5. The sperm reports of 7 out of 7 patients selected for review showed that the forward progression and motility were reported during the periods when the accuracy of this analysis had not been verified. 6. On a Recertification survey 05/30/2019 at 11:45 AM the laboratory staff confirmed the above findings.</p>
D5393	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c)</p> <p>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures</p>

necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the laboratory staff, the laboratory failed to document all preanalytic systems quality assessment activities for the years of 2017 through 2019. Findings include: 1. The laboratory's quality assurance (QA) documents from 2017 through 2019 were reviewed. 2. The quarterly preanalytic QA checklist failed to include as documented evidence of its review process, the patients and other preanalytic processes selected for review for 7 out of 7 quarters. 3. On a Recertification survey 05/30/2019 at 11:45 AM the laboratory staff confirmed the above findings.