

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1072639	(X3) Date Survey Completed 03/28/2018
Name of Provider or Supplier Piedmont Reproductive Endocrinology Group Pa	Street Address, City, State North Grove Medical Center Ste 220, Spartanburg, SC	
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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 03/28/2018, based on the laboratory procedure manual, lack of documentation, and testing personnel interview, the laboratory failed to ensure that quality control (QC) for the Vitrolife Microcell semen analysis test was performed and documented at least once each day for 19 of 19 months reviewed (June 2016 through December 2017). Findings include: 1. The laboratory procedure manual stated that two levels of Accubeads semen analysis QC should be performed each day of Vitrolife Microcell semen analysis testing and that all QC records would be reviewed to assure that no patient test results were reported until QC is performed and found to be acceptable. 2. Documentation of QC records were unavailable for review on the day of the survey for 19 of 19 months reviewed (June 2016 through December 2017). There was no corrective action available fore review for the missing QC documentation. 3. Testing personnel confirmed during an onsite interview on 03/28/2018 at 2:00pm that the laboratory had failed to ensure that QC was performed and documented as required for semen analysis testing.</p>