

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2230568	(X3) Date Survey Completed 12/08/2021
Name of Provider or Supplier Innovative Fertility Specialists Of Alabama	Street Address, City, State One Inverness Center Parkway, Suite 210, Birmingham, AL	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Tosoh AIA-900 quality control (QC) records and an interview with the Technical Consultant, the laboratory failed to ensure at least two levels of quality control were run and acceptable, prior to analyzing patient specimens. This was noted from October 13, 2021 to November 30, 2021. The findings include: 1. A review of the QC records for the Tosoh AIA-900 analyzer revealed from October 13, 2021 to November 30, 2021, level 1 and level 3 controls were run for Beta - Human Chorionic Gonadotropin (hCG). Level 3 control revealed a result of > 400 (making this control material outside of patient reportable range). 2. During an interview on 12/08/2021 at 1:35 PM, the Technical Consultant confirmed three levels of controls (Level 1, Level 2, and Level 3) were being run from Aug 12, 2021 (first day of patient testing) to October 12, 2021; and starting October 13, 2021, only Level 1 and Level 3 were run. Also, the Technical Consultant confirmed that Level 3 control from Beta-hCG was outside of the patient reportable range and yielded a > sign when run.</p>