

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0926984	(X3) Date Survey Completed 03/20/2018
Name of Provider or Supplier American Infertility Of Ny	Street Address, City, State 21 East 69th Street, New York, NY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory policies/procedures, annual competency records and an interview with the laboratory testing personnel, the laboratory failed to have a complete policy and procedure for personnel competency. Finding Include: It was confirmed by the laboratory testing personnel on March 20, 2018, at approximately 1:30 pm that the laboratory failed to have a complete written procedure for annual competency to include direct observation of routine patient test performance which is one of six required components to assess the testing personnel's competency annually.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and an interview with the laboratory testing personnel, the laboratory director failed to ensure that the annual competency review included direct observation. Refer to D5209</p>