

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2122277	(X3) Date Survey Completed 09/28/2018
Name of Provider or Supplier Carolinas Fertility Institute	Street Address, City, State 2614 E 7th Street, Suite C, Charlotte, NC	
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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, and laboratory director (LD) interview 09/28/18, the laboratory director failed to establish a quality assessment program to assure the quality of laboratory services provided. Review of laboratory policy and procedures revealed a quality assessment notebook containing multiple outlines and policies regarding quality assessment practices. Review of quality assessment notebook revealed the laboratory director had not established the quality assessment program for the laboratory services provided. Interview with laboratory director at approximately 11:00 a.m. confirmed the laboratory quality assessment program was not established. He stated that he has been working on an effective quality assessment program, but it was not complete and has not been enacted.</p>