

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2199657	(X3) Date Survey Completed 05/11/2021
Name of Provider or Supplier West Virginia Fertility Institute	Street Address, City, State 108 Washington St W Ste 102, Charleston, WV	
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
D0000	An announced, on site, initial survey was conducted at West Virginia Fertility Institute on May 11, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory director failed to provide written job descriptions for 5 of 5 high complexity laboratory personnel positions (laboratory director, clinical consultant, technical supervisor, general supervisor, and testing personnel). Findings: 1. Review of the written policies and procedures and personnel files identified no written job descriptions for the laboratory positions of laboratory director, clinical consultant, technical supervisor, general supervisor, and testing personnel. 2. Lack of documentation included no current description of the duties and responsibilities for each person involved in the laboratory testing process. 3. An interview with the laboratory director on 5/11/2021 at 10:00 AM confirmed the findings.</p>