

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2232520	(X3) Date Survey Completed 12/08/2023
Name of Provider or Supplier Xytex Laboratories	Street Address, City, State 11020 David Taylor Drive, Suite 310, 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
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based upon the absence of verification records and interview with the TS (Technical Supervisor) on 12/8/23, the Laboratory Director failed to ensure the accuracy of semen analyses performed in the laboratory prior to the initiation of patient testing. Findings: Review of laboratory records revealed the absence of documentation that the laboratory verified the accuracy of semen analyses prior to the initiation of patient testing. In interview at approximately 11:15 a.m., the TS confirmed he was unable to gather any data that would suffice for a method validation.</p>