

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0679659	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Shady Grove Fertility Pittsburgh	Street Address, City, State 6400 Brooktree Court, Suite 100, Wexford, PA	
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
D6023	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)</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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Roche Cobas e411 chemistry analyzer verification of performance specifications records and interview with the Office supervisor, the Laboratory Director failed to ensure acceptable levels of analytical performance were established and maintained for chemistry testing performed on the 1 of 1 Roche Cobas e411 analyzer from 1/8/2024 to the date of the survey. Findings Include: 1. The Director of Laboratory Services position description states, "Responsibilities include but are not limited to ensuring operation of equipment by overseeing preventative maintenance requirements and evaluating new equipment and techniques." 2. On the day of the survey, 07/16/2024 at 10:01 am, a review of the laboratory's verification of performance specifications records for the 1 of 1 Roche Cobas e411 (s/n 90D3-21) chemistry analyzer performed on 1/8/2024 revealed the Laboratory Director failed to verify that procedures used established acceptable levels of analytical performance prior to placing the instrument in use. 3. The laboratory could not provide documentation of the Laboratory Director's signature for verification of performance specifications performed on 01/08/2024 to ensure acceptable levels of analytical performance were established and maintained for the Roche Cobas e411 chemistry analyzer prior to use. 4. The Office supervisor confirmed the findings above on 07/16/2024 at 11:10 am.</p>