

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0679659	(X3) Date Survey Completed 02/19/2020
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based upon review of hematology records and personnel interview with the Laboratory Coordinator on the date of the survey, the laboratory failed to establish and maintain a maintenance protocol, to ensure accuracy for 2 of 2 pipettes, used for sperm counts for 2 of 2 years. Findings include: 1. At the time of the survey, the laboratory failed to provide documentation of calibration from (02/14/2018 through 02/19/2020), for the Hamilton 100 ul pipette and the Diamond Pro 100 - 1000 ul pipette. 2. The laboratory failed to provide a maintenance protocol for accuracy of pipettes, on the date of the survey. 3. During the survey (15:00 hours 02/19/2020), the Laboratory Coordinator confirmed the above findings.</p>