

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2047057	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier Shady Grove Andrology Center Llc At Pa	Street Address, City, State 735 Chesterbrook Blvd, Wayne, 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
D0000	An announced CLIA Recertification survey was conducted at the Shady Grove Andrology Center LLC at PA on 4/19/2023 by the Pennsylvania Department of Health (PA DOH). The laboratory was surveyed under 42 CFR Part 493 CLIA Requirements. Specific deficiencies cited are as follows: 1. On the date of the survey, 04/19/2023 at 11:00 am, interview with the laboratory manager (LM) revealed that multiple laboratories with different CLIA certificates were operating at the same location and using the same testing personnel and equipment from 02/09/2021 to the date of the survey. 2. The laboratory failed to meet the following conditions for multiple laboratories operating at the same location with different CLIA certificates and using the same personnel and equipment: - All records (personnel competency assessments) must be kept separate and distinct for each laboratory and must clearly show that each laboratory is operating independently. - The hours of operation must be specified for each laboratory. - The hours of operation for each laboratory must be separate and distinct. The times of testing cannot overlap or be simultaneous. 3. The LM confirmed the findings above on 04/19/2023 around 11:30 am.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory manager (LM), the laboratory failed to determine the performance specifications for 3 of the 3 months</p>

that the maklar counting chambers were used for semen analysis testing and were not affected by the relocation of the laboratory from January 2023 to the date of the survey. Findings Include: 1. On the day of the survey, 04/19/2023 at 10:45 am, the laboratory could not provide documentation showing that the performance specifications of the maklar counting chambers used for semen analysis testing for 3 of 3 months were not affected by the laboratory's relocation from January 2023 to April 2023. 2. The LM confirmed the finding above on 04/19/2023 around 11:30 am.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the quality control (QC) records, lack of documentation, and interview with the laboratory manager (LM), the laboratory director (LD) failed to ensure that a QC program was established and maintained to ensure the quality of services provided for 1 of 1 test performed in hematology from 02/09/2021 to the date of the survey. Findings Include: 1. On the day of the survey, 04/09/2023 at 10:44 am, the laboratory could not provide documentation of the QC performed for the following 1 of 1 tests performed in hematology from 02/09/2021 to 04/19/2023: - Complete semen analysis performed using the maklar counting chamber. 2. The laboratory performed 465 semen analysis examinations in 2022 (CMS 116 annual volume). 3. The LM confirmed the findings above on 04/19/2023 around 11:30 am.