

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0712194	<b>(X3) Date Survey Completed</b>  08/31/2023
<b>Name of Provider or Supplier</b>  Shady Grove Fertility Ctr Of Pa- Wayne, Pa	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of Andrology Laboratory Proficiency Testing (PT) Attestation records, laboratory procedure manual and interview with Technical Supervisor (TS) #1, the Laboratory Director (LD) or designee failed to sign attestation statements for 3 of 4 Hematology PT events in 2021 and 2022. Findings include: 1. The laboratory's standard operating procedure "Alternate Proficiency Assessment Methods for Semen Analysis" states, "These records will be kept along with the attestation statement signed by the laboratory director or designee for a minimum of two years from the date of the proficiency testing event." 2. On the day of survey, 08/31/2023 at 8:50 am, review of 2021 and 2022 Andrology Laboratory PT Attestation records revealed the LD or designee did not sign the following attestation statements for semen analysis: 1st event performed on 04/22/2021 2nd event performed on 11/01/2021 1st event performed on 05/06/2022 3. TS #1 confirmed the above findings on 08/31/2023 at 10:20 am</p>