

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0909225	(X3) Date Survey Completed 12/13/2023
Name of Provider or Supplier Main Line Fertility Fort Washington	Street Address, City, State 467 Pennsylvania Ave, Suite 202b, Fort Washington, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's sperm morphology quality control (QC) records and interview with the general supervisor (GS), the laboratory failed to document the intended reactivity of the stain used for sperm morphology examinations each day of patient testing in 2023. Finding Include: 1. On the day of the survey, 12/13/2023 at 12:07 pm, review of the laboratory's sperm morphology stain QC records revealed the laboratory did not document the Astral stain reactivity for sperm morphology examinations each day of patient testing in 2023. 2. Laboratory's sperm morphology stain procedure stated that stain is checked for reactivity each day of use. 3. The GS confirmed the findings above on 05/08/2023 around 01:00 pm.</p>