

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0699703	(X3) Date Survey Completed 03/03/2020
Name of Provider or Supplier Reproductive Medicine Institute	Street Address, City, State 2425 West 22nd St, Ste 102, Oak Brook, IL	
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 procedures manual; patients test records; quality control (QC) records, and interview with the technical supervisor, the laboratory failed to test staining materials for intended reactivity each day it tested patient's specimens. Findings: 1. There were no procedures that described the laboratory's process for performing and documenting QC of the staining used to report morphology of semen specimens. 2. The surveyor reviewed 6 patients test records which included the patients' work sheets as well as the final report. 3. Review of QC records show that the laboratory documented its QC results on a form titled, "AQC Sperm Morphology Quality Control. 4. There was no documentation to show what date patients' morphology slides were stained. 5. The surveyor could not tell if QC of the morphology was performed when patients' slides were stained. 6. At 12:30 PM on March 3, 2020, the technical supervisor confirmed the surveyor's findings.</p>