

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2123490	<b>(X3) Date Survey Completed</b>  05/26/2021
<b>Name of Provider or Supplier</b>  Reproductive Medicine Institute	<b>Street Address, City, State</b>  387 Shuman Blvd - Ste 200e, Naperville, IL	
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>D5473</b>	<p><b>CONTROL PROCEDURES</b> 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 laboratory policies and procedures; patients test records; quality control records; and interview with the General Supervisor (GS), the laboratory failed to test staining materials for intended reactivity each day of use when it performed Sperm Morphology Procedures. Findings: 1. On survey date May 25, 2021 at 10:45 AM, the surveyor reviewed the laboratory's procedures manual. On a page titled, "Sperm Morphology Procedure," under "Quality Control" #8, the procedure reads as follows: "Check product performance by observing the stained slide and documentation of stain performance (see morphology stain performance documentation form)." 2. On survey date May 25, 2021 at 11:00 AM, the surveyor requested the following records: a. 10 patients' test reports b. Corresponding Quality Control records for dates the request 10 patients above were tested. 3. Review of 10 patients test records along with the corresponding Quality Control (QC) records revealed that there was no documentation to show that the laboratory performed and documented QC performance of its Sperm Morphology stain for 2 of 10 patients test records reviewed for the following dates: a. 03/25/2021 b. 04/21/2021 4. On survey date May 26, 2021 at 11:30 AM, the (GS) confirmed the surveyor's findings.</p>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p>

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures; application for CLIA certification (116); patients test records; quality control records (QC); and interview with the General Supervisor (GS), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic systems as specified. Findings: 1. Review of the laboratory's policies and procedures revealed that the laboratory included a section titled, "QUALITY CONTROL/QUALITY ASSURANCE." Under item #4 it reads as follows: "Quality assurance parameters are measured and documented." 2. On survey date May 26, 2021 at 10:00 AM, review of the 116 revealed that the laboratory has a test volume of 274 tests performed annually. 3. Review of 10 patients' test records and the corresponding QC records revealed that there was no documentation to show QC performance of Sperm Morphology Stain each day patients' specimens were tested for 2 of 10 patients. See D5473 4. There was no documentation to show Quality Assessments were performed. 5. On survey date May 26, 2021 at 11:30 AM, the GS confirmed the surveyor's findings.