

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2101776	(X3) Date Survey Completed 09/29/2022
Name of Provider or Supplier Reproductive Medicine Associates	Street Address, City, State 731 Alexander Road, Princeton, NJ	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate coded results obtained from the American Association of Bioanalysts (AAB) for Andrology & Embryology event S2 2020. The findings include: 1. The laboratory did not evaluate Code ? (This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus) response from AAB for the following: a) Antisperm Antibody IgG+IgA sample 7 in Andrology & Embryology events S2 2020 . b) Sperm Cell ID and Sperm Viability sample 8 in Andrology & Embryology event S2 2020. 2. The TP on 9/29/22 at 1:20 pm that the laboratory failed to evaluate the above mentioned coded results.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with</p>

	<p>the Testing Personnel (TP), the laboratory failed to verify the accuracy of Andrology & Embryology test results obtained from the American Association of Bioanalysts (AAB) for the S2 2020 event. The findings include: 1. The laboratory received a 100 but results were not graded. 2. There was no documented evidence the laboratory verified: a. Antisperm Antibody IgG+IgA b. Sperm Cell ID 3. The TP confirmed on 9/29/22 at 1:20 pm accuracy of the PT results were not verified</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Staining Station and interview with the Testing Personnel (TP), the laboratory failed to label all Coplin staining jars used for Semen Morphology testing from 7/31/19 to the date of the survey. The TP confirmed on 9/29/22 at 2:00 pm that all staining jars were not labeled.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Semen Morphology reagents and interview with the Testing Personnel (TP), the laboratory used expired Semen Morphology reagent from 8/9/22 to the date of survey. The findings include: 1. Hem 3 Stat Pack received 4/13/21 expired 8/9/22. 2. Approximately 84 patients were tested with the expired reagent. 3. The TP confirmed on 9/29/22 at 1:30 PM that the laboratory used expired reagent.</p>