

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2114553	<b>(X3) Date Survey Completed</b> 06/05/2018
<b>Name of Provider or Supplier</b> Reproductive Medicine Associates	<b>Street Address, City, State</b> 109 Professional View Drive, Freehold, NJ	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform a CA correctly on one out of one TP on 12/1/17 and 6/1/18. The findings include: 1. Criteria # 5 (Testing proficiency sample) and 6 (Assessmnet of problem solving skills) were not assessed. 2. The TP confirmed on 6/5/18 at 11:00 am that CA was not performed correctly.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor review of Procedure Manual (PM), observation of maintenance sticker and interview with the Testing Personnel (TP), the laboratory failed follow every six month Microscope Maintenance (MM) frequency in the calendar year 2017. The finding includes: 1. There were no maintenance records available to substantiate that the laboratory performed maintenance in 2017. 2. The TP confirmed on 6/5/18 at 11:00 am that MM was not performed in 2017. b) Based on surveyor review of PM,</p>

	<p>observation of centrifuge and interview with the TP, the laboratory failed to follow procedure PNLAAND 310 from 1/24/17 to the date of survey. The finding includes: 1. The PM stated centrifuge specimens at 1,500 rpms but the centrifuge speed was programmed 1,700 rpms. 2. The TP confirmed on 6/5/18 at 10:30 am that the PM was not followed.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that specimen source was accurate on the FR from 1/24/17 to the date of survey. The TP confirmed on 6/5/18 at 10:30 am that the specimen source was not correct on the FR.</p>
<p><b>D5807</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the Reference Interval (RI) was correct on the FR for pH test performed on Semen specimen from 1/24/17 to the date of the survey. The finding includes: 1. The PM had a pH range of <math>\geq 7.2</math> but the FR had a range of <math>&gt;7.2</math>. 2. The TP confirmed on 6/5/18 at 10:45 am that the laboratory failed to have the correct pH test RI on the FR.</p>
<p><b>D6102</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Personnel Files (PF) and interview with the Testing</p>

Personnel (TP), the laboratory director failed to ensure that all personnel records were included in PF for one of one TP from 1/24/17 to the date of survey. The findings include: 1. There was no training record in the PF. 2. There were no transcripts of education to substantiate the diploma certificate. 3. The TP confirmed on 6/5/18 at 11:00 am that records in the PF were not complete.