

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0998945	(X3) Date Survey Completed 01/30/2018
Name of Provider or Supplier Reproductive Medicine Associates	Street Address, City, State 25 Rockwood Place, Englewood, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain work records for PT performed with the American Associations of Bioanalysts (AAB) in S1 of 2016 and 2017 for andrology testing events. The TP #1 listed on CMS form 209 confirmed on 1/30/18 at 1:30 pm that the work records were not maintained.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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:</p>

Based on surveyor review of the Competency Assessment (CA) records received via email and email conversation with the Administrative Assistant, the laboratory failed to perform CA correctly on three out of three testing personnel from 2/4/16 to the date of survey. The finding includes: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. The CA on Testing Personnel #1 who was employed for 7 months in January was dated 1/2018 to 12/2018.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Administrative Assistant via email, the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from 2/4/16 to the date of the survey.