

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0998946	(X3) Date Survey Completed 02/18/2020
Name of Provider or Supplier Reproductive Medicine Associates	Street Address, City, State 475 Prospect Ave, West Orange, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL), Test Records (TR) and interview with the Testing Personnel (TP), the laboratory failed to retain male patient TR for Semen Analysis tests from 1/1/20 to the date of the survey. The finding includes: 1. From a random sample of ten male patients found in the AL eight out of ten TR were not available for review. 2. TP stated TR were not filed by the males name. 3. TP stated he was unable to locate the TR without the accompanying female name. 4. TR requested were for a review of the semen analysis results obtained manually with the Makler Chamber. 5. The TP #1 listed on CMS form 209 confirmed on 2/18/20 at 1:40 pm all patient TR were not retained in the patients name.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 Records (PR) and interview with the Testing</p>

Personnel (TP), the Laboratory Director failed to ensure that the education record for one of two testing personnel was available on the date of the survey. The TP #1 listed on CMS form 209 confirmed 2/18/20 at 1:30 pm that all education records were not available.