

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0999230	(X3) Date Survey Completed 03/27/2018
Name of Provider or Supplier Reproductive Medicine Associates	Street Address, City, State 81 Veronica Avenue, Somerset, 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
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Temperature Charts (TC) and interview with the Testing Personnel (TP), the laboratory failed to accurately monitor and document Corrective Action (CA) when the temperature where Hematology reagents were stored did not meet the established manufacturer specifications from 1/1/18 to the date of the survey. The findings include: 1. The reagent manufacturer stated Refrigerator Temperature (RT) must be 2-8 degrees Celsius (C) but the range on the TC was 2-8 +/- 2.0 C. 2. A review of the 2018 TC revealed that RT was out of range 50 out of 60 days. 3. There was no documented evidence of CA taken when the RT was out of range. 4. The TP confirmed on 3/27/18 at 9:45 am that the CA wasn't taken.</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 lack of Personnel Records (PR) and interview with the Testing Personnel</p>

(TP), the Laboratory Director failed to ensure that one of one TP had appropriate education and training documented prior to patient testing from August 2017 to the date of survey. The TP confirmed on 3/27/18 at 10:00 am that education and training was not documented.