Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0119398	01/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Center For Reproductive Medicine	200 A Route 73, Voorhees, 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	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Testing Personnel (TP), the laboratory failed to retain Semen Analysis patient work sheet records from 2/9/15 to the date of survey. The findings include: 1. The plan of correction of 4/20/17 survey stated "Retention of work sheets for two years. Reviewed by director of work sheets every six months." 2. The TP # 1 listed on the CMS form 209 stated on 1/23/19 at 10:15 am that she misunderstood the requirement and confirmed that work sheets were not retained. Note: This deficiency was cited in 4/20 /17 survey report.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory records and interview the Testing Personnel (TP), the laboratory failed to perform and document semen analysis patient specimens in duplicate from 2/9/15 to the date of survey. The findings include: 1. The

	Plan of Correction (POC) of 4/20/17 survey stated "Semen analysis protocol has been revised to include a written procedure for counting patient samples in duplicate." The attachment with POC stated "We will perform testing on all semen specimens in duplicate." 2. There were no records to substantiates POC was followed. 3. The TP # 1 listed on the CMS form 209 confirmed on 1/23/19 at 10:45 am that the laboratory did not perform patient specimens in duplicate. Note: This deficiency was cited in 4/20 /17 survey report.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to indicate the "Test Report Date" on Semen Analysis FR from 2/9/15 to the date of survey. The finding includes: 1. The Plan of Correction of survey 4/20/17 stated " P.O.L. Laboratory final report has been changed from Date to report Date." 2. The laboratory changed Endocrinology reports but not Semen Analysis (SA) reports. 3. TP # 1 listed on the CMS form 209 confirmed on 1 /23/19 at 11:00 am that the "Test Report Date" was not on SA FR. Note: This deficiency was cited in 4/20/17 survey report.