Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2064026	01/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Huntington Reproductive Center Medical Group	8112 Milliken Ave Ste 101-1, Rancho Cucamonga, CA	

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 laboratory's policy & procedure, quality control data and random patient testing records, and interview with the laboratory Director, the laboratory failed to retain patient test records including instrument printouts documenting the analytic system activities for at least 2 years. The findings include: a. The laboratory reported a semen analysis test results on 05/05/2017 for the patient accession #542366. The laboratory did not provide any document showing that the analytic activities, i.e. sperm presence or absence, sperm count and motility were performed. Due to the lack of analytic test records, it could not be assured that the test was actually performed by the laboratory. b. On January 18, 2018 at 3:10 pm laboratory Director affirmed that the laboratory did not have any analytic records for the above patient. c. The laboratory's testing declaration form, signed by the laboratory Director on January 15, 2018, stated that the laboratory performs 639 tests annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory

	director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of patient testing records, lack of analytical data and documentation, and interview with the laboratory Director, the laboratory Director failed to assure compliance with the regulations. The findings include: a. See D3031