Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2064026	08/29/2025
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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) (a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's testing records, policy & procedures and interview with the laboratory technical supervisor on August 29, 2025, at 12:35 p.m., the laboratory failed to retain its sperm count test validation records. The findings include: 1. The laboratory performed sperm count test using 2 methods: automated CASA system and manual count with Mekler chamber. Surveyor review of some test records showed a large variation in the manual repeat count. To verify if this variation was within the laboratory's established precision range, the surveyor asked for the test validation records. However, the laboratory failed to provide the test validation records. Therefore, the accuracy of the laboratory's reported test results cannot be assured and may have potential to harm patients. 2. The laboratory technical supervisor on August 29, 2025, at 12:35 p.m., affirmed that the laboratory did not have the validation records and may have been misplaced. 3. The laboratory's testing declaration form signed by the laboratory director on August 28, 2025, stated that the laboratory performed approximately 500 sperm count 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 laboratory's testing records, policy & procedures and interview with the laboratory technical supervisor on August 29, 2025, at 12:35 p.m., the laboratory director failed to ensure the test records retention requirement. The findings include: See D3033.