Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2305816	08/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Huntington Reproductive Center Medical Group	9339 Genesee Ave Ste 125, San Diego, 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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . Based on observation of the Olympus CX41 Microscope (serial number 1611449) and Makler chamber for manual microscopy; and the Hamilton Thorne CEROS II (serial number 3194000457) Computer Assisted Semen Analysis (CASA) test system, reviews of the the FDA website, the Hamilton Thorne website, and laboratory records; the lack of laboratory records, and interview with the Technical Supervisor and the Testing Person, it was determined the laboratory failed to establish performance specifications for Accuracy, Precision, Analytical Sensitivity, Analytical Specificity and Interfering substances, Reportable Range, and any other specification applicable to the laboratory's Semen Analysis. Findings included: 1. The laboratory performed Semen Analysis utilizing a manual microscopy method to idenify Sperm Morphology and the CASA method to determine Sperm Count and Motility. a. The manual microscopy procedure is a Textbook method: i. Stained microscope slides are analyzed for sperm morphology. ii. The Makler chamber is used to manually determine sperm count. b. The Hamilton Thorne computer assisted microscopy method is not approved for clinical use: i. The Hamilton Thorne website affirmed (8

	/11/25 at 5:10 PM) that the CEROS II CASA system was "Not for clinical diagnostic procedures in USA - for research purposes only". ii. The manufacturer Hamilton Thorne was not found in FDA's website for Medical Devices Database, CLIA, affirming (8/11/25 at 5:15 PM) the CASA test system was not FDA-approved. 2. The laboratory failed to have laboratory records establishing performance characteristics of it's Semen Analysis, as follows: a. Protocols specifying intruments and materials /samples used, frequency and dates of testing, testing personnel; b. Worksheets, Data, calculations, dated; c. Reports analyzing the results to establish the following specifications, and not limited to: i. Accuracy, ii. Precision, iii. Analytical Sensitivity, iv. Analytical Specificity, and substances interfering with the test (to establish criteria for Specimen rejection). v. Reportable Range of results, vi. Any other characteristics, such as comparing the laboratory's manual methods to the computer-assisted method. 3. The Technical Supervisor and the Testing Person affirmed (8/07/25 a 4:00 PM) the aforementioned failure to establish and validate test performance specifications for the laboratory's Semen Analysis at this location. 4. The reliability and quality of results reported for Semen Analysis could not be assured. Seven cases selected from the timeframe June 2024 - August 7, 2025, for laboratory and clinical review are, as follows: Date Accession # ---------- 7/17/24 1502032 10/11/24 1538704 (276025) 11/07/24 1550150 5/20/25 1629442 5/20/25 1630022 7/02/25 1647886 8/05/25 1660667 5. The laboratory stated the total test volume of 1,000 Semen Analyses annually (CMS116 CLIA Application, 8/04/25). .
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: . Based on the lack of laboratory records and deficiency cited, the Laboratory Director is herein cited for deficient practice in ensuring the laboratory's procedures for establishing and validating the accuracy, precision, and other specifications of it's Semen Analysis were adequate and complete. See D5423. .
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: . Based on the lack of laboratory records and deficiency cited, the Laboratory Director is herein cited for deficient practice in providing overall administration and oversight of the laboratory to ensure programs for quality assessment of laboratory requirements to identify failures as they occur. Findings included: 1. Under the Laboratory Director's overall administration of responsibility, the laboratory failed to establish a program of self audits to identify and correct errors as they occur. See D5423 .
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)

	(b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: . Based on the lack of laboratory records and deficiency cited, the Technical Supersvisor is herein cited for deficient practice in responsibility for establishing and validating test performance specifications of the laboratory's Semen Analysis. See D5423.