

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1063413	(X3) Date Survey Completed 02/15/2019
Name of Provider or Supplier Hrc Fertility - Encino	Street Address, City, State 15503 Ventura Blvd, Ste 200, Encino, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of random patient test results, laboratory's policy, procedure manual, and interview with testing personnel it was determined that the laboratory failed to establish criteria and description for the semen viscosity. The findings included: a. Based on review of the laboratory's policy and procedure manual, the description of a, "Watery" viscous semen is not included in the laboratory's procedure manual and yet it was a result entered. b. For one (1) out of eight (8) random patient test results reviewed covering period from 1/5/2017 to 2/7/2019, one (1) patient's viscosity result described as, "Watery." c. The testing personnel and the technical supervisor</p>

confirmed (2/15/2019, 12N) that the laboratory has no documentation to show that the, "Watery" description for viscosity is not one of the choices for a result.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on request, lack of laboratory's policy and procedure on semen viscosity description as, "Watery", interview with the testing personnel, and technical supervisor it was determined that the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. See D 5403.