Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2111678	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Rodeo Drive Women's Health Center	421 N Rodeo Dr, Penthouse 1, Beverly Hills, 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	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory policy & procedure, random patient testing records, quality control data, and interview with the laboratory Director, the laboratory failed to include test calculations and interpretation of results into the laboratory's test procedure. The findings include: a. The laboratory has developed TERC FISH test which is done at another facility. The laboratory interprets and reports the test result. The laboratory's procedure did not have any calculation and interpretation of the test result. b. The laboratory Director, on 2/15/2018 at 2:20 pm, confirmed that the procedure does not have the interpretation and need to be updated.

	c. The laboratory testing declaration form signed by the laboratory director on 1/15 /2019 states that the laboratory performs 2,330 tests, annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of random patient testing records, quality control data, and interview with the laboratory Director, the laboratory failed to include a negative and a positive control material in each day patient specimens are assayed or follow an established IQCP. The findings include: a. The laboratory reported TERC FISH result for the patient, accession # TF-19-00024 as positive however, no quality control material was included during patient testing. Since no proper quality control materials were used at the day of the patient sample testing, the validity of the obtained and reported result can not be assured. b. The laboratory Director, on 2/27/2019 at 12:35 pm, confirmed that no quality control material is used for the above tests. c. The laboratory testing declaration form signed by the laboratory director on 2/26/2019 states that the laboratory performs 2,330 tests, annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 Surveyor review of patient test records, and policy, procedure and quality control records for FISH test, and interview with the laboratory director, it was determined that the laboratory director failed to ensure the quality controls are established to assure the quality of laboratory services provided (See D5445).