Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0922822	12/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Drs Ford & Rothman, Ctr For Cosmetic & Clinical	18310 Montgomery Village Avenue #700, Gaithersburg, MD	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) and record review and interview with the laboratory staff, the laboratory did not follow written procedures for performing quality checks on potassium hydroxide (KOH) used to detect dermatophytes in skin scrapings. Findings: 1. The procedure "KOH Procedure," "Quality Control" in the SOPM states, "the 20% KOH will be examined semi-annually for contamination." 2. A review of "KOH/Scabies/Nail Fungus Test Logs" from January 2021 through December 2022 showed that results of the KOH contamination checks were logged 0 of 2 times in 2021 and 1 of 2 times in 2022. 3. During an interview on 12/16/2022 at 10:15 AM, the laboratory staff confirmed that the laboratory did not document the quality checks as stated in the SOPM.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final patient reports in the laboratory information system, and interview with the vice president of technical processing, the laboratory failed to ensure that the final test report included the correct address of the laboratory where histopathology slides are interpreted. Findings: 1. The laboratory moved to its new location in July of 2022. A final patient report reviewed from November 2022 still had the old address listed on the final report. 2. During an interview on 12/16/2022 at 11:25 AM, the vice president of technical processing confirmed that the name and address of the laboratory where histopathology slides are interpreted was not correctly documented on patient final reports.