Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1027742	11/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Foothill Dermatology Medical Center	2301 E Foothill Blvd Ste 100, Glendora, 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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for H & E quality control (QC) slides, random patient test results and interview with the laboratory staff, it was determined that; the laboratory failed to each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. The findings included: a. The laboratory's policy and procedure under the title, " Policy and Procedure for acceptance or rejection of control slide" stated, " Step 2: The quality of H&E stain, control slide will be reviewed by the lab director Dr. Sidhu and he will accept or reject the control slide. Step 3: If the Control slide is rejected all tissue slides will be returned immediately and re-cuts will be ordered. Which will be documented in our quality control log book." b. There was no documentation (daily QC slide and log book records) presented on the day of the survey (11/1/2019, 1330). c. For seven (7) out of eight (8) random patient test results reviewed covering period from 11/17/2017 to 9/27/2019, seven (7) have no documentation shown for the QC slides and on the laboratory's log book. d. The laboratory staff confirmed (11/1/2019, 1330) that the laboratory has no documentation to show for the QC slide and records.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for H&E QC slides, patient test reports, and interview with the laboratory staff it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. See D 5473 b. See D 5803
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for a test report, random patient test results and interview with the laboratory staff, it was determined that; the laboratory failed to have a test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. The findings included: a. The laboratory's policy and procedure under the title, "Collection of Specimens" stated: " Dr Sidhu will then process to read the slide and dictate microscopic description, which will be transcribed, and make into a patient report." b. For seven (7) out of eight (8) random patient test results reviewed covering period from 11/17/2017 to 9/27/2019, seven (7) patients have no report maintained as part of the patient's chart. d. The laboratory staff confirmed (11/1/2019, 1330) that the laboratory has no documentation to show of patient test reports.