Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0528669	10/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
English Dermatology	1242 E Mckellips Rd, Ste 103, Mesa, AZ	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of verification documentation and interview with the facility personnel, the laboratory failed to verify the accuracy of DTM testing performed under the sub-specialty of Mycology at least twice annually. Findings include: 1. The laboratory began DTM testing under the sub-specialty of Mycology on March 10, 2017, with an approximate annual test volume of 20. 2. No documentation was presented for review during the survey conducted on October 26, 2018 to indicate the laboratory verified the accuracy of the DTM test, which is not included subpart I, at least twice annually since testing began. 3. The facility personnel acknowledged that the laboratory failed to verify the accuracy of the test indicated above at least twice annually since testing began.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on lack of room temperature records for review and interview with the facilty personnel, the laboratory failed to monitor and document the temperature of the room where DTM test vials are stored and testing occurs. Findings include: 1. The laboratory performs DTM testing under the sub-specialty of Mycology, with an approximate annual test volume of 20. 2. No documentation was presented for review to indicate the laboratory monitored and documented the temperature of the room where testing occurs from March 10, 2017 through November 13, 2017. 3. The facility personnel confirmed that the laboratory did not have room temperature records from the time period indicated above.
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 lack of quality control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required. Findings include: 1. The laboratory began DTM testing using the Remel Dermatube medium under the sub-specialty of Mycology on March 10, 2017, with an approximate annual test volume of 20. 2. The Quality Control section of the manufacturer's package insert for the DTM medium states, "All lot numbers of Dermatophyte Test Medium (DTM) have been tested using the following quality control organisms and have been found to be acceptable. Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported". 3. No documentation of Quality Control testing was provided for review during the survey conducted on October 26, 2018 to indicate the laboratory checked each batch of media for its ability to support growth and inhibit specific organisms and produce a biochemical response, from the day testing began on March 10, 2017. 4. The facility personnel confirmed that the laboratory did not perform and document controls as required and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for the DTM test. 5. The number of patients tested during the time period indicated above could not be determined at the time of the survey.
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 lack of test reports for review and interview with the facility personnel, the laboratory failed to provide the test report for three out of three patient records reviewed during the survey. Findings include: 1. The laboratory performs DTM testing in the sub-specialty of Mycology, with an approximate annual test volume of 20. The laboratory utilizes an electronic medical record (EMR) system to maintain patient test reports. 2. No test report was presented for review in the EMR for three of out three patients (T.R. on 06/14/17, G.P. on 10/26/17, A.F. on 09/13/18). 3. The facility personnel confirmed that the laboratory failed to enter the patient's test reports into the EMR as indicated above.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's test reporting policy for KOH testing and review of patient test reports, the laboratory failed to follow established policies on reporting KOH test results. Findings include: 1. The laboratory performs KOH testing in the sub-specialties of Mycology and Parasitology, with an approximate annual test volume of 50. It is the practice of the laboratory to enter KOH test results from the KOH test log to the patient's electronic medical record (EMR). 2. The laboratory's established policy and procedure titled, "KOH Workflow" states, "Reportable Range - A normal result is negative. The reportable range of this test is either positive or negative. Report Result - Results are to be reported on the attached KOH Prep Log." 3. Review of KOH test result for patient B.C. on 03/23/17 indicated the results as negative on the KOH test log. The test results entered into the EMR for this patient indicated, "A KOH prep was ordered and evaluated from the leg, showing positive findings within normal realm." 4. The facility personnel confirmed that the laboratory failed to follow established policies and report the KOH test result as either negative or positive.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of Quality Control procedure and documentation for review, the laboratory director failed to ensure that a quality control program is established and maintained to assure the quality of laboratory services provided. See D5445 for findings.