Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2045609	08/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southeastern Skin Cancer & Dermatology	104j E Briscoe Way, Madison, AL	

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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on reviews of proficiency testing (PT) records, quality assurance (QA) records, the laboratory procedure manual, the temperature/humidity logs, and interviews with the Laboratory Director and the Laboratory Coordinator, the surveyor determined the laboratory failed to ensure the corrective actions taken effectively remediated problems identified in the general laboratory systems. The findings include: 1. A review of the 2017 API (American Proficiency Institute) PT records revealed the laboratory obtained the following scores and results for Mycology Culture testing performed on Dermatophyte Test Medium (DTM): A) 2017-A with a failing score of 60%; the laboratory had reported "No Growth" for samples #03 and #05. Expected results were Microsporum canis and Trichophyton rubrum respectively. B) 2017-B with a score of 80%; the laboratory had reported "No Growth" for a sample with expected results of Trichophyton rubrum. C) 2017-C with a score of 80%; the laboratory had reported "No Growth" for a sample with expected results of Trichophyton rubrum. 2. The only corrective action documented for the above surveys was the Laboratory Director reviewed the results with the testing personnel, with reviews of the procedure and possible websites for additional training and knowledge. In reviews of the returned results the laboratory had failed to noticed the same organism (Trichophyton rubrum) had failed to grow in three consecutive surveys, and to determine the possible significance. In an interview at 8/14/2018 at 3:00 PM, the ineffectiveness of the corrective actions taken was discussed with the Laboratory

	Director. 3. A review of the environmental logs revealed the laboratory was only documenting temperatures on days when MOHS Surgery was performed. However, patient and PT specimens were set-up and incubated on other days with no record of room temperature on those days. (Refer to D5413.) The surveyor noted temperatures in the laboratory were cold (less than 68 degrees Fahrenheit) each day temperatures were recorded in January-May and November-December 2016-2018. In an interview on 8/14/2018 at 4:00 PM, this concern was reviewed and confirmed with the Laboratory Coordinator. 4. A review of the Procedure Manual revealed no procedure for the step by step performance of Mycology Cultures. (Refer to D5403.) During an interview on 8/14/2018 at 4:00 PM, the Laboratory Coordinator was unable to specify the temperature at which Mycology Cultures should be incubated because this was not specified in a procedure. However a review of the DTM manufacturer's "Certificate of Analysis" revealed quality control organisms had been grown on each lot of media at temperatures of 68-80 degrees Fahrenheit (or 20-27 degrees Celsius). 5. A review of the 2016-2018 monthly QA records revealed Proficiency Testing, Patient Test Management, and QA were included on the monthly reviews, however no problems had been identified by the laboratory over the two year period. 6. A review of the above findings was discussed and confirmed with the Laboratory Coordinator during the exit summation on 8/14/2018 at 4:50 PM. .
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 a review of the Procedure Manual, and an interview with the Laboratory Coordinator, the laboratory failed ensure a step by step procedure for Mycology Cultures and performing Potassium Hydroxide (KOH Prep) examinations was included in the manual. The findings include: 1. A review of the Procedure Manual revealed the "Mycology Procedure" only stated what on-site tests were performed for Mycology (KOH, DTM [Dermatophyte Test Medium cultures] and Rapid Staining method). 2. During an interview on 8/14/2018 at 4:12 PM, the Laboratory Coordinator confirmed the facility did not have step by step procedures that included how to perform the test, any required quality control, interpretation of results, and reporting of the results for Mycology cultures or KOH Preps. .

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 reviews of the temperature/humidity records, the laboratory test menu, and an interview with the Laboratory Coordinator, the laboratory failed to monitor and document room temperatures each day of Mycology Culture incubation and performance in 2016 - 2018. The findings include: 1. A review of the laboratory test menu obtained during the entrance tour on 8/14/2018 at approximately 1:00 PM revealed the laboratory performed Mycology cultures, and incubated the specimen set up on Dermatophyte Test Medium at room temperature for two weeks in a laboratory drawer. 2. A review of the environmental records revealed the testing personnel only documented room temperatures on days when MOHS Surgery was performed (usually two days a week). 3. In an interview on 8/14/2018 at 4:00 PM, the Laboratory Coordinator confirmed the staff only recorded environmental parameters on days of MOHS Surgery. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on an observation of mycology cultures made during the entrance tour, and an interview with the Laboratory Coordinator, the laboratory failed to ensure two out of four cultures on patient samples were plated on in-date culture media. The findings include: 1. During the entrance tour on 8/14/2018 at approximately 1:15 PM, the surveyor noted two patients' cultures were set up on expired Troy Dermatophyte Test Medium: lot number 1704514 with an expiry of 2/14/2018, and lot number 1720107 with an expiry of 7/20/2018. 2. The above noted findings were reviewed and confirmed by the Laboratory Coordinator at 1:20 PM on 8/14/2018. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

	This STANDARD is not met as evidenced by: Based on a review of the 2017 API (American Proficiency Institute) Hematology Proficiency Testing (PT) records, and an interview with the Laboratory Director, the Director failed to ensure proficiency testing results were submitted within the timeframes established by the PT program. The was noted on one of three 2017 Microbiology surveys reviewed. The findings include: 1. A review of the 2017 API PT records revealed the second event Microbiology survey received a score of 0% for Potassium Hydroxide (KOH Prep), due to "Failure to participate". 2. During an interview on 8/14/2018 at 3:00 PM, when asked why the laboratory had received a score of 0% for KOH on the 2017-Event #2 survey, the Laboratory Director stated the laboratory had failed to submit their results on time. Thus the above findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor