Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0278426	01/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Southernmost Dermatology Llc	1411 White St, Key West, FL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP) A, the laboratory failed to document the annual competency assessment on 2 out of 2 (A, B) testing personnel for 2017 and 2018 period. Findings include: Review of employee documentation showed that the laboratory failed to have documentation of annual competency assessment on 2017 and 2018 for TP A and B. During an interview on 01 /16/2019 at 10:30 AM, with TP A, she confirmed that there was no competency assessment documented for the period of reference.
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 record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) Stain and fungal cultures at least twice annually for 1 out of 2 years reviewed (2017- 2018). Findings include: Review of laboratory's peers review records showed that there was no peer review documented for H&E stain for year 2018. Review of fungal cultures revealed only one verification. During an interview with Testing Person A at 11:00 a.

	m. on 01/16/2019, she confirmed that there was no documentation of the accuracy verification for H&E stain for 2018 and for fungal cultures only one done on 2018.
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 record review, interview with office manager (OM) and lack of documentation, the quality assurance (QA) failed to prevent the verification of H&E stain and fungal cultures in 1 out 2 years reviewed Findings include: Based on review of the Quality Assurance policy (QA) revealed that the laboratory director (LD) will ensure the comparison of test results at least twice annually. There was no documentation of the review of the LD to prevent the failure to verify at least twice a year H&E stain reading and interpretation for 2018, nor for the fungal cultures done only once during 2018. During an interview on 01/16/2019 at 10:30 AM, the OM confirmed that there was no documentation for the QA review for 2018.