

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1018060	(X3) Date Survey Completed 02/01/2018
Name of Provider or Supplier Sarasota Skin And Cancer Center Inc	Street Address, City, State 2179 S Tamiami Trl Ste 101, Osprey, 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
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with the Medical Assistant, the laboratory failed to evaluate the accuracy of the Scabies and Potassium Hydroxide (KOH) testing at least twice a year for 1 (2016) out of 2 years(2016-2017) for the Scabies testing and 2 (2016 and 2017) out of 2 years for the KOH testing (See D5217). This is a repeat deficiency from the recertification survey conducted on 2/12/2014.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Medical Assistant, the laboratory failed to evaluate the accuracy of the Scabies and Potassium Hydroxide (KOH) testing at least twice a year for 1 (2016) out of 2 years(2016-2017) for the Scabies testing and 2 (2016 and 2017) out of 2 years for the KOH testing. This is a repeat deficiency from the recertification survey conducted 02/12/14. Findings Included: Review of peer</p>

reviews for Scabies found them done 03/10/17 and 03/19/17. There was no documentation of reviews performed for 2016. Review of peer reviews for KOH found them done 01/25/17 and 11/22/16. No other documentation of reviews were provided. During an interview on 02/01/18 at 2:00 PM the Medical Assistant revealed that no other peer reviews were available for review. Review of the recertification survey conducted on 02/12/14, revealed that not performing Scabies peer review was a repeat deficiency. The plan of correction (signed and dated by the Laboratory Director 03/03/14) stated that "the Laboratory Director will review and complete form quarterly to ensure accuracy of scabies slide interpretation, even if tests have not been performed proficiency testing will be done."

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 record review and interview with the Office Manager, the laboratory failed to include the address of the laboratory location that testing was performed for 3 out of 3 patient reports pulled in the subspecialty of Mycology and Parasitology. Findings Included: Review of patient report #1 for Scabies testing (Parasitology) dated 03/10/17, patient report #2 for Potassium Hydroxide (KOH) testing (Mycology) dated 01/25/17, and patient report #3 for KOH testing dated 11/22/16 all did not have the address of the location where the testing was performed. During an interview on 02/01/18 at 3:00 PM the Office Manager confirmed that the patient report for the KOH and Scabies testing did not have the address of where the testing was performed.