Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1033712	(X3) Date Survey Completed 02/26/2019
Name of Provider or Supplier Bay Dermatology And Cosmetic Surgery Pa	**Street Address, City, State** 34941 Us Hwy 19 N, Palm Harbor, 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	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 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. This CONDITION is not met as evidenced by: Based on record review and interview with the office staff, the laboratory failed to evaluate the accuracy of the Scabies and Potassium Hydroxide (KOH) testing at least twice a year for 2 out of 2 years (2017-2018) for the Scabies testing and KOH testing (See D5217). This is a repeat deficiency from the recertification survey conducted on 01/25/2017.
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 review of employee competency records and Laboratory Personnel Report (CMS -209), and interview with the Office Manager, the laboratory failed to perform competency evaluations on 2 of 2 Testing Personnel (#B for 2017 - 2018) and (#C whose hire date was 06/2017 did not have competency evaluation for 2018) who

	perform potassium hydroxide (KOH) and Scabies testing in the subspecialties of Mycology and Parasitology for 2 of 2 (2017-2018) years reviewed. Findings Included: Review of employee competency records and the Laboratory Personnel Report (CMS - 209) revealed no competency evaluations performed on Testing Person #B for 2017-2018 and #C for 2018 who perform KOH and Scabies testing. Interview on 02/26 /2019 at 11:50 AM confirmed that the laboratory had competency forms but documented competency evaluations for Testing Person #B and #C were not available.
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 interview with the Office Manager, the laboratory failed to evaluate the accuracy of the Scabies and Potassium Hydroxide (KOH) testing at least twice a year for 2 out of 2 years(2017-2018) for the Scabies testing and the KOH testing. This is a repeat deficiency from the recertification survey conducted 01/25 /2017. Findings Included: Review of peer review records for Scabies and KOH revealed that documentation had not been performed for 2017-2018. Interview on 02 /26/18 at 10:50 AM the Office Manager confirmed that peer reviews were not available for review. Review of the recertification survey conducted on 01/25/2017, revealed that not performing Scabies and KOH peer review was a repeat deficiency. The plan of correction (signed and dated by the Laboratory Director on 02/10/2017) stated that "A new test order form has been implemented which now includes test accuracy.The Quality Assurance will be done at least every 6 months if not sooner with the convenience of the new form. Staff has been trained on the new form. Manager will monitor this to ensure this remains compliant."
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the Laboratory Director failed to ensure that the laboratory documented the training of individuals that performed subspecialty testing of mycology (Potassium hydroxide (KOH)) and parasitology (Scabies) on patient specimens. Findings included: 1. Record review of training and competency records revealed that Testing Personnel #C, who had started 6 /2017 but did not have KOH or Scabies testing training records. 2. Interview on 02/26 /2017 at 11:45 AM, with Office Manager stated Testing Personnel #C had started 06

	/2017 and had been trained but the laboratory had not documented the KOH and Scabies training.