

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1007260	(X3) Date Survey Completed 05/11/2018
Name of Provider or Supplier Bay Dermatology & Cosmetic Surgery Pa	Street Address, City, State 115 Highland Ave, Largo, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory failed to perform competency evaluations on 5 (#B, #C, #D, #E, -#F) out of 6 personnel listed on the CMS 209 for 2 out of 2 years (2016-2018) reviewed. Findings Included: Review of the CMS 209 Laboratory Personnel Report revealed Personnel #A was the Laboratory Director, Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and Testing Person. Personnel #B held the position of Technical Consultant, Technical Supervisor, and Testing Person. Personnel #C, D, E, and F all held the position of Testing Person. Review of the Quality Assurance Policy last reviewed by the Laboratory Director on 05/09/18 stated under personnel "The competency of testing personnel will be evaluated and documented annually by the Laboratory Director or an appropriate, designated technical supervisor or consultant to ensure that all staff maintains their competency in testing; Semi-annual performance assessments during the first year and annual assessments thereafter will be conducted." Review of employee files revealed that Personnel #B, C, D, E, and F did not have any competency evaluations for the positions that they held in the Laboratory since at least May of 2016. During an interview on 05/11/18 at 11:45 AM the Office Manager confirmed that there were no competency evaluations completed on Personnel #B-F.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</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.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Office Manager the laboratory failed to verify the accuracy of testing twice a year for 1 (2017) of 2 years (2016-2017) reviewed for Mycology and 2 of 2 years (2016-2017) for Parasitology. Findings Included: Review of quality assurance peer review found no peer reviews completed in 2017 for KOH (Potassium hydroxide) testing in Mycology and no peer reviews completed in 2016 and 2017 for Scabies testing in Parasitology. Review of policy and procedures last reviewed by the Laboratory Director on 05/09/18 stated for KOH and Scabies testing that "A program has been set up to review 1% of the results performed by the laboratory staff of Bay Dermatology. The reviews are performed by the Laboratory Director or an appropriate designated staff member of Bay Dermatology semi-annually and all cases that are reviewed are documented on the appropriate review sheet/log and are signed by the reviewing physician." During an interview on 05/11/18 at 11:50 AM the Office Manager confirmed that there were no additional peer reviews to verify the accuracy of testing completed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Office Manager the laboratory failed to document QA (Quality Assurance) for the laboratory for 2 out of 2 years (2016 - 2018) reviewed. Findings Included: Review of the Quality Assurance Policy last signed by the Laboratory Director on 05/09/18 stated that "the office maintains a Quality Assurance program that monitors all testing. A program has been set up to review 1% of the test results performed by the Bay Dermatology laboratory staff." It also stated that "Quarterly meetings will be conducted with relevant staff members to communicate the results of corrective action, quality control reviews and to address any concerns affecting laboratory performance." No documentation of QA activity or minutes from the quarterly meetings was provided. During an interview on 05/11/18 at 11:50 AM the Office Manager confirmed that there was no documentation of the QA performed or minutes from the quarterly meetings.