

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1007261	(X3) Date Survey Completed 07/14/2025
Name of Provider or Supplier Bay Dermatology & Cosmetic Surgery Pa	Street Address, City, State 1009 Dale Mabry Hwy, Lutz, 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
D0000	An announced CLIA recertification survey was conducted at Bay Dermatology & Cosmetic Surgery on 7/14/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>(e)(12) 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;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that prior to testing patients' specimens, one (Testing Personnel D) of four (Testing Personnel A, B, C, and D) had received the appropriate training and demonstrated they could perform all testing operations reliably to provide and report accurate results. Findings included: 1. The laboratory Procedure Manual reviewed by the Laboratory Director on 6/25/25 included Training and Competency Assessment SOP which stated the Laboratory Director will determine the competency of all personnel who are involved in pre-analytic, analytic, and post-analytic testing. Competency assessment to be done after the training, at 6 months, and annually thereafter. Training records shall be sufficiently detailed to provide confirmation that individuals performing particular tasks have been properly trained. 2. The CMS-209 Laboratory Personnel Report signed by the Laboratory Director 7/11/25 listed four Testing Personnel (TP-A, TP-B, TP-C, and TP-D). 3. Review of TP-D's records failed to include documented training records for this laboratory prior to performing patient testing. Patient logs revealed TP-D was testing and reporting patients' results independently by 8/16/2024. The "Start" competency for KOH was dated 11/22/2024</p>

by the Laboratory Director and the first for Histopathology testing 3/25/25. 4. The Laboratory Director stated via phone on 7/14/25 at 11:40 a.m. TP-D began testing patient testing 8/2024 and confirmed there was no documentation of training or demonstrated competency prior to patient testing and reporting.