

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2140803	(X3) Date Survey Completed 07/28/2025
Name of Provider or Supplier Bay Dermatology And Cosmetic Surgery Pa	Street Address, City, State 125 4th Ave Ne, Saint Petersburg, 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 initial certification survey was conducted at Bay Dermatology and Cosmetic Surgery PA on 7/28/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
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 of one (Testing Personnel A) who performed Histology testing, had received the appropriate training and demonstrated they could perform all testing operations reliably to provide and report accurate results. Findings included: 1. The Compliance Procedure Manual was reviewed and approved by the Laboratory Director on 3/14/25 included Training and Competency Assessment SOP which stated the Laboratory Director will determine the competency of all personal 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 and that their ability to perform the responsibilities has been assessed and signed by the Laboratory Director. 2. The CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 7/21/25 listed one Testing Personnel (TP-A) who performed patient Histology testing. 3. Review of TP-A's records failed to include documented training records for this laboratory prior to performing patient testing. Patient Histology log documented TP-A</p>

tested and reported patients' results independently on 4/25/25. There was no initial competency for TP-A prior or on 4/25/25 for Histology testing. 4. The Office Manager on 7/28/25 at 10:10 AM confirmed TP-A's records failed to include documentation of training or demonstrated competency prior to patient testing and reporting.