

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0950291	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier Coastal Dermatology	Street Address, City, State 1310 34th Street N Suite C, Texas City, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, CMS 116 application form, , CMS 209 Laboratory Personnel Report (CLIA) form, H&E Stain QC logs from January 2024 to July 2024, and confirmed in an interview, the laboratory failed to document H&E stain QC acceptability for 19 of 19 days by the testing personnel. The findings were: 1. Review of the laboratory's policy revealed no stain QC acceptability policy. 2. Review of the laboratory's CMS 116 application form, signed by the laboratory director on 08/12/2024, revealed the laboratory's operation hours was 7:00 am to 2:00 pm on Mondays. 3. Review of the laboratory's CMS 209 Laboratory Personnel Report (CLIA) form, signed by the laboratory director on 08/08/2024, revealed the laboratory identified 1 testing personnel which was the laboratory director. 4. Review of the laboratory's H&E stain QC logs from January 2024 to July 2024 revealed no documentation of H&E stain QC acceptability for 19 of 19 days by the testing personnel. 01/15/2024 01/22/2024 01/29/2024 02/05/2024 02/12/2024 02/26/2024 03/04/2024 03/25/2024 04/15/2024 05/01/2024 05/13/2024 05/20/2024 06/03/2024 06/10/2024 06/17/2024 07/01/2024 07/15/2024 07/22/2024 07/29/2024 5. Review of the laboratory's CMS 116 application form, signed by the laboratory director on 08/12</p>

/2024, revealed the laboratory's annual volume was 165. 6. An interview with the technical consultant on 08/13/2024 at 10:40 am in the laboratory confirmed the above findings. Key: CMS= Center of Medicare and Medicaid Services QC=Quality Control H&E=Hematoxylin & Eosin