

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1097650	(X3) Date Survey Completed 05/11/2022
Name of Provider or Supplier Palm Harbor Dermatology Pa DbA Dermatolgy	Street Address, City, State 5310 Clark Rd Ste 201, Sarasota, 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 Dermatology of Coastal Sarasota on 05/11/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to ensure quality control (QC) for hematoxylin and eosin (H&E) stains were documented and acceptable before reporting patient results from 12/19/19 - 05/11/22. Findings included: Record review of the Daily QC Worksheets for H&E stains revealed no documentation to indicate if the control slides were acceptable or not acceptable for 22 (09/29/20, 10/08/20, 10/15/20, 10/22/20, 11/05/20, 11/12/20, 11/19/20, 12/3/20, 12/10/20, 12/17/20, 10/21/21, 01/13/22, 01/20/22, 01/27/22, 02/17/22, 02/24/22, 03/10/22, 03/17/22, 03/24/22, 04/07/22, 04/21/22, and 05/05/22) out of 105 days from 12/19/19 through 05/11/22. Review of the laboratory procedure titled Quality Control Measure for Modified Hematoxylin & Eosin Routine Stain revealed "A quality control slide will be performed every day that the stain is placed into use. The Mohs [micrographically oriented histographic surgery] surgeon will review the slide in order to evaluate the stain quality." On 05/11/22 at 11:10 AM, the Laboratory Director stated the testing personnel were implying that the H&E QC was acceptable when approving the "Daily QC Worksheet" even though it was not documented.</p>