

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0945208	(X3) Date Survey Completed 04/21/2022
Name of Provider or Supplier A Comprehensive Dermatology	Street Address, City, State 1575 W Big Beaver Rd, Suite C12, Troy, MI	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL), the laboratory failed to follow their procedure for annual review for 2 (2020 and 2021) of 2 years reviewed. Findings include: 1. Record review of the "Quality Assessment Policy" revealed a lack of documentation of review for 2 (2020 and 2021) of 2 years. 2. An interview on 4/21/2022 at 9:51, the LL confirmed the policy had not been reviewed and signed by the Laboratory Director for 2020 and 2021.</p>
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory liaison (LL), the laboratory failed to detect an incorrect site on the final report for 1 (20-0389B) of 13</p>

patient reports reviewed for two years. Findings include: 1. Record review for 1 (20-0389B) of 13 patient reports reviewed revealed the site of the procedure was incorrect on the final report as follows: i. requisition and specimen log - Posterior left scalp ii. final report - Anterior left scalp 2. During the interview on 4/22/2021 at 10:24 am, the LL confirmed the final laboratory test report in the patient's paper chart did not match the site on the paper requisition and specimen log.