

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2026211	(X3) Date Survey Completed 02/04/2025
Name of Provider or Supplier Hampton Dermatology Pc	Street Address, City, State 325 Meetinghouse Lane, Ste J, Southampton, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), lack of waived test patient result, inventory, and Quality Control (QC) records, as well as interview with the Laboratory Director (LD), the laboratory failed to retain waived test documentation. FINDINGS: 1. There was no documentation of waived urine pregnancy patient test results, waived test kit QC, lot number, and expiration date inventory records from 2023 through survey date. 2. The current, approved SOPs did not include instructions for performing such record documentation and retention. 3. LD confirmed the findings on February 4, 2025, at approximately 12:00 P.M.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:

Based on review of Mohs map and patient test reports as well as interview with the LD, the laboratory failed to document name and address of the laboratory location where the test was performed. FINDINGS: 1. There was no documentation of laboratory name and address where on-site laboratory testing was performed. 2. LD confirmed the findings on February 4, 2025, at approximately 12:00 P.M.