

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2272658	(X3) Date Survey Completed 10/30/2025
Name of Provider or Supplier Long Island Dermatology	Street Address, City, State 1615 Northern Blvd Suite 400, Manhasset, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), lack of Quality Assessment (QA) policies, as well as interview with the Office Manager (OM), the laboratory failed to retain Quality Control (QC) records documenting all analytic system activities. FINDINGS: 1. There was no documentation of twice year verification for calendar year 2023 through survey date. 2. The current, approved SOPs did not include instructions for retaining such records for minimum two years. 3. The OM confirmed the findings on October 30, 2025, at approximately 11:00 A.M.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, lack of training and competency documents, as well as interview with the OM, the laboratory failed to perform and follow policies and procedures of training and competency. FINDINGS: 1. There was no documentation of Testing Person (TP) #1 and #2 training and competency assessment. 2. This is</p>

	<p>contrary to the instructions indicated in the current, approved SOPs. 3. The OM confirmed the findings on October 30, 2025, at approximately 11:00 A.M.</p>
<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, lack of QA policies, as well as interview with the OM, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory system. FINDINGS: 1. There was no documentation of annual QA performance and review from 2023 through the survey date. 2. The current, approved SOPs did not include instructions for performing an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where on-site laboratory testing was performed. 3. The OM confirmed the findings on October 30, 2025, at approximately 11:00 A.M.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the SOPs and manufacturer's specifications, lack of maintenance records, as well as interview with the OM, the laboratory failed to perform and document equipment maintenance and function checks with at least the frequency specified by the manufacturer. FINDINGS: 1. There was no documentation of microscope maintenance from 2023 through the survey date. 2. The current, approved SOPs did not include instructions for performing and maintaining records for such activity. 3. The OM confirmed the findings on October 30, 2025, at approximately 10:30 A.M.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on review of SOPs, lack of QA policies, as well as interview with the OM, the Laboratory Director (LD) failed to draft, approve quality assessment programs to assure the quality of laboratory services provided and to identify failures in quality as they occur. FINDINGS: 1. The current, approved SOPs did not include QA policies</p>

for performing an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where on-site laboratory testing was performed. 2. The OM confirmed the findings on October 30, 2025, at approximately 11:00 A.M.