

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2214982	(X3) Date Survey Completed 03/11/2025
Name of Provider or Supplier Clark Dermatology	Street Address, City, State 55 Newton Sparta Road, Newton, NJ	
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
D5429	<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 surveyor review of the Maintenance Records (MR) for the Linistat Linear Stainer (LLS), surveyor review of the LLS operators guide and interview with the Office Manager (OM), the laboratory failed to perform and document maintenance defined by the manufacturer for the LLS used for Histopathology tests from 2/1/24 to 3/11/25. The findings include: 1. There was no documented evidence maintenance was performed on the LLS that was defined by the manufacturer. 2. The OM confirmed on 3/11/25 at 1:45 pm, maintenance defined by the manufacturer was not performed.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to establish a maintenance protocol for the Linistat Stainer used for Histopathology tests from 2/1/24 to 3/11/25 The findings include: 1. The PM did not have a maintenance protocol for the Linistat Stainer used</p>

for Histopathology tests. 2. The OM confirmed on 3/11/25 at 1:30 pm, the laboratory did not have a maintenance protocol for the Linistat Stainer.

D6173

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

This STANDARD is not met as evidenced by:
Based on surveyor review of Intraoperative Reports (IR), Electronic Medical Records (EMR) and interview with Office Manager (OM), Testing Personnel (TP) failed to document accurate test results for Histopathology tests from 2/18/25 to 3/11/25. The finding includes: 1. The IR for case number AM 25-043 performed on 2/18/25 had a MOHS defect size of 2.0 x 0.8cm 2. The EMR stated a Post-Op size of 2.0 x 1.8cm 3. The IR and EMR for case number AM 25-043 did not correlate. 4. The OM confirmed on 3/11/25 at 1:50 pm, TP did not document accurate Histopathology test results.