

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2163816	(X3) Date Survey Completed 11/17/2025
Name of Provider or Supplier Dermaclinique Llc	Street Address, City, State 3085 Martin Luther King St N, Saint Petersburg, 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 Dermaclinique LLC on 11/17/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor the room temperature and humidity, and the cryostat temperature for two days (09/15 and 09/24 /2025) of twenty one days reviewed (Sept 3, 4, 10, 15, 18, 24, 25 and January 8, 9, 15, 16, 22,23, 29, 30 in 2025 and July 15, 16, 22, 23, 29, 30 in 2024), and failed to include acceptable ranges for the cryostat temperature, and room temperature and humidity on the forms used for documenting the aforementioned for three (09/2025, 01 /2025, 07/2024) of three months reviewed for the subspecialty of Histopathology. Findings included: 1. The MOHS Specimen Logs for 09/2025, 01/2025, and 07/2024 were reviewed. Testing was performed in 09/2025 on the 3rd, 4th, 10th, 15th, 18th, 24th, and 25th. For 01/2025 testing was performed on the 8th, 9th, 15th, 16th, 22nd, 23rd, 29th, and 30th. For 07/2024 testing was performed on the 15th, 16th, 22nd, 23rd, 29th, and the 30th. 2. The MOH'S Quality Assurance and Quality Control Checklist forms for 09/2025, 01/2025, and 07/2024 were reviewed. There were no</p>

acceptable ranges for the cryostat temperature, or room temperature and humidity. Additionally there was no documentation of the aforementioned for 09/15/2025 or 09/24/2025. 3. Interview with the Laboratory Director on 11/17/2025 at 11:55 a.m. confirmed the above.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document a control slide of known reactivity for hematoxylin and eosin (H&E) stained tissue was acceptable for one (01/30/2025) day of twenty one days reviewed (Sept 3, 4, 10, 15, 18, 24, 25 and January 8, 9, 15, 16, 22,23, 29, 30 in 2025 and July 15, 16, 22, 23, 29, 30 in 2024) reviewed for testing performed for the subspecialty of Histopathology. Findings included: 1. The MOHS Specimen Logs for 09/2025, 01/2025, and 07/2024 were reviewed. The log for 01/2025 revealed testing was performed on 01/30/2025. 2. The Staining Quality Control Forms for 09/2025, 01/2025, and 07/2024 were reviewed. The form was used to document the H&E stain quality of the quality control slides for each day of testing, was evaluated by the testing personnel, and documented whether the H&E stain quality was acceptable or unacceptable. There was no documentation for 01/30/2025. 3. The Lab Director was interviewed on 11/17/2025 at 11:55 a.m. They confirmed the above.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory's Quality Assurance failed to identify the cryostat temperature, room temperature and humidity were not documented for two days (09/15 and 09/24/2025) of twenty one days reviewed (Sept 3, 4, 10, 15, 18, 24, 25 and January 8, 9, 15, 16, 22,23, 29, 30 in 2025 and July 15, 16, 22, 23, 29, 30 in 2024), failed to identify the forms used to document cryostat temperature, and room temperature and humidity did not have the acceptable ranges for three of three months (09/2025, 01/2025, 07/2024), and failed to identify the acceptability of the quality control slide was not documented for one day (01/30/2025) of twenty one days reviewed for the subspecialty of Histopathology. Findings included: 1. See D5413. 2. See D5601. 3. The Monthly Quality Assurance Checklists for 09/2025, 01/2025, and 07/2024, signed by the Laboratory Director "9/31/25", 01/31/2025, and 07/31/2024 were reviewed. There was no indication any problems were identified in any of the months. 4. Interview with the Laboratory Director on 11/17/2025 at 11:55 a.m. confirmed the above.