

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2097373	(X3) Date Survey Completed 02/18/2025
Name of Provider or Supplier DermSouth Pa	Street Address, City, State 10970 Shadow Creek Parkway Suite 340, Pearland, TX	
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	A recertified survey was completed on 02/18/2025. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 the review of the laboratory's policy, maintenance records from September 2024 to February 2025, patient logs, and confirmed in an interview, the laboratory failed follow its own policy to perform maintenance on 1 of 1 cryostat (SN: S15049209). The findings were: 1. Review of the laboratory's policy under D. Cryostat Care revealed "*Defrosting (completed every 6-8 weeks...)" 2. Review of the laboratory's maintenance records from September 2024 to February 2025 for Cryostat revealed the Cryostat was defrosted on 11/19/2024 and then on 02/10/2025. Defrost maintenance on 11/19/2024 Due 01/19/2024 Next defrost maintenance on 02/10/2025 Due 4/10/2025 3. Review of the laboratory's patient logs from 01/20/2024 to 02/09/2025 revealed 16 patients had testing performed. 01/20/2025 Surg# 017 01/20/2025 Surg# 018 01/20/2025 Surg# 019 01/20/2025 Surg# 020 01/27/2025 Surg# 021 01/27/2025 Surg# 022 01/27/2025 Surg# 023 01/27/2025 Surg# 024 02/03/2025 Surg# 025 02/03/2025 Surg# 026 02/03/2025 Surg# 027 02/03/2025 Surg# 028 02/03/2025</p>

Surg# 029 02/03/2025 Surg# 030 02/03/2025 Surg# 031 02/03/2025 Surg# 032 4. An interview on 02/18/2025 at 10:53 am in the lab, the facility director confirmed the above findings.