

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2180395	(X3) Date Survey Completed 02/22/2024
Name of Provider or Supplier Dermisurgery Associates - El Campo	Street Address, City, State 3703 Fm 2765 Suite E, El Campo, 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	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.
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the review of the laboratory's records in 2023, CMS 116 application, and confirmed in an interview, the laboratory failed to have documentation for 2 of 2 comparison evaluations twice a year for 2 cryostat instruments in 2023. The findings were: 1. The surveyor's direct observation on 2/22/2024 at 10:30 am in the lab revealed the laboratory had 2 cryostat instruments. Thermo HM525 NX (Model#: 513119015) Avantik QS11 (SN: 54981) 2. An interview with the histotechnologist on 2/22/2024 at 10:40 am in the lab confirmed the laboratory used both cryostat for patient testing. 3. Review of the laboratory's records in 2023 revealed the laboratory failed to have documentation for 2 of 2 comparison evaluations twice a year for 2 cryostat instruments in 2023. 4. Review of the laboratory's CMS 116 application, signed by the laboratory director on 2/15/2024, revealed the annual volume was 320. 5. In an interview on 02/22/2024 at 11:46 am in the lab, the director (as on the sign-in sheet) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services</p>