Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2180395	07/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermsurgery Associates - El Campo	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	An initial recertification was performed on 7/14/2022. 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 of Participation in the CLIA program, and recertification is recommended.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy, laboratory and patient test records from 2021 and 2022, and confirmed in interview, the laboratory failed to document establishment studies for one of three tests: Mart-1/Melan-A (Melanoma Marker) Antibody-3 cocktail stain. Findings included: 1. Review of the package insert for the Epredia Mart-1/Melan-A (Melanoma Marker) Antibody-3 cocktail stain (Rev 0513200) under Limitations and Warranty revealed "our products are intended for research use only are not approved for clinical diagnosis, drug use or therapeutic procedures." 2. Review of the laboratory policy under Validation revealed "for consistent application of the Mart-1 protocols, an establishment study will be implemented at new sites to validate the Mart-1 staining protocol. The histologist will

	implement the study with directive from laboratory director (LD). The LD will ensure the performance characteristics are addressed and documented." 3. Review of the laboratory records available revealed no documentation of the establishment studies for the Mart-1 stain used for patient testing. 4. Random review of patient test records from 2021 and 2022 revealed the laboratory performed the following twelve patients with Mart-1 stain. 03/25/2021 Patient ID 066 04/08/2021 Patient ID 085 04/15/2021 Patient ID 092 04/22/2021 Patient ID 097 11/11/2021 Patient ID 287 11/18/2021 Patient ID 291 12/02/2021 Patient ID 299 01/27/2022 Patient ID 023 02/17/2022 Patient ID 043 03/10/2022 Patient ID 069 05/05/2022 Patient ID 119 06/09/2022 Patient ID 147 5. An interview with the HR/OP Director on 7/14/2022 at 1115 hours in the laboratory confirmed the above findings.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient records, and confirmed in interview, the laboratory quality assurance (QA) plan failed to identify and correct problems in analytic systems. Refer to D5423