

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1103581	(X3) Date Survey Completed 10/15/2021
Name of Provider or Supplier Westlake Dermatology & Cosmetic Surg	Street Address, City, State 800 S Highway 281, Marble Falls, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality control records, patient logs, and interview, the laboratory failed to ensure the Hematoxylin and Eosin (H&E) stain used in Mohs was stained predictably for 2 of 19 days of patient testing reviewed. Findings follow. A. Review of the laboratory's on-line Compliance Portal under Pathologist H&E where the intended reactivity of the H&E stain was documented from 02/05/2021 - 10/08/2021 for 19 days of patient testing showed no documentation of controls for 02/05/2021 and 04/30/2021. B. Review of the patient logs showed seven Mohs cases were reported on 02/05/2021 and 04/30/2021, respectively. C. Interview with the histotechnologist on October 14, 2021 at 1500 hours in the Mohs laboratory confirmed the findings.</p>