

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0953379	(X3) Date Survey Completed 11/03/2022
Name of Provider or Supplier Us Dermatology Partners	Street Address, City, State 5125 Preston Suite 150, Pasadena, 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 of Participation in the CLIA program, and recertification is recommended. .
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: A. Based on the review of laboratory's QC records from 9/15/22 to 10/13/22, patient reports, and confirmed in an interview found the laboratory failed to document QC materials for intended H&E stain reactivity to ensure predictable staining characteristics for Mohs histopathology slides each day of use for two of seven days reviewed. The findings were: 1. Random review of the laboratory's QC records from 9/15/22 to 10/13/22 revealed no documentation of the QC materials for intended staining characteristics of the H&E stain for Mohs histopathology slides prior to patient testing on each day of use for two of seven days reviewed. 9/29/22 10/13/22 2. Review of the patient reports for the above dates revealed 17 patients had Mohs histopathology slides. 9/29/22 PMS ID: 4139625 9/29/22 PMS ID: 4420037 9/29/22 PMS ID: 2676554 9/29/22 PMS ID: 5659653 9/29/22 PMS ID: 5695115 9/29/22 PMS ID: 4405605 9/29/22 PMS ID: 4363845 9/29/22 PMS ID: 5662982 9/29/22 PMS ID: 5520917 10/13/22 PMS ID: 5688514 10/13/22 PMS ID: 5345880 10/13/22 PMS ID: 4358787 10/13/22 PMS ID: 4309940 10/13/22 PMS ID: 4347653 10/13/22 PMS ID: 2695938 10/13/22 PMS ID: 5644516 10/13/22 PMS ID: 5730242 3. An interview</p>

with the Laboratory Director on 11/3/22 at 10:48 am in the lab confirmed the above findings. Key: QC=Quality Control H&E=Hematoxylin & Eosin. B. Based on the review of the laboratory's policy, QC records, CMS 116 application, and confirmed in an interview found the laboratory failed to document stain QC acceptability for 20 of 20 days reviewed for one of one stains: H&E Stain. The findings were: 1. Review of the laboratory's policy revealed no stain QC acceptability policy. 2. Review of the laboratory's QC records revealed no documentation of stain QC acceptability for H&E stain by surgeon/pathologist for 20 of 20 days reviewed. 3. Review of the laboratory's CMS 116 application signed by the LD on 9/20/22 revealed the annual volume was 2400. 4. An interview with the lab tech on 11/3/22 at 10:20 am in the lab confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services QC=Quality Control H&E=Hematoxylin & Eosin LD=Laboratory Director