

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1021286	(X3) Date Survey Completed 01/18/2018
Name of Provider or Supplier Us Dermatology Partners Georgetown	Street Address, City, State 700 San Gabriel Village Blvd, Ste 105, Georgetown, 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	The laboratory was surveyed and found to be in compliance with the conditions of the CLIA regulations found at 42 CFR 493.and recertification is recommended.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory policy, and interview with facility personnel, the laboratory failed to label an aliquot of xylene with the preparation dates, expiration dates, and storage requirements for 1 of 1 aliquot of xylene. The findings included: 1. At 10:35 hours on 01/18/2018, the surveyor observed an aliquot labeled "xylene" in the laboratory's flame proof cabinet. 2. Review of the laboratory's policy "Histopathology - Mohs Surgery" stated the following: "4.2 Preparation and labeling 4.2.3. All reagents are to be labeled with the following information: Reagent Dilution Date prepared Technician Temperature for storage (if not room temperature)." 3. In an interview at 10:35 hours on 01/18/2018 in the laboratory, the Office Manager confirmed the aliquot of xylene was missing preparation dates, expiration dates, and storage requirements.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observations, review of laboratory policy, and interview with facility personnel, the laboratory failed to ensure 2 of 6 margin marker ink containers had not been used when they exceeded their expiration dates. The findings included:

1. At 10:35 hours on 01/18/2018, the surveyor observed 2 of 6 margin marker ink containers that had expired and were available for testing: 1) Stat Lab Red margin Marker -Lot 34371 - Expiration: 11/2016 2) Stat Lab Blue margin marker - Lot: 34949, Expiration: 12/ 2016
2. Review of the laboratory's policy "Histopathology - Mohs Surgery" stated the following: "4.3 Storage Use and Handling 4.3.3 - Do not use reagent after expiration date"
3. In an interview at 10:35 hours on 01/18/2018 in the laboratory, the Office Manager confirmed the 2 margin marker ink containers had exceeded their expiration date and had been used in patient testing. The laboratory reported performing an estimated 573 Mohs cases per year.