Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1004117	(X3) Date Survey Completed 05/30/2018
Name of Provider or Supplier Lakeway Dermatology & Skin Cancer Center Pa	**Street Address, City, State** 3464 Rr 620 South, Bee Cave, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Based on surveyor observations and interview with facility personnel, the laboratory failed to ensure 1 of 1 stain marking dye aliquot was labeled with identify, storage requirements, preparation and expiration dates on May 30, 2018. The findings included: 1. At 10:40 hours on 5/30/2018, the surveyor observed a small plastic container that had an aliquot of orange tissue marking dye. The container had previously contained Stat lab 10 percent neutral formalin. The container did not have any markings about the identity, storage requirements, or preparation and expiration dates of the new substance. 2. In an interview at 10:49 hours on 5/30/2018, the Regional Clinical Manager confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other 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 and interview with facility personnel, the laboratory

	failed to ensure that 6 of 6 mounting media supplies that had exceeded the expiration date where not available for patient testing on 5/30/2018. The findings included: 1. At 09:26 hours on 5/30/2018, the surveyor observed the following expired mounting media reagents on top of the of laboratory's cryostat in a blue rectangular box: Richard-Allan Scientific Neg-50 Blue Reference: 6502B Lot: 337633 Expiration: 2 /2018 Elapsed time of expiration: 90 days Richard-Allan Scientific Neg-50 Orange Reference: 6502O Lot: 340596 Expiration: 1/2018 Elapsed time of expiration: 118 days Richard-Allan Scientific Neg-50 Pink Reference: 6502P Lot: 343155 Expiration: 1/2018 Elapsed time of expiration: 118 days Richard-Allan Scientific Neg-50 Clear Reference: 6502 Lot: 304565 Expiration: 1/2018 Elapsed time of expiration: 118 days Richard-Allan Scientific Neg-50 Green Reference: 6502G Lot: 344329 Expiration: 2 /2018 Elapsed time of expiration: 90 days Richard-Allan Scientific Neg-50 Yellow Reference: 6502Y Lot: 344953 Expiration: 2/2018 Elapsed time of expiration: 90 days 2. In an interview at 09:30 hours on 5/30/2018, the Regional Clinical Manager stated the laboratory had previously employed a Histotech that would color code the mounting media when processing specimens but that Histotech was no longer working in this laboratory.