

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2064088	(X3) Date Survey Completed 11/13/2018
Name of Provider or Supplier Collins Advanced Dermatology Institute	Street Address, City, State 311 S Hwy 183, Leander, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, review of patient records, and interview with facility personnel, the laboratory failed to ensure the Potassium Hydroxide (KOH) reagent for skin preparations was within date for use for 11 of 11 patients tested between September 17, 2018 and November 2, 2018. The findings included: 1. Based on surveyor observations at 09:33 hours on 11/13/2018 in the laboratory, the Potassium Hydroxide (KOH) reagent that was stored beside the microscope had exceeded the expiration date. HealthLink 10 percent KOH Lot: 1725509 Expiration date: 2018-09-12 Elapsed time: 62 days 2. Based on a review of patient records, the expired KOH solution had been used to test 11 patients on the following days: 09/17/2018 09/18/2018 09/24/2018 10/02/2018 10/03/2018 10/16/2018 10/19/2018 10/23/2018 - 2 patients 10/29/2018 11/02/2018 3. In an interview at 09:35 hours on 11/13/2018, the office manager stated the laboratory had recently become aware of the expired reagent and that additional KOH reagent was ordered.</p>