

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2100099	(X3) Date Survey Completed 11/14/2018
Name of Provider or Supplier Collins Advanced Dermatology Institute	Street Address, City, State 1750 Red Bud Lane, Round Rock, 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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on review of histopathology slides, patient records, and interview with facility personnel, the laboratory failed to retain slides for 52 of 74 cases in 2017. The findings included: 1. At 14:16 hours on 11/14/2018, the surveyor requested slides from case CR17-054 from 9/19/2017. In an interview at 14:16 hours in the laboratory, the Histotechnologist stated the laboratory did not have some of the slides from the year 2017 available for review, including case CR17-054 from 9/19/2017. 2. Based on review of the retained slides, the laboratory did not have slides for the following cases: CR17-023 CR17-024 CR17-025 CR17-026 CR17-027 CR17-028 CR17-029 CR17-030 CR17-031 CR17-032 CR17-033 CR17-034 CR17-035 CR17-036 CR17-037 CR17-038 CR17-039 CR17-040 CR17-041 CR17-042 CR17-043 CR17-044 CR17-045 CR17-046 CR17-047 CR17-048 CR17-049 CR17-050 CR17-051 CR17-052 CR17-053 CR17-054 CR17-055 CR17-056 CR17-057 CR17-058 CR17-059 CR17-060 CR17-061 CR17-062 CR17-063 CR17-064 CR17-065 CR17-066 CR17-067 CR17-068 CR17-069 CR17-070 CR17-071 CR17-072 CR17-073 CR17-074 3. In an interview at 14:16 hours on 11/13/2018 in the laboratory, the office manager stated the slides to the cases listed above had been on top of a cabinet and had been lost after professional movers had moved the cabinet.</p>
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, 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 13, 2018 and October 24, 2018. The findings included: 1. Based on surveyor observations at 13:40 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 12 patients on the following days: 09/13/2018 - 2 patients 09/20/2018 09/21/2018 09/27/2018 10/03/2018 10/04/2018 10/09/2018 10/10/2018 10/11/2018 10/24/2018 3. In an interview at 13:40 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.