Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1088765	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Acacia Dermatology	2131 N Locust Ave, Lawrenceburg, TN	

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	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) 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. This STANDARD is not met as evidenced by: Based on review of patient number eight test report, slide retention for patient number eight, and interview with testing personnel number one, the laboratory failed to retain histopathology slides for at least 10 years in 2018. The findings include: 1. Review of patient number eight test report revealed patient testing for dermatopathology with a test report date of 08.14.2018. 2. Review of patient number eight slide retention revealed no slides could be located. 3. Interview with testing personnel number one on August 16, 2018 at 2:00 pm confirmed the laboratory failed to retain histopathology slides for at least 10 years in 2018 when the slides for patient number eight could not be located.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Review of the laboratory's policy titled "Proficiency Testing," the laboratory form

	titled "QA Report-Proficiency Testing for Histopathology," and interview with the laboratory director, the laboratory failed to verify the accuracy of histopathology procedures twice a year in 2017. The findings include: 1. Review of the laboratory's policy titled "Proficiency Testing" revealed the following statement: Once every year, the technician will randomly select one histopathology case and subject it to microscopic examination by a qualified dermatologist or pathologist. 2. Review of the laboratory's form titled "QA Report-Proficiency Testing for Histopathology 2017" revealed verification of accuracy of histopathology procedures was performed once in 2017. 3. Interview with the laboratory director on August 16, 2018 at 12:30 pm confirmed the laboratory failed to verify the accuracy of histopathology procedures twice a year in 2017.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to have a procedure for the use of special stains (Refer to D5401), failed to ensure reagents were not used past their expiration date (Refer to D5417), and failed to document quality control procedures (D5601).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedure manual, and interview with the laboratory director, the laboratory failed to have a procedure for the use of special stains in 2018. The findings include: 1. Observation of the laboratory on August 16, 2018 at 1:00 pm revealed the following special stains in use for patient testing: HMB45 Mart-1 Biocare Sox10 PAS Alcian Blue S100 2. Review of the laboratory's procedure manual revealed there were no procedures for the use of the special stains. 3. Interview with the laboratory director on August 16, 2018 at 2:15 pm confirmed the laboratory uses the special stains for patient testing and failed to have a written procedure for the use of the special stains.
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 observation of the laboratory and interview with testing personnel number one, the laboratory failed to ensure reagents and stains were not used past their expiration date in 2018. The findings include: 1. Observation of the laboratory on August 16, 2018 at 1:00 pm revealed the following reagents and stains that were in use for patient testing: KOH Lot #K16C81, expiration date = 2016-12-08 HMB45 Lot #3900215A, expiration date = 01/2017 Mart-1 Lot #5565714AP, expiration date = 05 /2017 Biocare Sox10 Lot# 021016, expiration date = 2018/02 Alcohol 70% Lot # A140.07.29.15, expiration date =07/2018 PAS expiration date=01.05.2018 Alcian Blue expiration date=11.28.17 2. Interview with testing personnel number one on August 16, 2018 at 12:30 pm confirmed that the laboratory uses the reagents and special stains to perform patient testing and failed to ensure reagents and stains were not used past their expiration date in 2018.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records and interviews with testing personnel number one and the laboratory director, the laboratory failed to document control procedures in 2018. The findings include: 1. Observation of the laboratory on August 16, 2018 at 1:00 pm revealed the following vials of special stains: SOX-10, Mart-1, HMB-45, S100, PAS, Alcian Blue. 2. Review of the laboratory's records revealed no documentation of quality control for the special stains. 3. Interview with testing personnel number one on August 16, 2018 at 1:00 pm confirmed the observed stains were in use for patient testing. 4. Interview with the laboratory director on August 16, 2018 at 2:15pm confirmed the laboratory uses the special stains for patient testing and failed to document control procedures in 2018.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of the education documents for testing personnel number one and interview with testing personnel number one, the laboratory director failed to ensure testing personnel have the appropriate education for the complexity level of testing

	performed. The findings include: 1. Review of the education documents for testing personnel number one revealed testing personnel number one does not have the minimum required educational degree for performing grossing of histopathology specimens. 2. Interview with testing personnel number one on August 16, 2018 at 1 pm confirmed that testing personnel number one performs grossing of histopathology specimens, and the laboratory director failed to ensure testing personnel had the appropriate level of education for the complexity level of testing performed.