Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0949890	04/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Dermatology Center	2210 West Main Street, Russellville, AR	

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
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: Through review of the CMS 116 form sumitted by the laboratory, review of "proficiency test" results for two of two testing personnel for the years of 2019 and 2020 it was determined that the laboratory failed to verify the accuracy of KOH and wet preparation testing at least twice annually. Findings follow: A) The CMS 116 applicaton submitted by the laboratory stated that 113 provider performed microscopy procedures, identified as KOH and wet preparations were performed annually. B) Review of the "proficiency test" reports for two of two testing personnel for the years of 2019 and 2020 revealed that the exact same three photographs were presented as "KOH"," Scabies" and "Trich" challenges for both of the testing personnel for the four events reviewed. Review of the identical three photographs twice annually over a two year period does not verify the accuracy of findings.
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: Through review of CMS 116 form, laboratory procedure manual and lack of

	documentation it was determined that the laboratory failed to have a procedures for the performance of KOH and Wet preparation microscopic examinations. Findings follow: A) Review of the CMS 116 form provided by the laboratory indicated that the laboratory performs microscopic examinatation of KOH and Wet preparations. B) No procedures for the microscopic examination of KOH and Wet preparations were found during the review of the laboratory policy and procedure manual. C) Upon request, the laboratory was unable to produce procedures for the microscopic examinations of KOH and Wet preparations
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: Through observation and interview it was determined that one of one KOH/Stain solution used to perform KOH microscopic preparations was expired in one of one examination rooms toured. Findings follow: A) During a tour of the laboratory on 4/8 /21 at 10:45 AM one of one bottles of Healthlink Chlorazol Black KOH/Fungal stain, lot # 8094 expiration date 2020-04-04, was observed in the cabinet in one of one examination rooms toured. B) In an interview on 4/9/21 at 10:45 the testing personnel, identified as number one on the CMS 209 form, said that supplies for performing KOH microscopic evaluations were placed in every examination room and the bottle of KOH/Fungal stain identified above had exceeded its expiration date and was available for use.