Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0437040	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Associates In Dermatology And Cutaneous Surgery	222 South Woods Mill Road Suite 710 North, Chesterfield, MO	

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: Based on review of twice yearly verification documents and interview with laboratory staff (A) the laboratory failed to perform accuracy verification for potassium hydroxide (KOH) testing at least twice annually during 2018 and to date June 4, 2019. Findings: 1. The laboratory did not have documentation to show verification of accuracy for the KOH procedure at least twice annually during 2018 and to date June 4, 2019. 2. Interview with laboratory staff (A) on June 4, 2019 at 2:20 PM confirmed the laboratory failed to verify the accuracy of the KOH test at least twice annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's individual quality control plan (IQCP), observation of DTM (dermatophyte test medium) in use for patient fungal culture

	testing on June 4, 2019, lack of quality control (QC) documentation and interview with laboratory staff (A), the laboratory director failed to maintain the QC program. Findings: 1. The laboratory's IQCP approved by the laboratory director states, " Associates in Dermatology to perform a minimum of a positive and negative control on each new lot/ batch (DTM media). A quality control kit will be purchased and Associates in Dermatology will perform a positive and negative control with each new batch of media purchased." 2. Observation of DTM media in use on June 4, 2019 revealed ten patient fungal cultures incubating in DTM media vials lot # D-1295-1018 and three patient fungal cultures incubating in DTM media vials lot # D-1310-0119. 3. The laboratory did not have documentation available to show it performed a positive and negative control with DTM culture media lot # D-1295-1018 and lot # D-1310-0119 before or concurrent with patient testing. 4. Interview on June 4, 2019 at 2:20 PM, staff (A) confirmed the laboratory did not have QC documentation for each lot of DTM fungal media in use for patient testing. Interview confirmed the laboratory director failed to maintain the QC program to ensure QC acceptability of DTM fungal media for patient testing.