Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0690730	04/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Associated Dermatology & Skin Cancer Clinic	50 S Last Chance Gulch, Suite 3, Helena, MT	

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
D0000	Based on an on-site recertification survey conducted on 4/10/18, deficiencies were cited for Associated Dermatology and Skin Cancer Clinic in Helena, MT.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to enroll for proficiency testing for dermatophyte test media (DTM) media from 5/6/16 to 4/10/18. The findings include: 1. A review on 4/10/18 at 2:30 p.m. of patient reports with growth on DTM were reported as "Growth on DTM consistent with Corynebacterium, Negative for Dermatophytosis" and "Growth on DTM consistent with Corynebacterium. Negative for fungus." 2. On 4/10/18 at 3:00 p.m., a box of Troy Biologicals DTM media vials (lot number 1713101) was observed in a laboratory refrigerator for growth and identification of yeast, dermatophytes, and fungi. 3. A review on 4/10/18 at 3:30 p.m. of the reportable options programmed into the computer for patient test reports included: a. "Growth on DTM consistent with T-Mentag." b. "Growth on DTM consistent with T-Rubrum." c. "Growth on DTM consistent with Penicillium Mold." d. "Growth on DTM consistent with T. Mentagraphytes." e. "Growth on DTM consistent with Microsporum species." f. "Growth on DTM consistent with Trichophyton species." g. "Growth on DTM

	consistent with Mustelus Canis." h. "Growth on DTM consistent with Corynebacterium." i. "Growth on DTM consistent with Saccharomyces." j. "Growth on DTM consistent with Bacterial Growth." k. "Growth on DTM consistent with Yeast." l. "2nd opinion requested. Sent to State Lab." m. "Positive. Sent to State Lab for identification." n. "No Growth/Negative." o. "Contaminant." p. "Color Change on DTM False Positive." q. "Bacterial over Growth." 4. On 4/10/18 at 3:37 p.m., staff member A stated staff member B and C read the DTM media. Staff member B reports the organism using one of the reportable options while staff member C sends all vials with positive growth to the state lab for identification. 5. A review on 4/10/18 at 4:10 p.m. of the proficiency testing documentation from the American Society of Dermatopathology lacked documentation of proficiency testing for DTM when genus and species levels of yeasts, dermatophytes, and fungi are identified.