Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0481662	10/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Associated Dermatologists - Baylor	411 N Washington Ave Ste 4000, Dallas, 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
D0000	Entrance and exit conferences were held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of laboratory policy and the laboratory's American Proficiency Institute (API) KOH proficiency testing records from 2019 (1st, 2nd, and 3rd events) and 2020 (1st and 2nd events), and staff interview, it was revealed the laboratory failed to have documentation evaluating proficiency testing results returned as 0%

	"Failure to Participate" by the proficiency testing agency for the 2nd event of 2020. Findings included: 1. The laboratory policy titled "PT (Proficiency Testing) Participation KOH" (reviewed and signed by the laboratory director on 09/29/2020) stated, "Review of Proficiency Testing Results ... ...2. The review includes, but is not limited to: ....d. Investigation of results when intended to be graded but were not." 2. Review of the API proficiency testing results for 2020 2nd Event Performance Summary revealed the laboratory received a score of 0% with a note of "Failure to Participate." 3. In an interview on 10/08/0202 at 1045 hours, the laboratory representative was asked to why the performance summary was failure to participate. The laboratory representative stated that she thought the results had been submitted to API. The laboratory representative was asked if the laboratory investigated the results. She stated the laboratory did not investigate the results. This confirmed the above findings. Word Key: KOH=Potassium hydroxide
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 laboratory policy, laboratory proficiency testing (PT) records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated ectoparasite analysis at least twice annually for 2 of 2 testing events in 2019. Findings included: 1. The laboratory policy (reviewed and signed by the laboratory director on 09/29/2020) stated the following: "Principle of the Test: Some ectoparasites can be found and identified by office procedures. Although techniques vary depending on the ectoparasite sought, all are designed to ensure obtaining a specimen from which the organism can be found and identified. Diagnostic Value: The ectoparasites include: scabies, Pediculosis capitis (head lice), Pediculosis corporis (body lice), Pediculosis pubis (pubic lice, 'crabs'), chiggers (Eutrombicula alfreddugesi, E. splendens, Trombicula autumnalis, and other Trombicula species), and psocid lice (book lice) ... ...Bi-annually a sample analysis will be provided by testing the specimen in duplicate. The results obtained with the duplicate should be recorded on the KOH Quality Control Log." 2. Review of the laboratory's proficiency testing records revealed the laboratory failed to verify the accuracy of ectoparasite analysis at least twice annually for 2 of 2 testing events in 2019. 3. In an interview on 10/08/0202 at 1045 hours, the laboratory representative was asked for documentation of twice annual accuracy for ectoparasite analysis for 2019. The laboratory representative stated that the laboratory rarely performed the test and did not perform twice annual accuracy. This confirmed the above findings.