

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0070557	(X3) Date Survey Completed 04/04/2018
Name of Provider or Supplier Dermatology Associates Of Concord Inc	Street Address, City, State 290 Baker Avenue Ext, Concord, MA	
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	A CLIA recertification survey was conducted for the Dermatology Associates of Concord, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: Tzanck smear examinations: a) The laboratory's policy is to have another provider check the smear and documenting the second review as a means of verifying the accuracy of the Tzanck smear examination. b) A review of Tzanck smear examinations for calendar years 2017 and 2018 revealed that there was no twice annual accuracy verification performed for Tzanck smears. During the time period review the laboratory had performed 11 patients between 5/1/17 and 1/8/18. c) The histotechnician interviewed on 4/3/18 at 10:35 am confirmed that accuracy verifications had not been performed twice annually for the Tzanck smear procedure. Dermatopathology skin slide examinations: a) The dermatopathologist examining skin slides for initial diagnosis sends out randomly generated cases to another dermatopathologist for review. b) A review of skin slide case reviews for calendar year 2017 revealed that there were 21 cases randomly selected for review for skin slide examinations initially performed during the time period of January through June of 2017. These cases were sent along with a cover letter dated September 12, 2017 to another dermatopathologist for review. The second review of 17 randomly selected cases for skin slide examinations initially performed during the time period of July through December of 2017. These cases were sent along with a cover letter dated</p>

March 15, 2018 to another dermatopathologist for review. c) Based on the date of the second cover letter, the laboratory failed to perform the skin slide case reviews twice annually during calendar year 2017. d) The histotechnician interviewed on 4/6/18 at 9:45 am, by telephone, confirmed that accuracy verifications had not been performed twice annually for skin slide examinations cases during calendar year 2017.