

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2074426	(X3) Date Survey Completed 01/31/2020
Name of Provider or Supplier Dermatology Associates Llc	Street Address, City, State 128 Carnegie Row, Norwood, 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 P.C. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with the Manager of Clinical Services on 01/31/2020, the laboratory did not document and maintain a copy of all PT records as evidenced by the following: The surveyor reviewed American Proficiency Institute (API) PT records for calendar year 2019 (2 testing events). The review revealed that the signed attestation statement provided by the PT program was not available for the 2019 API Microbiology Event # 3. The Manager of Clinical Services confirmed in an interview on 01/31/2020 at 10:50 AM that the attestation statement for 2019 API Microbiology Event # 3 was not signed by the analyst and laboratory director. .</p>
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) review and interview with the Manager of Clinical Services on 01/31/2020, the laboratory director failed to effectively review and evaluate PT results obtained on proficiency testing performed as specified in subpart H of this part as evidenced by the following: The surveyor reviewed American Proficiency Institute (API) PT records for calendar year 2019 (2 testing events). The review revealed that the laboratory director failed to review and evaluate the 2019 API Microbiology Event # 3. The Manager of Clinical Services confirmed in an interview on 01/31/2020 at 10:50 A.M. that the laboratory director failed to review and evaluate the 2019 API Microbiology Event # 3. .

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) record review and interview with the Manager of Clinical Services on 01/31/2020, the laboratory director (LD) failed to ensure a corrective action plan was followed when any proficiency testing (PT) results are found to be unacceptable as evidenced by the following: The surveyor reviewed the American Proficiency Institute (API) PT records for calendar year 2019 (2 testing events). The review revealed that the laboratory had received an unacceptable score of 50% for KOH/Wet Mount for 2019 API Microbiology Event # 3 and no corrective action was conducted for the unacceptable analyte results. The Manager of Clinical Services confirmed in an interview on 01/31/2020 at 10:50 A.M. that the laboratory did not have documentation indicating that the laboratory investigated the KOH/Wet Mount unacceptable results. The laboratory performs 30 KOH/Wet Mount tests annually.