

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2121950	(X3) Date Survey Completed 07/12/2018
Name of Provider or Supplier Dermatology Associates Of Lombard	Street Address, City, State 500 East 22nd St, Lombard, IL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to establish and follow written policies and procedures to assess employee and consultant competency. Findings: 1. Review of Laboratory Personnel Report - CLIA (CMS FORM 209), revealed that the laboratory listed person in the following positions: a. Personnel # 1 listed as Laboratory Director (LD); Clinical Consultant (CC); Technical Supervisor (TS); General Supervisor (GS); and Testing Personnel (TP). b. Personnel # 2 listed as TP c. Personnel # 3 listed as TP d. Personnel # 4 listed as CC and TP 2. Review of personnel records revealed that there was no documentation to show that a competency assessment was performed on the Personnel # 4 who is listed as one of the Clinical Consultants. 3. During survey date 07/12/18 at 3:00 PM, the histology technician confirmed the surveyor's findings.</p>
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 review and interview, the laboratory failed to verify the accuracy of histopathology and mycology tests performed. Findings: 1. Review of laboratory</p>

procedures revealed the following procedure for Proficiency Testing (PT): "Semi-annually, the tech or Risk Manger will send two cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatopathologist." 2. Review of PT records revealed that testing personnel #4 was Pathologist or reviewing surgeon for June 2017; December, 2017; and June 2018 for histopathology procedures for testing personnel # 1. There was no documentation to show that PT procedures were performed to verify the accuracy of tests performed by Testing Personnel # 4 (Pathologist). 3. During survey date 07/12/18 at 2:30 PM, testing personnel # 4 confirmed the surveyor's findings.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on review and interview, the laboratory failed to perform and document maintenance activities as specified in paragraph (b) (1) (i) of this sections. Findings:
1. Review of the laboratory's procedures manual revealed that there were maintenance procedures for both the Air Filter and Microscope. The procedures are as follows: a. "Air filter is cleaned as part of the maintenance every 6 months. b. "Preventative maintenance and grounding checks are done 6 months. 2. Review of the Air Filter records revealed that the air filter was installed on 02/02/17. However, there was no documentation to show that the Air Filter had ever been changed. Review of a sticker, titled, "Filter Cell Status" was stuck on the Air Filter body where the following information was recorded: a. Filter Type: Charcoal Filter b. Date Filter Installed 02/02 /17 c. Last Filter Check (no date was recorded). d. Date of Next Filter Check (no date was recorded). 3. The histology technician told the surveyor that the laboratory has 3 microscopes. There was no documentation to show that maintenance was performed on 3 of 3 microscopes that the laboratory uses. 4. During survey date 07/12/18 at 2:30 PM, the histology technician confirmed the surveyor's findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review and interview, the test report did not indicate the name and address of the laboratory location where the test was performed. Findings: 1. Review of 4 patients test reports revealed that the name and address of the laboratory location where Histopathology and Mycology tests are performed was not documented on the final reports of 4 of 4 patients' reports. 2. During survey date 07/12/18 at 3:00 PM, the histology technician confirmed the surveyor's findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review and interview, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of each phase of testing, and whether supervisor or director review is required for specimen processing, test performance, or result reporting. Findings: 1. Review of Laboratory Personnel Report - CLIA (CMS FORM 209) revealed that persons were listed for the following positions: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor d. General Supervisor e. Testing Personnel 2. Review of the laboratory's procedures manual revealed that the laboratory director only assigned herself to the position of laboratory director and Laboratory Supervisor. There was no documentation to show that the laboratory director assigned, in writing the duties and responsibilities to a specific person for the following positions in the laboratory: a. Clinical Consultant b. Technical Supervisor c. General Supervisor e. Testing Personnel 3. During survey date 07/12/18 at 3:00 PM, testing personnel # 4 told the surveyor that he occasionally reads pathology slides. There was no documentation to show that the laboratory director assigned this person the responsibility of reading slides and diagnosing patients. Testing personnel confirmed the surveyor's findings

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review and interview, the technical supervisor failed to be responsible for the following: A. Identifying the training needs and assuring that each individual

performing tests receives regular in-service training and education appropriate for the type and complexity of laboratory services performed. B. Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures. Findings: 1. Review Laboratory Personnel Report - CLIA revealed that along with the laboratory director, there were 3 other persons listed as testing personnel performing tests. One of 3 testing personnel was new personnel 2. Review of personnel records revealed that there was no documentation to show that the new person had been trained to perform the duties of a histology technician. 3. There was no documentation to show that competency assessments were performed in 2017 and 2018.for 2 of 3 testing personnel. 4. During survey date 07/12/18 at 2:30 PM, the histology technician confirmed the surveyor's findings