

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2152967	(X3) Date Survey Completed 05/02/2019
Name of Provider or Supplier Dermatology Associates Inc	Street Address, City, State 7640 W Sylvania Avenue, Suite E, Sylvania, OH	
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:</p> <p>Item I: Based on record review, and an interview with the Histotech, the laboratory failed to establish and follow a written policy and procedure to assess competency of the Clinical Consultant (CC), Technical Supervisor (TS), and General Supervisor (GS) as specified in the personnel requirements in subpart M. All 24 patients tested at this laboratory, beginning 3/14/19, have the potential to be affected. Findings Include: 1. Review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 4/24/19, found 1 person, in addition to the Lab Director, serving as CC, TS, and GS. 2. Review of the laboratory's policy and procedures failed to find a policy and procedure for assessing the competency of the CC, TS and GS based on the regulatory responsibility of those roles, at a frequency determined by the laboratory. 3. An interview with the Histotech, on 5/2/19 at 2:06 pm, confirmed that the lab did not have a policy or procedure for assessing the competency of CC, TS and GS based on the regulatory responsibility of those roles, at a frequency determined by the laboratory. Item II: Based on record review, and an interview with the Histotech, the laboratory failed to establish and follow a written policy and procedure to assess competency of the MOHS Testing Personnel (TP) as specified in the personnel requirements in subpart M. All 24 patients tested at this laboratory, beginning 3/14/19, have the potential to be affected. Findings Include: 1. Review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 4/24/19, found 1 person serving as the MOHS TP. 2. Review of the laboratory's policy and procedures failed to find a policy and procedure for assessing the competency of the TP performing MOHS testing procedures, which included the appropriate timeframe</p>

of assessment, and the 6 required procedures of competency assessment. 3. An interview with the Histotech, on 5/2/19 at 2:06 pm, confirmed that the lab did not have a policy or procedure for assessing the competency of the MOHS TP which included the appropriate timeframe of assessment, and the 6 required procedures of competency assessment.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Histotech, the laboratory failed, when not provided by the manufacturer, to establish the accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results for the test system, reference intervals, and any other performance characteristic required for MOHS test procedures performed, before reporting patient test results. All 24 patients tested at this laboratory, beginning 3/14/19, have the potential to be affected. Findings Include: 1. Review of the laboratory's policies and procedures did not find any policy and procedure for conducting and establishing performance specifications for the MOHS testing procedures, implemented on 3/14/19. 2. An interview with the Histotech, on 5/2/19 at 1:32 pm, confirmed the laboratory did not have a performance specification policy and procedure established, and failed to document any performance specification activities for the MOHS test procedure, prior to testing patient specimens and reporting patient results.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Histotech, the Laboratory Director (LD) failed to ensure that 19 out of 19 policies and procedures were approved and available to all personnel responsible for any aspect of the testing process. Findings Include: 1. Review of the laboratory's policy and procedures found 19 procedures signed and approved by the individual serving as the Clinical Consultant (CC), Technical Supervisor (TS), and General Supervisor (GS) and not the LD. Although the laboratory can delegate to the TS the responsibility of making the procedure manual available, the LD cannot delegate the responsibility for signing, and thus approving, new and revised procedures. 2. An interview with the Histotech, on 5/2/19

at 2:22 pm, confirmed the policies and procedures were not signed and approved by the LD prior to implementation on 3/14/19.

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 upon a record review and an interview with the Histotech, the Laboratory Director (LD) failed to specify the duties and responsibilities of the Clinical Consultant (CC), Technical Supervisor (TS), and General Supervisor listed on the CMS-209. All 24 patients tested at this laboratory, beginning 3/14/19, have the potential to be affected. Findings include: 1. Review of the CMS-209 form found 1 individual, in addition the the Lab Director, listed as performing duties of a CC, TS and GS. 2. Review of policies and procedures failed to find evidence that the duties and responsibilities of the CC, TS, and GS were specified in writing , with regulatory responsibilities delegated to that individual by the LD. 3. An interview with the Histotech, on 5/2/19 at 12:07 pm, confirmed that the LD failed to specify the duties and responsibilities of the CC, TS and GS in writing, with regulatory responsibilities delegated to that individual by the LD.