

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2137582	<b>(X3) Date Survey Completed</b>  08/27/2019
<b>Name of Provider or Supplier</b>  Dermatology Associates	<b>Street Address, City, State</b>  13401 S Ridgeland Ave, Palos Heights, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 of laboratory records and interview with a laboratory representative; the laboratory failed to establish policies and procedures to assess competency for personnel involved in pathology testing. Findings Include: 1. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of all personnel involved in pathology testing. 2. On survey date 08-27-2019 at 1:52 pm, the office manager confirmed the laboratory failed to establish a competency assessment policy for personnel involved in pathology testing.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with a laboratory representative; the laboratory failed to establish a procedure manual for all tests performed in the specialty of pathology. Findings Include: 1. Review of laboratory's policy and procedure manual revealed the laboratory failed to have procedure in place for the</p>

interpretation of pathology slides. 2. On survey date 08-27-2019, at 1:52 pm, the office manager confirmed the laboratory failed to have a procedure for the interpretation of pathology slides.

**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 of laboratory records, direct observation, and interview with a laboratory representative; the laboratory failed to establish and document preventative maintenance for the microscope used for the specialty of pathology. Findings Include: 1. Direct observation of the laboratory testing facility on 08-27-2019 at 11:50 am identified an Olympus BX43 microscope used for pathology slide reading. 2. Review of the laboratory's policy and procedure manual revealed the laboratory failed to establish a preventative maintenance protocol and document maintenance activities for the Olympus BX43 microscope. 3. Interview with the office manager at 1:52 pm on 08-27-2019 confirmed the laboratory failed to establish a maintenance protocol for the microscope and document maintenance activities.

**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 of laboratory records and interview with a laboratory representative; the laboratory's test reports failed to indicate the name and address of where testing was performed for 5 of 5 pathology test reports reviewed. Findings Include: 1. Review of 5 of 5 patient test reports (Patient Identifiers: P1, P2, P3, P4, P5) for pathology testing failed to indicate the following: a. The name and address of the laboratory location where the grossing and interpretation of pathology slides was performed. 2. During survey date on 08-27-2019, at 1:52 pm, the above findings were confirmed by the office manager.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with a laboratory representative; the laboratory director (LD) failed to ensure a quality assessment program was established and maintained to assure the quality of laboratory services provided. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to establish quality assessment program. 2. On survey date 08-27-2019 at 1:52 pm the office manager confirmed the LD failed to establish a quality assessment program.

**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 of laboratory records and interview with the laboratory director (LD); the laboratory director failed to specify, in writing, the responsibilities and duties for all personnel engaged in the preanalytic, analytic, and postanalytic phases of testing for pathology. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the LD failed to specify, in writing, the responsibilities and duties of each person engaged in the performance of pathology testing. 2. On survey date 08-27-2019 at 1:52 pm, the office manager confirmed the LD failed to specify, in writing, the responsibilities and duties for all the personnel involved in pathology testing.