

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2188242	(X3) Date Survey Completed 05/14/2024
Name of Provider or Supplier Metro Dermatology Of Ny Pc	Street Address, City, State 144-72 Northern Blvd - Ste 203, Flushing, NY	
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 the lack of training documentation, competency evaluation documentation, as well as interview with the Laboratory Director (LD), the LD failed to draft, approve a training, competency evaluation policy as well as perform, document clinical consultant (CC) and testing personnel (TP) training, six-month, and annual competency evaluations. FINDINGS: 1. The LD failed to draft and include a written training, competency evaluation policy comprising of the following guidelines: a. Direct observations of routine patient test performance, specimen preparation, processing, and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observations of instrument maintenance performance and function checks. e. Assessment of patient test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. f. Assessment of problem-solving skills. 2. There was no documentation of CC and TP training, six-month, and annual competency evaluations. 3. The LD confirmed the findings on May 14, 2024, at 11:30 A.M.</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 the lack of twice-yearly verification records, the laboratory failed to verify the accuracy for KOH testing. This was confirmed with the LD on May 14th, 2024, at 1:30pm.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL 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: D5401 Based on the lack of SOPs and interview with the LD, the laboratory failed to draft, approve procedures for all tests, assays, and examinations performed by the laboratory. FINDINGS: 1. There was no SOP that includes written instructions for potassium hydroxide (KOH) patient specimen preparation, processing, analysis, and result reporting. 2. The LD confirmed the findings on May 14, 2024, at 11:30 A.M.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of SOPs, lack of Quality Assurance (QA) policies, lack of CC and TP personnel training records, competency evaluations, as well as interview with the LD, the LD failed to provide overall management for all phases of testing. FINDINGS: The LD failed to ensure: 1. Draft, approve QA policies for all phases of Provider Performed Microscopy Procedures (PPMP) and high complexity testing. Refer to D6021. 2. Perform, document TP training and competency evaluations. Refer D6029. 3. Draft, approve policies for monitoring personnel who perform PPMP and high complexity testing to assure training and competency. Refer to D6030. 4. Draft, approve written instructions for potassium hydroxide (KOH) patient specimen preparation, processing, analysis, and result reporting. Refer to D5401. 5. Specify in writing CC and TP duties and responsibilities for all phases of laboratory testing. Refer to D6032. 6. The LD confirmed the findings on May 14, 2024, at 11:30 A.M.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and</p>

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of QA policy and interview with the LD, the LD failed to draft, approve, and maintain a QA policy for all phases of the general laboratory system. FINDINGS: 1. There was no written QA policy to assure quality of laboratory services provided. 2. The LD confirmed the findings on May 14, 2024, at 11:30 A.M.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on the lack of SOPs, lack of CC and TP personnel training records, competency evaluations, as well as interview with the LD, the LD failed to ensure that training and competency evaluations were performed, documented for the TP responsible for PMP complexity testing. FINDINGS: 1. There was no policy that included a written training, competency evaluation policy. 2. There was no documentation of TP training, six-month, and annual competency evaluations. 3. The LD confirmed the findings on May 14, 2024, at 11:30 A.M.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on the lack of the laboratory's current, approved SOPs as well as lack of training and competency documentation, the LD failed to ensure that policies and procedures were established for monitoring personnel who conduct specimen testing to assure training and competency. FINDINGS: 1. There was no policy that included a

written training, competency evaluation policy. 2. There was no documentation of CC and TP training, six-month, and annual competency evaluations. 3. The LD confirmed the findings on May 14, 2024, at 11:30 A.M.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on the lack of personnel training, competency evaluation records as well as interview with the LD, the LD failed to specify in writing CC, TP duties and responsibilities for all phases of laboratory testing. FINDINGS: 1. There was no policy that included a written training, competency evaluation policy. 2. There was no documentation of CC and TP training, six-month, and annual competency evaluations. 3. The LD confirmed the findings on May 14, 2024, at 11:30 A.M.