

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2113498	(X3) Date Survey Completed 02/07/2018
Name of Provider or Supplier Northeast Dermatology	Street Address, City, State 2100 Marble Cliff Office Park, Ste B, Columbus, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the CMS Annual Test Volume form, record reviews, and interviews with Testing Personnel (TP) and the Laboratory Director, the laboratory failed to enroll in a Proficiency (PT) program for dermatopathology and KOH testing procedures performed that met the criteria in subpart I of this part. Findings Include: 1. Review of the laboratory's CMS "Annual Test Volume" form indicated Hematoxylin and Eosin staining and evaluation, Immunohistochemical staining and KOH staining were performed. 2. Review of the laboratory's 2016 and 2017 PT records found one record for 2017 from the Ohio State University peer reviews and no records for 2016 PT. 3. TP #4 and the Lab Director confirmed only one PT submission for 2017 and no PT for 2016. The interviews occurred on 02/07/2018 at 10:06 AM.</p>
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</p>

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.

This STANDARD is not met as evidenced by:
Based on record reviews and an interview with Testing Personnel (TP), the laboratory failed to document each step in the testing and reporting of results and maintain all records for 2017 Proficiency Testing (PT) samples. Findings Include: 1. Review of the laboratory's PT records found one document titled "2017 Spring Laboratory Proficiency Testing", by The American Society of Dermatopathology. 2. The surveyor requested attestation forms and results for 2017 PT from TP #4. TP #4 was unable to provide the requested documents. The interview occurred 02/07/2018 at 10:06 AM.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on record review and an interview with Testing Personnel (TP), the laboratory failed to have procedures approved, via signature and date, by the current Laboratory Director before use. Findings Include: 1. Review of the laboratory's "Scabies Prep" and "KOH for Fungal Elements" policy and procedure manuals, provided on the date of the inspection, found the policies and procedures were approved, via signature and date, on the following dates: "Scabies Prep" approved 01/16/2017 "KOH for Fungal Elements" approved 02/15/2017 "COPS" approved 02/05/2017 2. TP #4 confirmed the current Laboratory Director did not approve the laboratory's policies and procedures, via signature and date after becoming Lab Director for this laboratory in 2016. The interview occurred on 02/07/2018 at 10:37 AM.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's quality control records and an interview with Testing Personnel (TP), the laboratory failed to check for negative control reactions for immunohistochemical stains. Findings were as follows: 1. The laboratory microscopically interpreted and reported pathologic findings from

immunohistochemically stained slides that were prepared within their facility. The results of the immunohistochemical stain reactions were recorded on a form reviewed by the Lab Director. 2. A review of immunohistochemical stains performed and recorded for 2016-2018 revealed the lab consistently failed to record results for negative reactions. 4. TP #4 confirmed the laboratory did not process negative controls for immunohistochemical stains. The interview was conducted 02/07/2018 at 11:41 AM.

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 of the laboratory's documents, and an interview with Testing Personnel (TP), the Technical Supervisor (TS) failed to evaluate the competency of testing personnel to ensure the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings Include: 1. Review of the laboratory's competency assessing checklist titled "Cops Gross Examination Training", found no mention of the 6 elements of competency assessing for Testing Personnel. 2. TP #4 confirmed the competency assessments did not contain the 6 criteria as required. The interview occurred on 02/07/2018 at 9:32 AM.