

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0067526	<b>(X3) Date Survey Completed</b>  03/04/2025
<b>Name of Provider or Supplier</b>  New England Dermatology, Pc	<b>Street Address, City, State</b>  3455 Main St, Springfield, MA	
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>D2006</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure proficiency testing (PT) material is tested in the same manner as patient samples. Findings include: 1. Record review on 2/28/2025 of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation, Provider Performed Microscopy, PT records, 'Provider Potassium Hydroxide (KOH)/Scabies Proficiency Testing' Forms revealed: a. 2025 Event 1 - All samples were tested by 16 different testing personnel (TP) b. 2024 Event 3 - All samples were was tested by 14 different TP. c. 2024 Event 2 - All samples were tested by 17 different TP. d. 2024 Event 1 - All samples were tested by 16 different TP. e. 2023 Event 3 - All samples were tested by 16 different TP. f. 2023 Event 2 - All samples were tested by 15 different TP. g. 2023 Event 3 - All samples were tested by 16 different TP. 2. Staff interview on 2/28/2025 at 10:00 AM with the Clinical Manager for General Dermatology confirmed more than one TP looks at the photomicrographs and writes their results on the form noted in #1 above. 3. The laboratory performs 776 tests annually in the specialty of Microbiology.</p>
<b>D6029</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p>

(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 record review and staff interview, the laboratory director (LD) failed to ensure new testing personnel (TP) received training prior to testing patient samples. Findings include: 1. Record review on 2/28/2025 of the laboratory's CMS for 209, signed by the LD on 2/28/2025 revealed: a. One new TP performing Grossing, GTP1. b. Two new TP performing Potassium Hydroxide (KOH) and Scabies testing, KSTP1 and KSTP2. 2. Record review on 2/28/2025 of the laboratory's employee records revealed: a. GTP1 hired on 3/6/2024 did not have documented training before testing patient samples. b. KSTP1 hired on 1/15/2024 did not have documented training before testing patient samples c. KSTP2 hired on 3/18/2024 did not have documented training before testing patient samples. 3. Record review on 2/28/2025 of the KOH /Scabies laboratory's 'Training Checklist' procedure signed by the LD on 6/8/2023 revealed, "NEDLC laboratory requires PPM testing personnel should receive adequate training before they perform testing and reporting patient results for Potassium Hydroxide KOH examination." 4. Record review on 2/28/2025 of the MOHS laboratory procedure manual (MPM) revealed the MPM did not have a procedure to train new grossing testing personnel. 5. Staff interview on 2/28/2025 at 12:00 PM with the Clinical Manager for General Dermatology and the MOHS Clinical Supervisor confirmed the above new testing personnel did not have documented training before testing patient samples. 6. The laboratory performs 776 tests annually in the specialty of Microbiology and 13,628 tests annually in the specialty of Histopathology.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the Technical Supervisor failed to ensure testing personnel (TP) received annual competency assessment. Findings include: 1. Record review on 2/28/2025 of the laboratory's employee competency records revealed 2 of 13 KOH/Scabies TP did not have documented competency assessment in 2023 or 2024. 2. Staff interview on 2/28/2025 at 10:00 AM with the Clinical Manager for General Dermatology confirmed the above testing personnel did not have documented competency assessment in 2023 or 2024. 3. The laboratory performs 776 tests annually in the specialty of Microbiology.