

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0066983	(X3) Date Survey Completed 06/10/2025
Name of Provider or Supplier Northampton Integrative Medicine, Llc	Street Address, City, State 395 Pleasant St, Northampton, MA	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS) the laboratory failed to test proficiency testing (PT) samples in the same manner as patient samples. Findings include: 1. Record review on 6/10/2025 of the laboratory's 2023, 2024 and 2025 to date American Proficiency Institute PT attestation sheets revealed: a. 2 of 3 testing personnel did not participate in PT in 2023, 2024 or 2025 to date. b. The TS performed all PT testing in 2023, 2024 and 2025 to date. 2. Interview with the TS on 6/10/2025 at 10:45 AM confirmed the above findings. 3. The laboratory performs 46,373 tests annually in the specialty of subspecialty of General Immunology.</p>
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 record review and confirmed through an interview with the Technical Supervisor (TS) the laboratory did not have an ongoing mechanism to evaluate the TS and General Supervisor (GS) based on their CLIA responsibilities. This is a repeat</p>

deficiency cited at the 6/16/2023 survey. Findings Include: 1. Record review on 6/10/2025 of the laboratory's 2023, 2024 and 2025 to date personnel competency records revealed the laboratory did not have documented competency evaluation for the TS and GS based on their CLIA responsibilities. 2. Record review on 6/10/2025 of the laboratory's, procedure manual revealed, the procedure manual did not contain a procedure for assessing testing personnel (TP), TS or GS competency. 3. Record review on 6/10/2025 of the laboratory's plan of correction (POC) from the 6/16/2023 survey revealed a form had been created to assess the TS based on their CLIA responsibilities. The laboratory did not submit a form to assess the GS based on their CLIA responsibilities. 4. During staff interview on 6/10/2025 at 10:31 AM, the TS: a. Confirmed this is a repeat deficiency and the laboratory does not have documented competency assessment of the TS or GS based on their CLIA responsibilities. b. Confirmed the laboratory does not have a written competency procedure for TP, TS or GS. c. Stated, the TS was unable to locate the TS competency form noted on the POC from the 6/16/2023 survey. d. Confirmed the lab does not have a competency form to assess the GS. 5. The laboratory performs 46,373 tests annually in the subspecialty of General Immunology..

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on record review and interview with the Technical Supervisor (TS) the laboratory failed to monitor and record daily refrigerator temperatures. Findings include: 1. Record review on 6/10/2025 of the 2024 and 2025 temperature charts for laboratory refrigerator #13A used to store reagents for the Phadia N20533 General Immunology analyzer revealed the laboratory failed to record the refrigerator temperatures for the following time spans: a. 5/1/2024 to 5/27/2024. b. 7/26/2024 to 10/21/2024. c. 7 of 21 days in June, 2024. d. 4 of 105 working days from 1/1/2025 to 6/10/2025. 2. Record review on 6/10/2025 of the 2024 and 2025 temperature charts for laboratory refrigerator #10 used to store patient specimens revealed the laboratory failed to record the refrigerator temperatures for the following time spans: a. 5/1/2024 to 5/27/2024. b. 7/26/2024 to 10/21/2024. c. 7 of 21 days in June, 2024. d. 4 of 105 working days from 1/1/2025 to 6/10/2025. 3. Interview with the TS on 6/10/2025 at 12:30 PM, the TS: a. Confirmed the temperatures were not recorded for the above time spans for refrigerators #13A and #10. b. Stated, "Someone from another department records the temperatures." c. Confirmed the temperature charts are not reviewed for accuracy. 4. The laboratory performs 46,373 tests annually in the specialty of subspecialty of General Immunology.

D5785

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Technical Supervisor (TS) the laboratory failed to document corrective action when the refrigerator temperature were out of range. Findings include: 1. Record review on 6/10/2025 of the 2024 and 2025 temperature charts for laboratory refrigerator #13A used to store reagents for the Phadia N20533 General Immunology analyzer revealed: a. The temperature range for refrigerator 13A is 2 to 8 degrees Celsius. b. The laboratory failed to document corrective action when the refrigerator temperature was out of range for 6 days in 2024. c. b. The laboratory failed to document corrective action when the refrigerator temperature was out of range for 49 days from 1/1/2025 to 6/10/2025. 2. Record review on 6/10/2025 of the 2024 and 2025 temperature charts for laboratory refrigerator #10 used to store patient specimens revealed: a. The temperature range for refrigerator 10 is 2 to 6 degrees Celsius. b. The laboratory failed to document corrective action when the refrigerator temperature was out of range for 41 days in 2024. c. The laboratory failed to document corrective action when the refrigerator temperature was out of range for 5 days from 1/1/2025 to 6/10/2025. 3. Interview with the TS on 6/10/2025 at 12:30 PM, the TS: a. Confirmed corrective action was not documented when the above temperatures were out of range for refrigerator #13A and #10. b. Stated, "Someone from another department records the temperatures." c. Confirmed the temperature charts are not reviewed for accuracy. 4. The laboratory performs 46,373 tests annually in the specialty of subspecialty of General Immunology.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

(e)(12) 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 confirmed by staff interview with the Technical Supervisor (TS) the laboratory director (LD) failed to ensure new testing personnel (TP) received training prior to performing testing on patient samples. Findings include: 1. Record review on 6/10/2025 of the laboratory's TP records revealed 1 of 1 new testing personnel hired on 10/10/2023 did have documented training prior to testing patient samples. 2. During an interview with the TS on 6/10/2025 at 10:15 AM, the TS confirmed, the laboratory did not have documented training for 1 of 1 new TP hired on 10/10/2023 prior to performing testing on patient samples. 3. The laboratory performs 46,373 tests annually in the specialty of subspecialty of General Immunology.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

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

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests

patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Technical Supervisor (TS), the TS failed to perform competency assessment twice during the first year of patient testing for new testing personnel (TP). Findings include: 1. Record review on 6/10/2025 of the laboratory's competency records for 1 of 1 new TP hired on 10/10/2023 revealed: a. One competency record with the review period of 10/10/2023 to 7/1/2024 noted on the form. b. The laboratory did not perform a second competency for the new TP during the first year of patient testing. 2. During an interview with the TS on 6/10/2025 at 10:00 AM, the TS confirmed the above findings. 3. The laboratory performs 46,373 tests annually in the specialty of subspecialty of General Immunology.