

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0066983	(X3) Date Survey Completed 06/16/2023
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
D0000	A CLIA recertification survey was conducted for the Northampton Integrative Medicine, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
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 policy review and interview the laboratory failed to have and follow written policies and procedures to evaluate the competency of the technical supervisor as evidenced by the following: a) A review of employee competency records on 6/16/23 for two (2) laboratory personnel revealed that there was no competency assessment performed for the technical supervisor. b) The technical supervisor confirmed in an interview on 6/16/23 at 9:55 AM that a competency assessment had not been completed on him.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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.</p>

This STANDARD is not met as evidenced by:

Based on an interview, the laboratory director failed to ensure that documentation was maintained to verify that new laboratory personnel were appropriately trained for the type and complexity of the services offered as evidenced by the following: a) One (1) new laboratory technologist had been put into place since the last CLIA survey performed. There was no documentation maintained to verify that the technologist had received training in all aspects of the laboratory operation prior to performing specimen processing, testing, and reporting procedures. The only documentation available was training on the analytical aspects of the laboratory operation. There was no training documentation related to the pre-analytical and post-analytical aspects of the laboratory operation. b) Interview on 6/16/23 at 9:25 AM with the technical supervisor confirmed that training for the pre-analytical and post-analytical aspects of the laboratory operation was not documented.