

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0703542	<b>(X3) Date Survey Completed</b>  09/29/2021
<b>Name of Provider or Supplier</b>  North Quabbin Family Physicians	<b>Street Address, City, State</b>  201 South Main St Suite 1, Athol, 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>D0000</b>	A CLIA recertification survey was conducted for the North Quabbin Family Physicians laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide documentation to verify that validation studies had been performed for all performance characteristics prior to reporting out patient testing results as evidenced by the following: Medonic M-Series: a) A review of validation studies for the Medonic M-Series hematology analyzer revealed that there was no documentation of day to day precision studies being performed. b) The technical consultant confirmed in an interview on 9/29/21 at 10:45 AM that the studies had been performed but could not provide the documentation during the time of the survey. The laboratory performs approximately 16,152 complete blood counts annually. .</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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 record review and interview, the laboratory director failed to ensure that documentation was maintained to verify that testing personnel had the appropriate training for all aspects of the laboratory operation as evidenced by the following: a) Review of the CMS 209 Laboratory Personnel Report on 9/29/21 showed that there was one (1) new testing person hired and performing testing since the last CLIA recertification survey on 6/11/19. b) No documentation of training could be provided during the time of the survey for the one (1) new testing personnel to confirm that they were trained in all aspects of the laboratory operation. c) The technical consultant confirmed in an interview on 9/29/21 at 9:35 AM. that there was documentation maintained of initial training for the new testing person but was unable to provide the documentation during the time of the survey.