

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2231843	(X3) Date Survey Completed 04/02/2025
Name of Provider or Supplier Health Quality Primary Care	Street Address, City, State 217 Sutton Street, North Andover, 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 Health Quality Primary Care laboratory on 04/02/2025 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 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 record review and confirmed through an interview with the technical consultant (TC) the laboratory did not have an ongoing mechanism to evaluate the TC based on their CLIA responsibilities. Findings Include: 1. Record review on 04/02/2025 of the laboratory's 2023, 2024 and 2025 to date personnel competency records revealed the laboratory did not have documented competency evaluation for the TC based on their CLIA responsibilities. 2. Record review on 04/02/2025 of the laboratory's Procedures Manual, "Training and Competency" procedure revealed: a. The procedure's "Competency" section states "3. All employees will be tested for competencies annually". a. The procedure did not contain information about TC competency based on their CLIA responsibilities. 3. During staff interview on 04/02/2025 at 9:23 AM with TC, TC confirmed the laboratory does not have documented competency assessment of the TC based on their CLIA responsibilities. 5. The laboratory performs 48,400 tests annually in the specialties of Chemistry and Hematology annually.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on record review the laboratory failed review and evaluate verification data for Hemoglobin A1C (HA1C) testing prior to patient testing. Findings include: 1. Record review of the laboratory procedures manual, "Director Responsibilities" section "Responsibilities" part "9. Ensure the establishment and maintenance of acceptable levels on analytic performance for each test system." 2. Review of records for the TOSOH 68 HA1C analyzer revealed a new analyzer was introduced in the laboratory on February 26, 2025. 2. Verification data for the TOSOH 68 HA1C was not reviewed and signed by the Laboratory Director before patient testing was begun. 3. Interview with the Technical Consultant on 04/02/2025 at 11:28 AM confirmed the above findings. The laboratory runs 2738 Hemoglobin A1C tests annually.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:
Based on surveyor review of the laboratory's quality control (QC) records and Levy Jennings charts and interview with Technical Consultant (TC) the laboratory failed to ensure the results of control materials were within the acceptable ranges prior to reporting patient test results in the specialty of Chemistry. Findings include: 1. Review of the laboratory procedures manual "Director Responsibilities" section part "8. Ensure quality control programs are established and maintained." 2. Record review on 4/2/2025 of the laboratory's AU400 Chemistry QC records revealed no documentation of daily or monthly Levy Jennings charts review by the technical consultant (TC). 3. Interview on 4/2/2025 at 11:00 AM the TC stated "I review but there are too many papers to printout." The laboratory runs 46000 tests in the speciality of Chemistry annually.