Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 22D2231843	**(X3) Date Survey Completed** 10/14/2025
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	Based on desk review of proficiency testing (PT) record from 2024 through 2025, the laboratory failed to meet the following conditions, resulting in an initial unsuccessful PT participation: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition:Laboratories performing moderate complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) desk review conducted on 10/14/2025, the laboratory failed to successfully participate in proficiency testing for the hematocrit (HCT) Refer to D2130.

D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) desk review and review of the laboratory's graded 2025 PT results from American Proficiency Institute (API), the laboratory failed to achieve successful performance for the analyte, Hematocrit (HCT), in two out of three testing events. Findings include: 1. Review of the CASPER 0155 report revealed the following results: Analyte HCT 2025: Event 1 Score 0% Event 2 Score 20% 2. A record review conducted on 10/14/2025 of the American Proficiency Institute (API) proficiency testing records (2025 Hematology / Coagulation 1st Event and 2nd Event) confirmed the laboratory received the above results.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155 report and American Proficiency Institute 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155 report and American Proficiency Institute 2025 records, the laboratory director failed to ensure proficiency testing samples were tested as required. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2130.