

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2231843	<b>(X3) Date Survey Completed</b>  08/12/2025
<b>Name of Provider or Supplier</b>  Health Quality Primary Care	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on desk review of 2025 proficiency testing (PT) records, 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
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by:                      Based on a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and American Proficiency Institute (API) proficiency testing records, the laboratory failed to</p>

	<p>successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Routine Chemistry for the analyte Carbon Dioxide (CO<sub>2</sub>). Refer to 2096.</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155 report and American Proficiency Institute (API) 2025 proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of three consecutive testing events in the subspecialty of Routine Chemistry for the analyte Carbon Dioxide (CO<sub>2</sub>). Findings included: 1. Review of the CASPER 0155 report revealed the following results: Routine Chemistry 2025 1st Event: The laboratory received an unsatisfactory score of 20% for Carbon Dioxide (CO<sub>2</sub>).. Routine Chemistry 2025 2nd Event: The laboratory received an unsatisfactory score of 40% for Carbon Dioxide (CO<sub>2</sub>).. 2. A review of the American Proficiency Institute (API) proficiency testing records (2025 Chemistry - Core - 1st Event and 2025 Chemistry - Core - 2nd Event) confirmed the laboratory received the above results.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>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.</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>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 D2096.</p>