

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D1074511	(X3) Date Survey Completed 09/08/2025
Name of Provider or Supplier York Hospital Medical Services	Street Address, City, State 75 Us 1 Bypass, Kittery, ME	
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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing reports from the laboratory. The facility was found to be out of compliance with the conditions of the CLIA program. The following: CONDITION and STANDARD level deficiencies were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation proficiency testing D2089- 42 C.F.R. 493.845 Standard: Laboratories performing Moderate Complexity testing: Routine Chemistry
D2016	<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 review of the proficiency testing (PT) data report (Casper Report 155D) and</p>

staff interview, the laboratory failed to successfully participate for the regulated analyte Phosphorus. Refer to D2096.

D2089

ROUTINE CHEMISTRY

CFR(s): 493.841(c)

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the CASPER Proficiency Testing (PT) data report (155), and staff interviews, the laboratory failed to successfully participate in PT for Routine Chemistry. Findings include: 1. Record review on 8/29/2025 of the CASPER 155 report revealed scores of 0% for 2025 PT Event 1 and 2025 PT Event 2 for the analyte Phosphorus. 2. Email correspondence with the laboratory's Director of Compliance on 9/3/2025 confirmed the findings above. 3. The laboratory performs 1,000 tests annually in the specialty of Chemistry.