

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D0206020	(X3) Date Survey Completed 04/14/2025
Name of Provider or Supplier St Francis Hospital Resp Care Dept	Street Address, City, State 701 N Clayton St, Respiratory Therapy Dept, Wilmington, DE	
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 Recertification Survey was initiated on April, 14/2025, at approximately 10:00 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows: D2007, D2016, and D2096.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on interview and facility document and policy review, the laboratory failed to rotate proficiency testing (PT) samples among all staff performing routine testing. This was noted for 12 out of 12 proficiency testing events reviewed. Findings included: A "Point of Care Testing Policy," signed by the LD on 04/12/2022, revealed, "Proficiency samples will be rotated among all personnel who routinely test patient specimens and will be treated in the same manner as patient specimens." The following PT events administered by the College of American Pathologists (CAP) revealed all the samples were tested by the same individual, Testing Personnel (TP) #6, as evidenced by his signature on the following PT attestation forms: CAP AQ-A March 2023 Critical Care Blood Gas with Chemistry CAP AQ-B July 2023 Critical Care Blood Gas with Chemistry CAP AQ-C November 2023 Critical Care Blood Gas with Chemistry CAP AQ-A March 2024 Critical Care Blood Gas with Chemistry CAP AQ-B July 2024 Critical Care Blood Gas with Chemistry CAP AQ-C November 2024 Critical Care Blood Gas with Chemistry CAP SO-A March 2023 Blood Oximetry CAP SO-B July 2023 Blood Oximetry CAP SO-C November 2023 Blood Oximetry CAP SO-A March 2024 Blood Oximetry CAP SO-B July 2024 Blood</p>

Oximetry CAP SO-C November 2024 Blood Oximetry A CMS-209 "Laboratory Personnel Report (CLIA)" form, signed by the Laboratory Director (LD) on 04/08 /2025, revealed there were 14 other individuals listed as TP. During an interview on 04 /14/2025 at 3:30 PM, the Point-of-Care Testing Laboratory Manager, who served as the Technical Consultant (TC), confirmed all the staff on the CMS-209 form performed patient testing. The TC stated he did not know why the PT samples were not being rotated among all staff doing testing according to facility policy, as was the practice in other laboratory departments.

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 facility document review and interview, the facility failed to meet the condition of participation for Proficiency Testing: Successful Participation, as evidenced by failure to meet the standard requirements at D2096 for the specialty of Clinical Chemistry. The facility failed to successfully participate in proficiency testing (PT) for the blood gas analyte partial pressure of oxygen (pO2) for two consecutive events. Findings included: Graded reports for the College of American Pathologist (CAP) PT program revealed the facility failed to meet the standard requirements at D2096 by failing to successfully participate in two consecutive events for the blood gas analyte pO2. The scores for these events were as follows: 2024 AQ-C Critical Care Blood Gas with Chemistry: Score for pO2 was 0%. 2025 AQ-A Critical Care Blood Gas with Chemistry: Score for pO2 was 60%. Refer to D2096 for further details.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

(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.

This STANDARD is not met as evidenced by:

Based on facility document review and interview, the laboratory failed to achieve satisfactory performance for the blood gas analyte partial pressure of oxygen (pO₂) in the specialty of Clinical Chemistry, as evidenced by proficiency testing (PT) scores of less than 80 percent (%) for pO₂, for two consecutive PT events reviewed. Findings included: Graded reports for the College of American Pathologist (CAP) PT program revealed the facility failed to meet the standard requirements at D2096 by failing to successfully participate with a score of at least 80% in two consecutive events for the blood gas analyte pO₂ in the specialty of Clinical Chemistry. The scores for these events were as follows: 2024 AQ-C Critical Care Blood Gas with Chemistry: Score for pO₂ was 0% 2025 AQ-A Critical Care Blood Gas with Chemistry: Score for pO₂ was 60% During an interview on 04/14/2025 at 12:30 PM, the Point-of-Care Testing Laboratory Manager, who served as the Technical Consultant (TC), was shown the PT reports and he acknowledged they represented unsuccessful performance for the analyte pO₂ for the specialty of Clinical Chemistry.