Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D0206020	12/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
St Francis Hospital Resp Care Dept	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 conducted on December 9, 2025 at approximately 10:05 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, interview, and document review, the laboratory failed to document the corrective action activity associated with the failure and replacement of 1 of 2 blood gas instruments. Findings included: During an observation on 12/09/2025 at 10:20 AM, there was one RAPIDPoint 500 System blood gas instrument labeled with a serial number (SN) of 45605 in Room 447. During an observation on 12/09 /2025 at 10:25 AM, there was one RAPIDPoint 500 System blood gas instrument and a binder labeled with a SN of 45591 in the Intensive Care Unit (ICU). The facility verification records revealed data for three different RAPlDPoint 500 System analyzers labeled with a SN of 45605, 45591, and 45590. During an interview on 12 /09/2025 at 11:00 AM, the Technical Consultant (TC) stated the RAPIDPoint 500 System blood gas instrument with SN 45591 was retired and the current analyzer in ICU was labeled with a SN of 45590. The "Remote Service Report" dated 03/27/2025 and 04/09/2025 for the RAPIDPoint 500 System blood gas instrument with a SN of 45591 revealed the issues were resolved. The facility quality review meeting notes

	dated 04/2025, revealed "ICU RapidPoint 500 blood gas analyzer failed. Replacing it with the old analyzer from the ED [emergency department] that had been removed from service." During a follow-up interview on 12/09/2025 at 11:45 AM, the TC stated the RAPIDPoint 500 System blood gas instrument with a SN of 45591 was last used to test patients on 05/10/2025, and the current analyzer with a SN of 45590 was installed on 05/12/2025 and was first used to test patients on 05/17/2025. During an interview on 12/09/2025 at 1:23 PM, Testing Personnel #1 stated there was a log to record calls to the instrument manufacturer, but the log was not retained. During an interview on 12/09/2025 at 2:30 PM, the TC stated he recalled the hospital biomedical department had been consulted regarding the failure of the RAPIDPoint 500 System blood gas instrument with a SN of 45591, but there was no record of that consultation.