Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0223595	08/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Fauquier Medical Center, Llc D/B/A	500 Hospital Dr, Warrenton, VA	

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	An onsite Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00061733) was conducted at Fauquier Medical Center dba Fauquier Hospital Laboratory on August 28-29, 2024, by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follow and includes the Condition under 42 CFR part 493 CLIA Regulation: D2000 - 42 C.F.R. 493-80 Condition: Enrollment and Testing of Samples.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tours of the main laboratory and respiratory therapy department, review of proficiency testing (PT) records, laboratory policies and procedures and interviews, the laboratory enrolled and provided PT samples for whole blood glucose and blood gas analysis to the respiratory therapy department, which holds a separate CLIA certificate, for American Proficiency Institute (API) 2023 PT Events 1, 2, and 3 and 2024 Events 1 and 2. See D2013.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), ASPEN WEB CLIA 116, tours of the main laboratory and respiratory therapy department, review of proficiency testing (PT) records, laboratory policies and procedures and interviews, the laboratory failed to follow their established policy prohibiting referral of proficiency testing specimens by enrolling and providing PT samples for whole blood glucose, blood gas and oximetry analysis to the respiratory therapy department (RTD), which holds a separate CLIA certificate, for five (5) of five (5) American Proficiency Institute (API) PT events. The findings include: 1. Review of the main laboratory's CMS-116 form-Section VI WAIVED TESTING revealed no listing of Whole Blood Glucose performed on the Abbott i-STAT. Further review of Section VIII NON-WAIVED TESTING revealed no listing of the blood gas or oximetry analysis performed on the Radiometer ABL 800 ABG. 2. Review of the ASPEN WEB CLIA 116 PT info tab revealed the main laboratory was enrolled with API for whole blood glucose, blood gas and oximetry analytes. Review of the ASPEN WEB CLIA 116 PT info tab for the respiratory therapy department revealed a lack of enrollment in PT for 2023 events 1, 2, 3 and 2024 events 1, 2 by the respiratory therapy department. The MFI noted the RTD was enrolled in PT for 2024 Event 3. 3. In the entrance interview on August 28, 2024, at 8:45 AM with the laboratory and respiratory administrative director (LRAD), chief nursing officer (CNO), regulatory/accreditation coordinator (RAC), the Medical Facility Inspector (MFI) inquired where the whole blood glucose, and blood gas tests were performed. The LRAD stated "That testing is performed outside of the lab in the respiratory therapy department and intensive care unit (ICU). Those locations share a CLIA certificate. It was recommended during our previous Joint Commission inspection that we split out those locations from the main lab. I applied for a reactivation of their old CLIA number in December 2022 and we were notified in January 2023 that the reactivation was completed." The MFI requested to review documentation of PT enrollment for the respiratory therapy department. The LRAD explained "When I enrolled in October 2022 for calendar year 2023 PT, I enrolled the main laboratory and the RTD together under the main laboratory's CLIA number because the RTD did not have their own CLIA certificate yet. When I enrolled for 2024 calendar year, I forgot RTD had their own CLIA certificate." 4. During a tour of

	the main laboratory on August 28, 2024, at 9:00 AM, the surveyor observed no Radiometer ABL 800, or Abbott i-STAT analyzers located in the main laboratory. In a tour of the respiratory therapy department on August 28, 2024, at 9:30 AM and ICU at 9:40 AM, the surveyor observed an ABL 800 Flex Radiometer #1 (serial number 754R2799N017) located in Arterial Blood Gas Lab room 1726, and an ABL 800 Flex Radiometer #2 (serial number 754R2799N030) and i-STAT analyzer (serial number 370873) located in ICU room 2141. The LRAD explained the respiratory department (Arterial Blood Gas Lab and ICU lab) is supervised by the Cardiopulmonary and Respiratory Supervisor (CRS). 5. Review of the laboratory's instrument printouts for API Chemistry Core 2023 Events 1-3 and 2024 Events 1 and 2 revealed the PT printouts labeled as "ICU" for the following PT samples: 2023 Chemistry Core-1st Event-Samples BG-01, 02, 03, 04, 05 and BLX-01, 02, 03, 04, 05-performed on ABL #2 (ICU); IB-01, 02, 03, 04, 05-performed on i-STAT G (serial number 370873). 2023 Chemistry Core-2nd Event-Samples BG-06, 07, 08, 09, 10 and BLX-06, 07, 08, 09, 10-performed on ABL #2 (ICU); IB-06, 07, 08, 09, 10-performed on i-STAT G. 2023 Chemistry Core-3rd Event-Samples BG-11, 12, 13, 14, 15 and BLX-11, 12, 13, 14, 15-performed on ABL #2 (ICU); IB-11, 12, 13, 14, 15-performed on i-STAT G. 2024 Chemistry Core-1st Event-Samples BG-01, 02, 03, 04, 05 and BLX-01, 02, 03, 04, 05-performed on ABL #2 (ICU); IB-01, 02, 03, 04, 05-performed on i-STAT G. 2024 Chemistry Core-2nd Event-Samples BG-06, 07, 08, 09, 10 and BLX-06, 07, 08, 09, 10-performed on ABL #2 (ICU); IB-06, 07, 08, 09, 10-performed on i-STAT G. 6. Review of the main laboratory's policies and procedures revealed a policy, "Proficiency Testing, 7025-014" effective 12/2022, with the statements, "Policy ... Survey samples will not be sent to an outside reference laboratory (i.e. a laboratory that has a different CLIA number) of any kind ...The laboratory will not refer a proficiency testing specimen to a laboratory with a different CLIA number (even if the second laboratory is in the same health care system) ..." 7. The MFI requested to review a RTD specific PT policy. The laboratory provided a policy, "Review of Quality Control (QC) and Proficiency Testing (PT), 736-509 effective 12/2023" with the statement "Purpose: To define and establish guidelines for reviewing internal Quality Control and external Survey Proficiency samples to ensure they are processed through the laboratory in the same manner as patient samples in accordance with regulatory guidelines." 8. In a remote video interview with the laboratory and respiratory administrative director (LRAD), cardiopulmonary and respiratory supervisor (CRS), and regulatory/accreditation coordinator (RAC) on August 29, 2024, at 10:00 AM, the inspector inquired with the CRS what the process for performing PT was in the laboratory. The CRS stated "I am notified by the laboratory by phone or email when the PT samples arrive. I pick the specimens up and assign the samples to a therapist, rotating through the staff each event. Once the testing is completed, I gather all the documentation and enter the results for our samples in the computer. Once the evaluation is received back from API, I review the results online, printing out the evaluation when we miss a sample." 9. In an exit interview on August 29, 2024, at 10:30 AM with the LRAD, CRS, and RAC the above findings were confirmed.