

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0226808	(X3) Date Survey Completed 03/18/2025
Name of Provider or Supplier Retreat Hospital Blood Gas Laboratory	Street Address, City, State 2621 Grove Ave, Richmond, 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 announced CLIA validation survey was conducted at Retreat Doctors' Hospital Blood Gas Laboratory that concluded on March 18, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D6033 -42 CFR. 493.1409 Technical Consultant-Moderate Complexity.
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel competency assessment records, education documentation, and interviews, the technical consultant failed to qualify by education while assessing eight of nine personnel Rapid Point Blood Gas System competencies in calendar year 2024. Cross Reference D6035.</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of</p>

Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) competency assessment records, education documentation, and interviews, the technical consultant (TC) failed to qualify by education while assessing eight (8) of nine (9) testing personnel Rapid Point Blood Gas System competencies in calendar year 2024. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed that the laboratory director identified 9 TP qualified to perform moderate complexity blood gas testing utilizing the Rapid Point Blood Gas System analyzers during the review timeframe of January 2024 to the date of the validation survey on March 17, 2025. 2. Review of the laboratory personnel records revealed that TP #1 performed duties of TC in calendar year 2024. The inspector noted that annual Rapid Point competencies for TP #2 - #9 were assessed by TP #1 in calendar year 2024 (see Personnel Code Sheet). 3. Review of education documentation for TP #1 revealed a diploma of Health Services Administration. The inspector noted that the degree transcript outlined health administrative business credits with one 4.0 credit hour science class (human anatomy and physiology). 4. An interview with the Laboratory Manager, Quality Assurance Coordinator, Vice President (VP) of Quality, Director of Respiratory Therapy, and Chief Operating Officer on 3/17/25 at 4:30 PM and a follow up with the VP of

Quality on 3/18/25 at 10 AM confirmed the above findings.