Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0190921	04/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Allentown Women's Center Inc	31 South Commerce Way Suite 100, Bethlehem, PA	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation in the laboratory, review of laboratory temperature records, and interview with Testing Personnel(TP)#2, the laboratory failed to monitor daily temperatures to ensure reagent stability and proper operating conditions for 358 of 708 days from 4/10/2023 to 4/8/2025. Findings include: 1. On the day of survey, 4/8 /2025, at 11:30 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - 2 boxes Monoclonal QC Albacheck. Storage requirements 2C to 8C. - 2 Anti D Blend Albaclone. Storage requirements 2C to 8C. - 2 Stanbio Hemoglobin Set. Storage requirements 2C to 8C. - 6 Aimstep Pregnancy Test kits. Storage requirements 15C to 30C. - 3 Siemens Uristix. Storage requirements 15C to 30C. - 4 Siemens Multistix. Storage requirements 15C to 30C. - 3 Hemopoint Cuvettes. Storage requirements 15C to 30C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document refrigerator and room temperatures for 358 of 708 days from 4/10/2023 to 4 /8/2025. 3. The TP #2 confirmed the findings above on 4/8/2025 at 12:45 pm.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441

	The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the laboratory director (LD) and Testing Personnel (TP) #2, the LD failed to provide overall management and direction of the laboratory in accordance with 493.1445 from 4/10/2023 to 4/8/2025. Refer to D6089, D6091, D6101, and D6106,
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, proficiency testing results from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), and interview with testing personnel (TP)#2, the laboratory director failed to ensure proficiency testing samples are tested as required under subpart H of this part from 4 /10/2023 to 4/8/2025. Findings include: 1. On 4/8/2025, at 10:15 am, review of the laboratory's proficiency testing recordsrevealed proficiency testing samples were run by two different testing personnel for 2 of 4 testing events in 2024 and 2025. - AAB-MLE M1 2025 was tested by TP#2 on 2/10/2025, retested by TP#3 on 2/25/2025, and the results were reported to the AAB-MLE proficiency program on 2/21/2025. - AAB-MLE M3 2024 was tested by TP#3 on 9/19/2024, retested by TP#5 on 9/19/2025, and the results were reported to the AAB-MLE proficiency program on 9/22/2024. 2. The laboratory failed to provide documentation that directed patient testing to be performed in duplicate by different testing personnel. 3. TP#2 confirmed the findings on 4/8/2025 at 11:30 am.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing results from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) and interview with the testng personnel (TP) #2, the laboratory director failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for AAB-MLE 1of 3 testing events for Immunohematology in 2024. Findings include: 1. On 4/8/2025, at 9:50 am, review of the Laboratory's policy titled, "AAB Proficency Testing Policy", revealed the policy stated, "If testing is below 100%, whomever completed that specific failed test will need to submit documentation of the error and give the correct answer as well". 2.

	Review of AAB-MLE testing reports revealed the laboratory failed to submit 1 of 3 AAB-MLE PT (AAB-MLE M1 2024) reports to the PT agency by the due date in 2024. 3. The laboratory failed to provide documentation for the review and evaluation of AAB-MLE M1 2024 to ensure results were within acceptable limits and to identify failures that required corrective action. 4. TP#2 confirmed the findings on 4/8/2025 at 11:30 am.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) (e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (CMS 209), personnel qualification records, and interview with the laboratory director (LD), the LD failed to ensure 6 of 7 testing personnel (TP) employed that performed RhD typing examinations for determining recipient compatability met the minimum education requirements to perform high complexity testing from 04/10/2023 to 04/08/2025. Findings include: 1. On the day of survey, 4/8/2025, at 9:45 am, review of personnel qualifications revealed the LD failed to employ a sufficient number of TP that met the minimum education requirements to perform RhD testing to determine recipient compatability from 04/10/2023 to the day of survey. 2. The laboratory reported an annual test volume of 2308 RhD determinations in 2024 (CMS 116 estimated annual volume). 3. During interview, 04/08/2025 at 11:45 am, the LD confirmed the laboratory was aware RhD testing performed was high complexity and the 6 of 7 TP TP (CMS 209 TP #2,3,4,5,6,and 7) were not qualified.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with testing personnel (TP)#2, the laboratory director (LD) failed to ensure that 7 of 14 procedures available to personnel that performed testing were approved before use from 04/10 /2024 to 04/08/2025. Findings Include: 1. On the day of survey, 4/8/2025at 09:45 am, review of the laboratory's current procedure manual revealed the LD failed to approve the following 7 of 14 procedures used by personnel in the laboratory from 04/10/2024 to 04/08/2025: Quality Assurance and Improvement Plan Laboratory Policy and Procedure Manual Rh Typing Blood Bank Reagent Quality Control Out of House Testing Specimen Protocols Specimen Collection & Handling Glucose Testing Procedure 2. TP#2 confirmed the findings on 4/8/2025 at 11:00 am.
D6168	TESTING PERSONNEL CFR(s): 493.1487

	The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (Form CMS-209), personnel qualification records, and interview with laboratory director (LD), the laboratory failed to ensure 6 of 7 testing personnel (TP) that performed RhD typing examinations for determining recipient compatability met the minimum requirements of 493.1489 to perform high complexity testing from 04/10/2023 to 04/08/2025. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (CMS 209), personnel

	qualification records, and interview with the laboratory director (LD), the laboratory failed to ensure 6 of 7 testing personnel (TP) that performed RhD typing examinations for determining recipient compatability met the minimum requirements of 493.1489 to perform high complexity testing from 04/10/2023 to 04/08/2025. Findings include: 1. On the day of survey, 4/8/2025, at 9:45 am, review of the personnel qualification records revealed 6 of 7 testing personnel(TP) (CMS 209 personnel #2-7) did not meet the minimum qualifications to perform RhD typing examinations for determining recipient compatability (high complexity) from 4/10/2023 to 4/8/2025. 2. Competency assessment records revealed TP # 2-7 performed high complexity testing from 4/10 /2023 to 4/8/2025. 3. The laboratory reported an annual test volume of 2308 RhD determinations in 2024 (CMS 116 estimated annual volume). 5. The LD confirmed the findings above on 4/8/2025 at 11:45 am.