Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1051273	(X3) Date Survey Completed 08/26/2025
Name of Provider or Supplier Carle Health Cardiology Peoria	**Street Address, City, State** 112 Ne Crescent Ave, Peoria, IL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, competency records, the CMS-209 (Laboratory Personnel Report) and interview with the Technical Consultant (TC); the laboratory failed to follow the established competency policy for 1 of 32 testing personnel (TP). Findings Include: 1.Review of laboratory policy and procedure manual revealed a document titled "Bedside Testing Quality Management Guideline" which stated, "When an employee starts to work in an area that does point of care testing a training session is scheduled. The employee is trained by the point of care coordinator from proctor, Pekin or Methodist or at orientation by nursing professional development. The employee's competency is to perform the test is assessed and documented. For non-waived tests, a 6 month competency check must also be done in the first year." 2. Review of competency assessment records found the laboratory lacked documentation of competency assessments for 1 of 32 TP. The laboratory failed to have competency documents for TP #32 as listed on the CMS-209. 3. On survey date 08-26-25, at 12:45 pm the TC confirmed the laboratory failed to follow the competency assessment policy for 1 of 32 TP.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with technical consultant (TC); the TC failed to evaluate and document the performance of 1 of 32 TP at least semiannually during the first year the individual tests patient specimens. Findings include: 1. Review of competency assessment records found the laboratory lacked documentation of semiannual competency assessments for 1 of 32 TP. The laboratory failed to have semiannual competency documents for TP #32, as listed on the CMS-209. See D5209. 2. Interview with the TC on 08-26-2025 at 12:45 pm confirmed the TC failed to perform a semi-annual competency assessment for TP #32.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records, laboratory policy, lack of academic records, the CMS-209 (Laboratory Personnel Report), and interview with the technical consultant (TC); the laboratory failed to have qualifying academic records for 2 of 32 moderate complexity testing personnel (TP). See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records, laboratory policy, lack of academic records, the CMS-209 (Laboratory Personnel Report), and interview with the technical consultant (TC); the laboratory failed to have qualifying academic records for 2 of 32 testing personnel (TP) listed on the CMS-209 for moderate complexity testing. Findings include: 1. Review of personnel records found no academic records were available to qualify moderate complexity TP # 22 and TP # 29 listed on the CMS-209 form dated 08/27/2025. 2. Review of the laboratory's policy manual identified the policy, "Procurement of Diploma or GED of Moderate complexity Laboratory testing

	Guideline", which stated the following: "Statement of policy Clinical laboratory improvement amendments (CLIA) laboratory testing standards require that staff that performs moderate complexity testing to have at a minimum, a high school diploma or high school transcript, or general education development (GED) on file in the medical institution. 3. Interview with TC on 08/26/2025 at 12:48 pm revealed the laboratory was unable to retrieve the qualifying documents for TP # 22 and TP # 29 at the time of survey.