Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0713112	04/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
City Of Gary Department Of Health	1145 West 5th Ave, Gary, IN	

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 completed on 4/11/2024. It was determined that the following condition-level deficiencies existed: 42 C.F.R. 493.1409 Laboratories performing moderate complexity testing; technical consultant.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director failed to ensure the quality assessment program was maintained from July 2, 2021, until April 11, 2024. Findings Included: 1. Upon request for a policy on how and when quality assessments were performed, on 4/03/24 at 11:56 am, SP-2 (testing person) indicated quality assessments activities were performed quarterly and provided the policy titled "Syphilis Health Check" and "Laboratory Quality Assurance Problems" sheets. 2. Review of the policy "Syphilis Health Check", with no approval or effective date, indicated there were no requirements for how or when quality assessments would be performed. 3. Review of documents titled, "Laboratory Quality Assurance Problems", with dates ranging from 2/04/21 to 07/02/21, indicated the last documentation of a problem was on 7/2/2021. There was no documentation of quarterly meetings or assessments. 4. Review of document, "City of Gary Job Description", for SP-2, signed by the Department/ Division Head on 05/16/02, under: Principle Functions, stated the following regarding test performance specifications: a) Identifies problems that may adversely affect test performance or reporting of test

	results and either correct the problem or immediately notify the Technical Consultant (TC), Clinical Consultant (CC), or the Deputy Director. b) Documents all corrective actions taken when test systems deviate from the laboratory's established performance specifications. 5. Annual test volume for immunology testing is 896.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on lack of documentation, record review and interview, the laboratory: 1) failed to ensure two (SP-2 and Sp-5) of two personnel performing the duties of a technical consultant (TC) were qualified from January 31, 2024 to April 11, 2024 (Refer to D6035); and 2) failed to ensure the technical consultant performed competency assessments for one (SP-2) of two testing personnel from December 10, 2020 through January 31, 2024 (Refer to D6046).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (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 Pathology or possess qualifications that are equivalent to those required for such certification; 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 one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be

	qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure two (SP-2 and SP-5) of two personnel performing the duties of a technical consultant (TC) met qualification requirements from January 31, 2024, to April 11, 2024. Findings Included: 1. Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 4/04/2024, indicated: a) SP-2 was a testing person. b) SP-5 was a laboratory director, clinical consultant, and technical consultant. 2. Review of personnel documents indicated: a) A transcript document for SP-2 (testing person) confirmed an associate level degree in medical laboratory technology. SP-2 did not have a bachelor's degree. b) SP-5 was licensed as a physician in Indiana. SP-5 was the laboratory director for a Certificate of Provider Performed Microscopy Procedure laboratory since May 13, 2011. The testing performed did not include the specialty of immunology. SP-5 was hired on January 31, 2024. 3. Review of competency documents for SP-6 (testing person) titled "Microbiology & Immunology\ Laboratories, Annual Competency Assessment" showed testing person, SP-2, signed off on initial competency for SP-6 on 02/07/2024 for test samples quantified using test system: Therma Fisher Science, Sure View for rapid plasma regain (RPR): Syphilis Serology. 4. Upon request for a competency policy, on 04/03/24 at 11:34 am, Sp-2 indicated there was no policy available. 5. On 4/05/24 at 8:21 am, an email was sent to SP-5 (laboratory director) requesting documentation of one year experience in immunology to qualify as the technical consultant for Immunology testing. An email reply from SP-5 on 4/09/24 at 11:48 am, stated, they "do not have an immunology or pathology background." 6. On 4/11/2024 at 4:55 pm, during a phone call, SP-1 (administrator) confirmed the laboratory did not have anyone with a bachelor's degree and/or experience in immunology to fill the technical consultant position. 7. Annual test volume for immunology testing is 896.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review, lack of documentation. and interview, the technical consultant (SP-4) failed to perform competency for one (SP-2) of two testing personnel from December 10, 2020 through January 31, 2024. Findings Included: 1. Review of competency documents for SP- 2 (testing person) titled "Microbiology & Immunology\ Laboratories, Annual Competency Assessment" showed competencies were performed by SP-4 on 12/19/2019 and 12/10/20 for test samples quantified using test system: Therma Fisher Science, Sure View for RPR: Syphilis Serology. There was no documentation of competency assessments for 2021, 2022, or 2023. 2. Upon request for a competency policy, on 04/03/24 at 11:34am Sp-2, indicated they were not aware competency was required annually for all testing personnel and there was no policy available. 3. The following patient samples were quantified by SP-2 using test system: Therma Fisher Science, Sure View for RPR: Syphilis Serology without a competency assessment being performed: Patients Date PT#1 01/11/23 PT#2 02/10

	/23 PT#3 02/21/23 PT#4 02.23.23 PT#5 08/04/23 PT#6 10/06/23 PT#7 12/14/23 PT#8 01/18/24 PT#9 02/14/24 PT#10 04/04/24 4. Annual test volume for immunology testing is 896.