Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0716077	11/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Blue Island Health Center Of Cook County Health	12757 S Western Ave, Blue Island, 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
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 review of laboratory records and policies and interview; the laboratory failed to be enrolled in an HHS approved proficiency testing program for its blood gas testing. Findings include: 1. Review of laboratory records revealed that there was no documentation to show that the laboratory performed proficiency testing for blood gases. 2. On 11/13/18 at 11:00 AM, the surveyor asked the laboratory director to provide her with proficiency testing records. None was made available to the surveyor. The laboratory director told the surveyor that the technical consultant had enrolled the laboratory in proficiency testing a few days prior to the surveyor. The technical consultant told the surveyor that he was not sure the laboratory was enrolled in proficiency testing. 3. On 11/13/18 at 12:00 PM, the surveyor's findings were confirmed by the technical consultant.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.

	1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review and interview, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299 for it blood gas testing. Findings include: 1. The laboratory lacked a comprehensive procedure manual that encompassed, specifically, how this laboratory at this location operates. See tags D5203 and D5403 2. The laboratory director failed to ensure that personnel were qualified, trained, and competent to perform all phases of the testing process, including QC prior to patient testing. See tags D5209, D5417, D5431, and D5437 3. The laboratory failed to verify the accuracy, precision, and reportable range of the Istat analyzer prior to testing patients' specimens. See tag D5421 4. Test reports did not include the name and address of the laboratory performing the testing. See tag D5805
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to establish and follow written policies and procedures that ensure positive identification and optimum integrity of patients' specimens from the time of collection through completion of testing and reporting of results. Findings include: 1. Review of the laboratory's policies and procedures revealed that there were no written procedures that described the laboratory's system for how it identifies its patients during the testing process. 2. At 1: 30 PM on 11/13/18, the surveyor asked testing personnel how she identifies patients with similar names. Testing personnel told the surveyor that since she only performed one patients' test at a time, she just knew the patients by name. 3. At 2:30 PM on 11/13 /18, the laboratory director confirmed that there were no written procedures to ensure positive identification of patients specimens.
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 and interview, the laboratory failed to establish and following written policies and procedures to assess employee and consultant competency. Findings include: 1. Review of laboratory policies and procedures revealed that there were only procedures that say personnel competency should be performed on testing personnel. However, there were no procedures that described what parameters were to be included for the assessment. 2. Review of Laboratory Personnel Report - CLIA

	(FORM CMS 209) revealed that the following personnel were listed on the form. a. Laboratory Director who also serves as the Clinical Consultant b. A total of 1 Technical Consultant c. A total of 1 Testing Person 3. Review of personnel records revealed that there was no documentation to show what parameters should be included in the competency assessment for the following personnel: a. Technical Consultant b. Clinical Consultant c. Testing Personnel 4. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory did not have a comprehensive procedure manual that included all of the required information for performing and reporting blood gas results. The findings include: 1. The procedure manual did not include calibration and calibration verification procedures. 2. The procedure manual did not include the reportable range, normal, critical, or panic values for blood gases. 3. The procedure manual did not include control procedures. 4. The procedure manual did not include trouble shooting techniques or corrective actions to take to mitigate problems encountered in testing. 5. The procedure manual did not include limitations in the test methodology, including interfering substances. 6. The procedure manual did not include pertinent literature references. 7. The procedure manual did not include the laboratory's system for reporting patient test results accurately. 8. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on observation, review, and interview, reagents were used when they had exceeded their expiration date. Findings include: 1. At 1:30 PM on 11/13/18, the surveyor was taken to the laboratory where blood gas tests were performed. The only equipment in the laboratory were syringes for collecting specimens, an Istat analyzer, and a computer. There was no refrigerator for storing reagents in the laboratory. 2. Review of procedures manuals revealed that testing personnel were instructed as follows: "Store the main supply of cartridges at a temperature between 2 to 8 C (35 to 46 F)... Cartridges may be stored at room temperature (18 to 30 C or 64 to 86 F) for at least 14 days... Do not use after the labeled expiration date." 3. Review of the reagent cartridges in use revealed that the laboratory currently used Lot # W18152, with an expiration date of 2019-01-19. A hand written "OPEN" date of 11/06/18 and "EXPERATION" date of 01/06/19 was written on the box of cartridges. When the surveyor asked testing personnel why she gave the box of cartridges an expiration date of 01/06/19, testing personnel could not explain why. 4. There was no documentation to show that room temperatures (RT) were captured; that the 14 day expiration date (November 20, 2018) of the RT cartridges would be observed; and that this November 20, 2018 expiration date would be acted upon for reagents at room temperature. 5. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to demonstrate that they had performed their performance verification studies for their Istat. Findings include: 1. There was no documentation presented to the surveyor to demonstrate their performance specification verification was done. 2. At 1:00 PM on 11/13/18, documentation of another laboratory's verification records were handed to the surveyor. 3. It was revealed that Oak Forest Health Center did not perform any of the verification studies, nor did they collect data. 4. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to perform and document

	function checks as defined by the manufacturer. Findings include: 1. Review of the manufacturer's instructions revealed that the laboratory is required to perform daily verification of their Istat test system using an internal or external Electronic Simulator every 8 hours for blood gases. The procedure state, "If the internal Electronic Simulator is used, the "PASS" message will not be displayed on the handheld screen. The "PASS" record will appear in the handheld's stored results for transmission to the Central Data Station." 2. There was no record of either Internal or External Electronic Simulator verification available for review. 3. At 1:30 PM on 11/13/18, in an interview with testing personnel, it was revealed that the laboratory didn't have an External Electronic Simulator. Testing personnel stated that she just turns the Istat on and begins testing. 4. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D5535	ROUTINE CHEMISTRY CFR(s): 493.1267(a)(d) For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to perform and document calibration or verify calibration. Findings include: 1. Review of manufacturer's procedures revealed that there was no written protocol for calibrating the Istat analyzer. 2. Review of the laboratory's policies and procedures revealed that there were no written procedures to show that the laboratory established a calibration procedure when one was not provided by the manufacturer. 3. There was no documentation to show that the laboratory performed calibration or calibration verification on of the Istat. 4. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to test one sample of control (QC) material each 8 hours of testing using a combination of control materials that include both low and high values when it performed blood gas testing on patients' specimens. Findings include: 1. Review of the laboratory's application for CLIA Certification revealed that the laboratory has a 7 hour shift. There was no quality control documented each day of patient testing. 2. Review of the laboratory's policies and procedures revealed that there were no procedures that described the laboratory' process for performing QC. 3. At 1:30 PM on 11/13/18, the surveyor selected a total of 5 patients' test reports for review. There was no documentation to show that QC material was run on dates when patients' specimens were analyzed and blood gas

	results were reported for 5 of 5 patients on the following dates: a. 10/18/18 b. 11/05 /18 (two patients test reports) c. 11/06/18 d. 11/07/18 4. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review and interview, the test report did not indicate the name and address of the laboratory where the testing was performed. Findings include: 1. Review of 4 patients test reports revealed that the name and address where the test was performed was not documented on the reports of 4 of 4 patients test reports reviewed. 2. The reports contained the name and address of Cook County Health & Hospital Services Pulmonary and Physiology Laboratories at the top of the report page. 3. On 11/13/18 at 1:30 PM, in an interview with testing personnel, it was revealed that because they are considered a point of care testing site, the main hospital's address is on the test report. 4. On 11/13/18 at 2:00 PM, the laboratory director confirmed the surveyor's findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review and interview, the laboratory failed to have a director who provided overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. There was no documentation to demonstrate performance verification studies were performed on the Istat prior to patient testing. See tag D6013. 2. The laboratory director failed to ensure accurate and reliable testing. See tag D6014 3. The laboratory was not enrolled in a proficiency testing program. See tag D6015. 4. The laboratory director did not ensure Quality Control was established. See tag D6020 5. The laboratory director did not ensure Quality Assessment was established. See tag D6021. 6. The laboratory director did not assign duties and responsibilities or job descriptions to personnel in the laboratory. See D6032
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure verification procedures for performance specifications were established and performed. Findings include: 1. There was no documentation to show that this laboratory verified the manufacture's claims for accuracy, precision, reportable range, and other performance characteristics. 2. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure that laboratory personnel performed the test methods as required for accurate and reliable results. Findings include: 1. Review of personnel records revealed that there was no documentation of training or competency assessment of testing personnel. 2. At 2:30 PM on 11/13/18, the laboratory director confirmed the surveyor's findings.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure that the laboratory was enrolled in a HHS approved proficiency testing program for blood gas analysis. Findings include: 1. Review of laboratory records revealed that there was no documentation to show that the laboratory was enrolled in proficiency testing for 2018. 2. At 2:30 PM on 11/13/18, the laboratory director confirmed that the laboratory was not enrolled in proficiency testing.

D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure that the quality control (QC) program was established and maintained to assure the quality of laboratory services provided. Findings include: 1. There was no documentation of QC performance. 2. At 1:30 PM, on 11/13/18, in an interview with testing personnel, it was revealed that the laboratory had not performed and documented QC. 3. At 2:30 on 11/13/18, the laboratory director confirmed the surveyor's findings.
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 review and interview, the laboratory director failed to ensure that quality assessment (QA) programs were established and maintained to assure the quality of laboratory services. Findings include: 1. There were no QA records available for review. 2. At 1:30 PM, on 11/13/18, in an interview with testing personnel, it was revealed that the laboratory had not performed and documented QA. Testing personnel stated that there were no records available for review. 3. At 2:00 PM on 11 /13/18, the surveyor requested that the laboratory director show her documentation of his QA reviews. None was made available to the surveyor. 4. At 2:30 PM on 11/13 /18, the laboratory director confirmed the surveyor's findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director

	review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review an interview, the laboratory director failed to: specify in writing the responsibilities and duties of each consultant and each person engaged in the testing; identify which examination and procedures each individual is authorized to perform; specify whether supervision is required for test performance; and whether consultant or director review is required prior to reporting patient test results. The findings include: 1. Review of laboratory procedure manuals and personnel records revealed that there was no documentation to show that the laboratory director assigned the duties and responsibilities for the following positions: a. Laboratory Director b. Clinical Consultant c. Technical Consultant d. Testing Personnel 2. At 2:30 PM on 11 /13/18, the laboratory director confirmed the surveyor's findings.
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 review of personnel records and interview, the laboratory failed to 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. Findings include: 1. There were no acceptable educational credentials provided for the position of the technical consultant. See D6034. 2. Around 2:30 PM on 11/13/2018 the laboratoy director confirmed the surveyor's findings.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record reviews and personnel interview, the laboratory failed to employ one or more individuals who are qualified by education, training, and experience to provide technical consultation for its blood gas testing. Findings include: 1. Review of Laboratory Personnel Report - CLIA (FORM CMS 209) revealed that personnel # 2 (assigned the letter "B" on the CMS 209 by the surveyor) did not have documentation showing he qualified as the technical consultant. The technical consultant stated, he was waiting for the Human Resources (HR) department to fax his credentials over. HR faxed over foreign credentials. There was no documentation to show that these foreign credentials were evaluated by a US equivalent board to determine US acceptability. 2. At 2:00 PM, on 11/13/18, the surveyor asked personnel B how long

	he had been technical consultant of this lab. Personnel B told the surveyor he was just given the position of "technical consultant" of this laboratory, 3 days prior to the CLIA survey. 3. At 2:30 PM, on 11/13/18, the laboratory director confirmed the surveyor's findings.
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 record review and interview, the laboratory failed to have a sufficient number of individuals who met the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed. Findings include: Review of personnel records revealed that there were no documents to show how testing personnel qualifies to perform blood gas testing. See tag 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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview, testing personnel did not meet the minimum educational requirements for performing moderate complexity blood gas testing in the laboratory. Findings include: 1. Review of Laboratory Personnel Report - CLIA (FORM CMS 209), revealed that there was one person listed as testing personnel performing blood gas testing in the laboratory. 2. There was no documentation to show the highest level of education this person achieved. 3. There was no documentation to show this person was trained to perform blood gas testing. 4. At 2: 30 PM, on 11/13/18, the technical consultant confirmed the surveyor's findings.