Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2161703	06/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Union Medical Care Pllc	1262 East 14th Street, Brooklyn, NY	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a surveyor's review of the manufacturer's package inserts for the Genzyme OSOM Rapid Strep A, Alere Influenza A&B and an interview with the laboratory testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls for waived testing from January 10, 2019 through June 5, 2019. FINDINGS: 1. The laboratory testing person confirmed on June 5, 2019 at approximately 9:30 AM, the surveyor's findings that the required external positive and negative quality controls (QC) were not performed for the Rapid Strep A and for the Influenza A&B kits with each new kit opened from January 10, 2019 through the June 5, 2019. 2. The testing person confirmed the laboratory performs the QC and records the following: testing person initials, date performed and acceptable on each test kit box. However, once the kit is used it is discarded, therefore, there is no record that QC was performed. a. The laboratory did not have a patient log sheet for tests performed, the test order and result are recorded directly into the patient's electronic medical record (EMR). b. The surveyor could not determine the number of test kits used and patients tested from January 10, 2019 through June 5, 2019 since the kit boxes were discarded. c. The current OSOM Rapid Strep A test kit in use (lot # 191127 exp. 8/31/20) had the testing person's initials, and date performed.
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 lack of proficiency testing (PT) records and an interview with the laboratory testing person, the laboratory failed to enroll in Health and Human Services (HHS) approved PT program for the specialty Bacteriology/throat cultures and Hematology automated Complete Blood Count (CBC). FINDINGS: 1. The laboratory testing person confirmed on June 5, 2019 at approximately 10:00 AM that the laboratory did not enroll in an approved PT program for Bacteriology/throat cultures and for Hematology automated CBC. 2. The laboratory did not have a patient log sheet for CBC and throat cultures performed, the test order and results are recorded directly into the EMR. The surveyor used the annual total test volume recorded on the Center for Medicaid & Medicare Services (CMS) 116 form as follows: a. Bacteriology/throat culture 50 patients tested from January 10, 2019 through June 5, 2019. b. Hematology /CBC 20 patients tested from January 20, 2019 through June 5, 2019.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's available quality control records and an interview with the laboratory testing person, the laboratory failed to have complete quality control (QC) records available for the Diatron 3CP Abacus hematology analyzer (S/N #380085); the lot numbers for the 0.04 bacitracin disc and Select Strep Agar (SSA) used for Bacteriology/throat cultures. FINDINGS: 1. The laboratory testing person confirmed on June 5, 2019 at approximately 9:45 AM, that the manufacturer's control assay information sheets for hematology control material and QC records for lot to lot verification were not available from January 17, 2019 through June 5, 2019. a. The laboratory did not retain copies of previous control material assay sheets from January 17, 2019 through June 5, 2019. The surveyor could not determine the number of control material lots used for Hematology/CBC testing. 2. The surveyor could not determine the number of 0.04 bacitracin disc and Select Strep Agar (SSA) used for Bacteriology/throat culture. 3. The surveyor used the annual total test volume recorded on the CMS 116 form as follows: a. Bacteriology /throat culture 50 patients tested from January 10, 2019 through June 5, 2019. b. Hematology/CBC 20 patients tested from January 20, 2019 through June 5, 2019.
D5002	BACTERIOLOGY CFR(s): 493.1201

	If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on lack of procedures for Bacteriology testing, no QC records and an interview with the laboratory testing person, the laboratory failed to met the requirements for Bacteriology/throat culture testing. Refer to: D5209, D5291 D5403, D5471 and D5477.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the lack of procedures for Hematology, no QC records and an interview with the laboratory testing person, the laboratory failed to have met the requirements for Hematology testing. Refer to: D5209, D5291, D5403, D5407, D5421 and D5441
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 the lack of competency policies and procedures and an interview with the laboratory testing person, the laboratory failed to establish written policies and procedures to assess the competency of the laboratory testing personnel that perform both Bacteriology/throat cultures and Hematology/CBC testing. FINDINGS: The laboratory testing person confirmed on June 5, 2019 at approximately 10:00 AM, that the laboratory did not establish a written competency evaluation policy to include the six criteria to be followed for competency assessment: 1. Observation of routine test performance for waived, Hematology and Bacteriology testing. 2. Monitor the recording & reporting of test results. 3. Review of test results, worksheets, quality control records, proficiency test results and preventative maintenance records. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of test performance through proficiency testing samples or blind testing. 6. Assessment of problem solving skills.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231

	through 493.1236. This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) policies and procedures and an interview with the laboratory testing person, the laboratory failed to establish written policies and procedures to assess, monitor and identify problems and issues in the general laboratory system for both Bacteriology/throat cultures and Hematology testing. FINDINGS: The laboratory testing person confirmed on June 5, 2019 at approximately 10:00 AM, the laboratory did not establish a written QA policy for general laboratory systems to include the following: 1. patient confidentiality/test requisition/test report 2. patient identification & specimen integrity 3. compliant investigation 4. communication/internal & external 5. personnel competency assessment 6. proficiency testing/comparison testing 7. policy & procedure manual 8. quality control & calibration 9. routine laboratory maintenance & equipment function checks 10. test records (worksheets, printouts, etc.)
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 a surveyor's review of the manufacturer's manual for the Diatron 3CP Abacus hematology analyzer, lack of a general laboratory procedure manual and an interview the laboratory testing person, the laboratory failed to establish a written procedure manual for all aspects of Bacteriology/throat culture and Hematology testing from specimen collection through reporting patient test results. FINDINGS: The laboratory failed to establish a standard operating procedure (SOP) manual to include: 1) Specimen collection, labeling, storage, criteria for rejection and acceptance, processing, referral to reference laboratories 2) Quality control type, number, frequency and lot to lot verification of new controls for hematology analyzer; 3) Written hematology calibration procedures to include the frequency; 4) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability for both Hematology and Bacteriology; 5) Step-by-step performance procedure for Bacteriology and Hematology testing; 6) Turnaround time from sample

	collection to processing and final results entered into the EMR system; 7) Protocol for reporting alert values or panic values for hematology testing; 8) A written Proficiency testing (PT) policy including timely enrollment, PT testing review of reports received, the corrective action procedure for non-graded scores and any score less than 100%, and PT record retention.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's Diatron 3CP Abacus hematology analyzer manual and an interview with the laboratory testing person, the laboratory director failed to approve, sign and date this manual used by the testing personnel for CBC testing.
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 the surveyor's review of the laboratory's records and an interview with the laboratory testing person, the laboratory failed to establish and verify the performance specifications for the Diatron 3CP Abacus hematology analyzer which was installed on January 17, 2019. Patient testing was initiated on January 20, 2019. FINDINGS: 1. The laboratory testing person confirmed on June 5, 2019 at approximately 11:00 AM, that the laboratory had no records of a validation on the Hematology Analyzer. 2. Approximately 20 patients were tested and reported for CBC testing from January 20, 2019 through June 5, 2019.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Diatron 3CP Abacus hematology analyzer daily start-up & daily QC records and an interview with the laboratory testing person, the laboratory failed to establish the number and frequency of QC material tested during analyzer operation, establish criteria for run acceptability and remedial action to be taken for unacceptable QC. FINDINGS: 1. The laboratory testing person confirmed on June 5, 2019 at approximately 10:30 AM, that the laboratory failed to establish the number, type and frequency of controls for the hematology analyzer. 2. The laboratory failed to print and review the Levy-Jennings reports for shifts and trends from January 20, 2019 through June 5, 2019. 3. Approximately 20 patients' samples were tested and reported for Hematology during this time frame.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's observation of 0.04 bacitracin discs in the refrigerator and an interview with the laboratory testing person, the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin disc for positive and negative reactivity from January 10, 2019 through June 5, 2019. FINDINGS: 1. The laboratory testing person confirmed on June 5, 2019 at approximately 11:00 AM, that the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin discs for positive and negative reactivity. a. the laboratory did not perform QC for the current lot # 8338541 exp. 6/30/20 of bacitracin discs. b. The surveyor was unable to determine the lots of bacitracin discs used from January 10,2019 through June 5, 2019. 2. Approximately 50 patient specimens were tested and reported for throat culture during the same time period.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on the surveyor's observation of SSA media in the refrigerator and an interview with the laboratory testing person, the laboratory failed to check each new batch, lot number and shipment of SSA media for positive and negative reactivity from January 10, 2019 through June 5, 2019. FINDINGS: 1. The laboratory testing person confirmed on June 5, 2019 at approximately 11:00 AM , that the laboratory failed to: 1. Perform and document the sterility for the SSA Media; 2. Document the physical characteristics of the SSA Media for any deterioration; 3. The surveyor was unable to determine the lots of SSA media used from January 10, 2019 through June 5, 2019. The current lot #90606801 exp. 12/31/19 had not been tested for positive and negative reactivity. 4. Approximately 50 patient specimens were tested and reported for throat culture during the same time period.
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 surveyor findings and interview with the laboratory testing person, the laboratory director for Union Medical Care PLLC doing business as (dba) Kamin /Health Urgent Care @ O'HEL failed to provide overall management of the laboratory. The laboratory director, acting as technical consultant, failed to ensure that the laboratory: 1. Performed, documented and evaluated the validation study for the Diatron 3CP hematology analyzer, prior to patient testing, refer to D6013; 2. Enrolled in an HHS approved PT program for Bacteriology and Hematology, refer to D6015; 3. Established a QC program for Bacteriology and Hematology testing, refer to D6020; 4. Established QA program for all phases of laboratory testing, refer to D6021; 5. Established polices to monitor the testing personnel in all phases of laboratory testing, refer to D6030; 6. Establish a written SOP manual for all phases of laboratory testing, refer to D6031; 7. Specify in writing the responsibilities and duties for testing personnel, refer to D6032; 8. Testing personnel received training prior to patient testing for Bacteriology and Hematology, refer to D6045.
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 surveyor's review of laboratory records and confirmed in an interview with the laboratory testing person, the laboratory director of Union Medical Care PLLC

	dba Kamin/Health Urgent Care @ O'HEL failed to establish and verify the performance specification for the Diatron 3CP Abacus hematology analyzer, prior to patient testing. Refer to D5421.
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 the surveyor's review of laboratory records and an interview with the laboratory testing person, the laboratory director for Union Medical Care PLLC dba Kamin/Health Urgent Care @ O'HEL failed to enroll the laboratory in a HHS PT program for Bacteriology/throat culture and Hematology/CBC. FINDINGS: The laboratory testing person confirmed on June 5, 2019 at approximately 11:30 AM, that the laboratory initiated Bacteriology/throat culture on January 10, 2019 and Hematology testing on January 20, 2019 but did not enroll in an approved PT program. Refer to D2000.
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 surveyor's review of hematology start-up, daily QC records, lack of bacteriology QC records and an interview with the laboratory testing person, the laboratory director for Union Medical Care PLLC dba Kamin/Health Urgent Care @ O'HEL failed to ensure that the Hematology and Bacteriology QC programs were established and maintained. Refer to: D3031, D5441, D5471 and D5477.
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 laboratory's lack of QA policy & procedures, QA records and an interview with the laboratory testing person, the laboratory director for Union Medical Care PLLC dba Kamin/Health Urgent Care @ O'HEL failed to establish and maintain QA program for Hematology and Bacteriology testing. Refer to: D5291.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the lack of personnel competency policies and procedures and an interview with the laboratory testing person, the laboratory director for Union Medical Care PLLC dba Kamin/Health Urgent Care @ O'HEL failed to ensure that policies and procedures are established to assess the competency of testing personnel. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on lack of a general laboratory procedure manual and an interview with the testing person, the laboratory director for Union Medical Care PLLC dba Kamin /Health Urgent Care @ O'HEL failed to establish a written laboratory procedure manual and approve the Diatron manufacturer's manual to ensure that an approved manual is available to all laboratory personnel. Refer to D5403 and D5407.
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 the surveyor's review of personnel records and confirmed in an interview with the laboratory testing person, the laboratory director for Union Medical Care PLLC dba Kamin/Health Urgent Care @ O'HEL failed to specify, in writing, the duties and responsibilities of the staff involved in all phases of the Bacteriology and Hematology laboratory testing. Refer to D5209.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on the lack of testing personnel training and competency policies and procedures and an interview with the laboratory testing person, the laboratory director, acting as the technical consultant for Union Medical Care PLLC dba Kamin /Health Urgent Care @ O'HEL, failed to ensure that testing personnel were trained prior to patient testing for waived tests and Bacteriology and Hematology testing. Refer to D5209. FINDINGS: The laboratory testing person confirmed on June 5, 2019 at approximately 11:30 AM, that four of the four testing personnel did not have training for waived and moderately complex laboratory tests (Bacteriology and Hematology) prior to patient testing.