Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2161172	(X3) Date Survey Completed 06/05/2019
Name of Provider or Supplier Union Medical Urgent Care Pllc/Williamsburg	**Street Address, City, State** 70 Lee Avenue, 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 surveyor's review of the manufacturer's package inserts for OSOM Genzyme Infectious Mononucleosis, Meridian Bioscience Immuno Card Influenza A&B, Woodview Rapid Strep A , Arkay Assure Platinum Glucometer and Siemens Clinitek Status & Multistix 10SG urine dipsticks and interview with the practice manager, the laboratory failed to follow the manufacturer's requirements for performing external controls with each new kit for above tests. FINDINGS: 1. The surveyor reviewed the manufacturer's package insert and the quality control (QC) requirements for the test kits at survey. 2. The practice manager confirmed on June 5, 2019 at approximately 2:30 PM, that the laboratory failed to follow the manufacturer's requirements for external controls and perform the required QC for the following test kits and tests: OSOM Genzyme Infectious Mononucleosis requires positive and negative controls be tested with each new kit. Meridian Bioscience Immuno Card Influenza A&B requires positive and negative controls be tested with each new kit. Woodview Rapid Strep A requires positive and negative controls be tested with each new kit. Arkay Assure Platinum Glucometer & test strips requires normal and high level controls be tested with each new vial of test strips. Siemens Clinitek Status & Multistix 10SG urine dipsticks requires normal and high level controls be tested with each new vial of test strips. 3. The laboratory failed to record the lot numbers and expiration dates for the above test kits and vials of test strips. The surveyor was unable to determine the number of lots used for patient testing from March 1, 2019 through June 5, 2019. 4. Approximately 100 patients were tested and reported for the same time period.

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 practice manager, the laboratory failed to enroll in Health and Human Services (HHS) approved PT program for the sub-specialty Bacteriology/throat cultures. FINDINGS: 1. The practice manager confirmed on June 5, 2019 at approximately 2:30 PM that the laboratory did not enroll in an HHS approved PT program for Bacteriology/throat cultures. 2. The surveyor used the annual total test volume recorded on the Center for Medicaid & Medicare Services (CMS) 116 form to estimate how many patient specimens were tested. For Bacteriology/throat culture approximately 100 patients were tested from March 1, 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 lack of bacteriology QC records and an interview with the practice manager, the laboratory failed to have QC records for 0.04 bacitracin disc and Select Strep Agar (SSA) used for Bacteriology/throat cultures. FINDINGS: 1. The practice manager confirmed on June 5, 2019 at approximately 2:45 PM, that the laboratory did not perform QC for each lot and/or shipment of 0.04 bacitracin discs and Select Strep Agar (SSA) used for Bacteriology/throat culture from March 1, 2019 through June 5, 2019. 3. The surveyor used the annual total test volume recorded on the Center for Medicaid & Medicare Services (CMS) 116 form to estimate how many patient specimens were tested. For Bacteriology/throat culture approximately 100 patients were tested from March 1, 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 practice manager, the laboratory failed to met the requirements for Bacteriology/throat culture testing. Refer to: D3131, D5209, D5291, D5403, D5471 and D5477.
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 assessment policies and procedures and an interview with the practice manager, the laboratory failed to establish written policies and procedures to assess the competency of the laboratory testing personnel that perform Bacteriology/throat cultures testing. FINDINGS: The practice manager confirmed on June 5, 2019 at approximately 2:00 PM, 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 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. 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 practice manager, the laboratory failed to establish written policies and procedures to assess, monitor and identify problems and issues in the general laboratory system for Bacteriology/throat cultures testing. FINDINGS: The laboratory testing person confirmed on June 5, 2019 at approximately 2:45 PM, 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 9. routine laboratory maintenance 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 lack of a general laboratory procedure manual and an interview the practice manager, the laboratory failed to establish a written procedure manual for all aspects of Bacteriology/throat culture 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 for 0.04 bacitracin discs; 3) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability for Bacteriology; 4) Step-by-step performance procedure for Bacteriology testing; 5) Turnaround time from sample collection to processing and final results entered into the EMR system; 6) 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.
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 practice manager, the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin disc for positive and negative reactivity from March 1, 2019 through June 5, 2019. FINDINGS: 1. The practice manager testing person confirmed on June 5, 2019 at approximately 3:00 PM, 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 # 8355663 exp. 7/31/20 of bacitracin discs. b. The surveyor was unable to determine the lots of bacitracin discs used from March 1, 2019 through June 5, 2019. 2. Approximately 100 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 practice manager laboratory testing person, the laboratory failed to check each new batch, lot number and shipment of SSA media for positive and negative reactivity from March 1, 2019 through June 5, 2019. FINDINGS: 1. The practice manager confirmed on June 5, 2019 at approximately 2:00 PM , 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 current lot #9054771 exp. 7/2/19 and #90809799 exp. 8/2/19 had not been tested for positive and negative reactivity. 4. Approximately patient 100 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 practice manager, the laboratory director for Union Medical Urgent Care PLLC/Williamsburg doing business as (dba) Kamin/Health Urgent Care @ O'HEL failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Enrolled in an HHS approved PT program for Bacteriology, refer to D6015; 2. Established a QC program for Bacteriology testing, refer to D6020; 3. Established QA program for all phases of laboratory testing, refer to D6021; 4. Established polices to monitor the testing personnel in all phases of laboratory testing, refer to D6030; 5. Established a written SOP manual for all phases of laboratory testing, refer to D6031; 6. Specify in writing the responsibilities and duties for testing personnel, refer to D6032; 7. Testing personnel received training prior to patient testing for Bacteriology, refer to D6045.
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 practice manager, the laboratory director for Union Medical Urgent Care PLLC /Williamsburg dba Kamin/Health Urgent Care @ O'HEL failed to enroll the laboratory in a HHS PT program for Bacteriology/throat testing. FINDINGS: The practice manager confirmed on June 5, 2019 at approximately 2:30 PM, that the laboratory initiated Bacteriology/throat culture on March 3, 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 lack of bacteriology QC records and an interview with the practice manager, the laboratory director for Union Medical Urgent Care PLLC/Williamsburg dba Kamin/Health Urgent Care @ O'HEL failed to ensure that Bacteriology QC programs were established and maintained. Refer to: D3031, 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 and QA records and an interview with the practice manger, the laboratory director for Union Medical Urgent Care PLLC/Williamsburg dba Kamin/Health Urgent Care @ O'HEL failed to establish and maintain a QA program for laboratory 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 practice manager, the laboratory director for Union Medical Urgent Care PLLC/Williamsburg 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 practice manager, the laboratory director for Union Medical Urgent Care PLLC /Williamsburg dba Kamin/Health Urgent Care @ O'HEL failed to establish a written laboratory procedure manual to ensure that an approved manual is available to all laboratory personnel. Refer to D5403.
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 practice manager, the laboratory director for Union Medical Urgent Care PLLC/Williamsburg 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 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 practice manager, the laboratory director, acting as the technical consultant for Union Medical Urgent Care PLLC/Williamsburg dba Kamin/Health Urgent Care @ O'HEL, failed to ensure that testing personnel were trained prior to patient testing for waived and Bacteriology testing. Refer to D5209. FINDINGS: The practice manager confirmed on June 5, 2019 at approximately 2:30 PM, three of three testing personnel did not have training for waived and moderately complex laboratory tests (Bacteriology) prior to patient testing.