Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0664765	12/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Uptown Pediatrics Pc	1245 Park Ave, New York, 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
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 a review of College of American Pathologist (CAP) Proficiency Test reports and an interview with the laboratory director and testing person, the laboratory failed to enroll in PT that meets the criteria in Subpart I and is approved by HHS. Finding Include: On December 13, 2018, at approximately 12:30 pm the laboratory director and testing person confirmed that the laboratory was in a throat culture PT challenge which offers 3 specimens to include a Strep antigen challenge. The laboratory needs to enrolled in a 5 specimens challenge.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of PT records from CAP, the laboratory failed to successfully

	participate in a PT program approved by CMS for the test analyte Hematocrit (HCT) count for the first event of 2017 and the first event of 2018. No remediation was performed. The following scores were assigned: HCT 2017 first event = 60% 2018 first event = 20% This is considered unsatisfactory PT performance.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of CAP PT records and an interview with the laboratory director and testing person, the laboratory failed to participate and perform successfully in a PT program approved by CMS, for the specialty Hematology. The following score was assigned:Hematology 2018 first event = 77% This is considered unsatisfactory PT performance
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 a review of lack of quality control (QC) records and an interview with the laboratory director and testing person, the laboratory failed to have a complete procedure manual, validation of new tests and QC for bacteriology testing for the last two years. Refer to: D5403, D5423, and D5477
D5006	MYCOLOGY CFR(s): 493.1203 If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a lack of records and confirmed an interivew by the laboratory director and testing person, the laboratory failed to perform QC for the DTM media for the last two years. Refer to: D5477
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on a review of the proficiency test (PT) reports from College of American Pathologist (CAP), the laboratory failed to review and evaluate the PT scores that are less than 100%. Findings Include: On December 13, 2018 at approximately 12:30 pm, it was confirmed by the laboratory director and testing person that the laboratory failed to review and evaluate the following: 2017 third event Bacteriology = 89% 2018 second event HCT= 80% 2018 second event RBC = 80%
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 review of the laboratory procedure manual and an interview with the laboratory personnel, the laboratory failed to have a complete procedure manual. Findings Include: On December 13, 2018, at approximately 10:15 am it was confirmed by the laboratory director and testing person, that the laboratory failed to have procedures in place for 1) lot to lot verification and a 2) Quality Control criterion for hematology testing (number of controls used, frequency of control testing, remedial action and the acceptance for two of three controls within acceptable range, and frequency of calibration) and 3) QC procedure for throat culture testing using bacitracin disk, urine cultures and dermatophyte; 4). Although the laboratory has a procedure for Urine Colony counts they do not document the counts but documents as negative/positive - growth/no growth, refer for ID. A procedure for growth/no growth refer for ID is not available.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as

	applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a lack of validation records and an interview with the laboratory director, the laboratory failed to establish and verify the performance specifications for the Skin and Vaginal cultures using Strep Select Agar with Bacitracin disk. Findings Include: 1. On December 13, 2018, at approximately 10:30 AM it was confirmed by the laboratory director that skin and vaginal specimen were being placed on the SSA plates with bacitracin disk. 2. The laboratory failed to validate the SSA plates and bacitracin disk prior to testing skin and vaginal specimens. 3. Approximately 3722 patient specimens were tested and reported for skin and vaginal cultures for the past two years. 4. Please also note, a qualified high complexity director is required when an off-label use is instituted.
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: 1) Based on a lack of documentation and an interview with the laboratory director and testing person, the laboratory failed to perform quality control (QC) for each new lot number or each new batch of Strep Select Agar (SSA). Findings Include: On December 13, 2018, at approximately 10:30 am and confirmed by the laboratory testing person, the laboratory failed to perform sterility checks and document the physical characteristics of the SSA plates prior to patient use for the last two years. Approximately 3722 patient specimens were tested for throat cultures for the last two years. 2) Based on a lack of documentation and an interview with the laboratory director and testing person, the laboratory failed to perform QC for each new lot number or each new batch of Uricult Media. Findings Include: On December 13, 2018, at approximately 10:40 am and confirmed by the laboratory testing person, the laboratory failed to check each new lot number or batch of Uricult media for sterility, document the physical characteristics and check the media for its ability to support growth or inhibit specific organism or produce a biochemical response prior to patient use. Approximately 592 patient specimens were tested for urine cultures for the last two years. 3) Based on a lack of documentation an interview with the laboratory director, the laboratory failed to perform quality control for the fungal culture /dermatophyte media (DTM). Findings include: On December 13, 2018 at approximately 10:50 am and confirmed by the laboratory director, the laboratory failed to document the physical characteristics of each new lot or shipment of fungal culture media (DTM) and check each new lot number or batch of fungal cultures (DTM) for its ability to support growth or inhibit specific organisms or produce a

	biochemical response for the last two years. Approximately 136 patient specimens were tested and test results in release for fungal cultures for the last two years.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's QA policy and reviews and an interview with the laboratory director and testing person, the laboratory failed to follow their QA policy. Finding Include: On December 13, 2018 at approximately 12:50 PM, it was determined that although the laboratory has a QA program, the laboratory failed to identify and take corrective action for: 1. Not performing QC for bacteriology and mycology; 2. Not validating the SSA plates and bacitracin disk to perform skin and vaginal cultures; 3. PT remediation for failures and less than 100% score.
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 an interview with the laboratory testing person at the time of the survey, the director failed to provide overall management and direction for the laboratory. Findings Include: The director failed to ensure that: 1. Less than 100% PT scores were evaluated. Refer to D6018 2. A corrective action was performed tor the unsatisfactory PT result. Refer to D6019 3. QC was performed for DTM and SSA plates and Uricult media. Refer to D6020 4. Validation was performed for skin and vaginal specimens using SSA plates with bacitracin disk. Refer to D6021
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of CAP PT reports and confirmed in an interview with the

	laboratory director and testing person, the laboratory director failed to evaluate, identify problems and perform remediation if necessary for the less than 100% PT scores. Refer to D5211
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of CAP PT results for Hematology and lack of documentation, the laboratory director confirmed on Dec 13, 2018 at approximately 12:15 that the he failed to ensure that a corrective action plan was followed for the following unsatisfactory results: Refer to D2121 and D2122 Hematology 2018 first event = 77% Hematocrit 2017 first event = 60% 2018 first event = 20% Corrective action was not documented for the above unsatisfactory results.
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 a review of QC records an interview the laboratory testing person, the laboratory director failed to ensure that the QC program for bacteriology testing was maintained to assure quality of laboratory services. Refer to: 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 the surveyor's review of the laboratory's policy/procedure manual and an interview with the laboratory testing personnel, the laboratory director failed to ensure

	that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to D2121, D2122, D5211 ,D5403, D5423, D5477 and D5793