Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0859820	12/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Eckerson Pediatric Associates, Pc	200 East Eckerson Rd Suite 110, New City, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a lack of lack of the twice-annual verification records and an interview with the laboratory testing personnel, the laboratory has never verified the accuracy of the urine colony count testing at least twice per year. FINDINGS: On December 11, 2018, at approximately 11:45 AM the laboratory testing personnel confirmed that twice annual verification to verify the accuracy of urine colony count twice annually has never been performed. The testing personnel stated that they have never been told by their regulatory agency that they needed to perform this task or to perform proficiency test if necessary. Approximately 115 patient samples were tested and reported for colony counts during the last two years.
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: At approximately 12:30 pm on December 11, 2018, the laboratory failed to have procedures in place for 1) lot to lot verification for hematology; 2) Quality Control (QC) criteria for hematology testing to include: [a) number of controls used, b) frequency of control testing, c) remedial action; d) the acceptance for two of three controls within acceptable range, and e) frequency of calibration]; 3) QC procedure for throat culture testing using bacitracin disk, 4) twice annual verification for urine colony counts.
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 a review of quality control (QC) records and an interview with the laboratory testing personnel, the laboratory failed to test each new lot, or shipment of bacitracin (Taxo A) disks for positive and negative reactivity. Finding Include: On December 11, 2018, at approximately 11:00 AM, it was confirmed by the laboratory testing personnel that the laboratory failed to check the positive and negative reactivity of the Bacitracin disks in calendar years 2016 through July 2018.
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 a review of quality control (QC) records and an interview with the laboratory testing personnel, the laboratory failed to test each new lot, or shipment of Select Strep Agar for positive and negative reactivity. Finding Include: On December 11, 2018, at approximately 11:10 AM, it was confirmed by the laboratory nurse and the testing person that the laboratory failed to check each new batch lot number of media for its ability to support growth or inhibit specific organisms for the last two years.
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 personnel, the director failed to provide overall management and direction for the laboratory. Findings Include: The director failed to ensure that: 1. The QC program for bacteriology was maintained. Refer to D6020 2. The quality assessment (QA) program for bacteriology was maintained. Refer to D6021
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 personnel, the laboratory director failed to ensure that the QC program for bacteriology testing was maintained to assure quality of laboratory services. Refer to: 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 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 D5217 and D5403