

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0449107	(X3) Date Survey Completed 05/22/2018
Name of Provider or Supplier Johnson County Pediatrics	Street Address, City, State 8800 W 75th, Suite 220, Shawnee Mission, KS	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures, review of patient test reports, interview with the Technical Consultant on 5/22/18 at 9 am, and observation of testing personnel on 5/22/18 at 8:30 am, it was determined that the laboratory's procedure for Complete Blood Counts (CBC) did not include normal or reference ranges and the procedure for the Streptococcus culture did not include instructions for performing quality control. Findings include: Review of the procedure for CBC's did not include any normal or reference ranges. Review of patient's test reports for two patients, one less than two years of age and one greater than two years of age revealed that the normal or</p>

reference ranges reported were different ranges. Observation of testing personnel demonstrating how patient samples were run on the Meditonic analyzer revealed that they had to input whether the patient was less than two years old or greater than two years old. Interview with the Technical Consultant confirmed that the normal ranges reported were dependent on the age of the patient. Review of the Streptococcus culture procedure revealed that it did not include what quality control was to be performed and when. The package insert said that quality control should be run with each batch or lot number of media. Review of quality control records revealed that quality control was being performed with each shipment of media. This was confirmed by interview with the Technical Consultant.