| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D0881829 | 02/11/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pediatric Associates Of Brooklyn, Llp | 1421 East 2nd 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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of the Bacteriology/throat culture procedure, observation of two throat culture plates and an interview with the laboratory director/technical consultant/testing person, the laboratory failed to establish a throat culture procedure that defines the criteria for plating patient specimens. FINDINGS: 1. The the laboratory director/technical consultant/testing person confirmed on February 11, 2020 at approximately 2:30 PM, that the laboratory failed to establish a throat culture procedure that defines the criteria for plating patient specimens. a. the current throat culture procedure does not define the number of patient samples per SSA plate. b. the |

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| | surveyor observed two SSA plates with 4 patient samples per plate, no cross contamination was observed, plates were labeled according to the labeling procedure. c. the laboratory is currently using the Hardy Diagnostic SSA media, the insert does not state the number of patients per plate. 2. The laboratory director stated: "They have been performing throat culture testing using one plate and 4 patients per plate for 5 years and there were no issues with cross-contamination." |