Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0670455	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Partners Of Cleveland	23250 Chagrin Blvd, Suite 130, Beachwood, OH	

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	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 record review and an interview with the Laboratory Director, the laboratory failed to include in the their policies and procedures the urine culture and throat culture requirements for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. All patient urine cultures and throat cultures

performed from 04/04/2018 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the "Laboratory Procedures and Policies" manual, approved by the Laboratory Director and provided on the date of the inspection, did not find instructions for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable for urine culture and throat culture testing. 2. Review of the "URI-CHECK Plus" manufacturer's instructions revealed the following: "Specimen Requirements Proper collection techniques and prompt cultivation are essential...for detection of urinary tract infections if reliable results are to be obtained... 1. ...cleansing... 2. Midstream...collected in a sterile container... 3. ... urine specimens should be tested...as soon as possible after collection...forwarded to the laboratory for incubation. 4. Specimens which cannot be tested immediately... should be refrigerated (4C)...Do not refrigerate for more than 24 hrs. ...incubate at 35-37C for 18-24 hours. A count of 0-30 colonies should be considered non-significant... Counts between 31-300 organisms should be considered of doubtful significance. A count of 300 or more colonies per slide or...confluent growth...should be considered significant and indicative of urinary tract infection. ...presumptive identification... Additional biochemical tests are necessary for definitive identification." 3. Review of five out of five of the laboratory's final patient urine culture test reports found the following reported results: 06/10/2019 growth 07/05/2019 negative 10/03/2019 no growth 07/17/2020 no growth 07/17/2020 no growth 4. Review of the "Bacitracin disc for identification" manufacturer's instructions found the following: "Bacitracin Differentiation Disks are...for use in qualitative procedures for the differentiation and presumptive identification of bacteria isolated in throat cultures. ...Specimens should be collected and handled following recommended guidelines. ...1. Inoculate a blood agar plate...of the test organism... 2. Using aseptic technique, place a Bacitracin Differentiation Disc onto the inoculated media using sterile forceps or the Single Disc Dispenser. 3. Lightly touch the disc with the sterile forceps to ensure complete contact between the disc and agar surface. 4. Invert and incubate plates at 35-37C in CO2 for 18-24 hours. 5. Observe for a zone of inhibition around the discs. ...Any zone of inhibition of growth from a beta-haemolytic isolate surrounding the bacitracin disc is indicative of a presumptive Group A streptococci. ...a. Other groups of beta-hemolytic streptococci, such as Group B, C, F, and G, may be susceptible to bacitracin. b. Beta-hemolytic streptococci susceptibility to bacitracin should be reported as presumptive identification of Group A streptococci. c. Final identification of Group A streptococci is made by additional tests including, biochemical, fluorescent antibody techniques, latex agglutination, or serological Lancefield grouping tests. d. ...Bacitracin discs on primary culture media may yield only 70% accuracy." 5. Review of four out of four of the laboratory's final patient throat culture test reports found the following reported results: 10/23/2019 POS gp A strep 10/25/2019 neg grp A strep 07/13/2020 neg gp A strep 10/23/2020 Positive GRP STR 6. The Laboratory Director confirmed that the laboratory did not include in the urine culture and throat culture policies and procedures the requirements for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. The interview occurred on 11/04/2020 at 10:45 AM. C; degrees Celsius hrs; hours CO2; carbon dioxide %; percent POS; positive neg; negative gr, grp, GRP; group strep, STR; streptococci

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation and an interview with the Laboratory Director, the laboratory failed to follow the manufacturer's instructions for the incubation environment of the Bacitracin discs, utilized for throat Group A Streptococcus (strep) testing procedures and result reporting. All patient throat cultures performed from 04 /04/2018 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the Bacitracin disc for identification manufacturer's instructions revealed the following statements: "...incubate plate at 35-37C in CO2 for 18-24 hours. .....Any zone of inhibition of growth from a beta-haemolytic isolate surrounding the bacitracin disc is indicative of a presumptive Group A streptococci. ... a. Other groups of beta-hemolytic streptococci, such as Group B, C, F, and G, may be susceptible to bacitracin. b. Beta-hemolytic streptococci susceptibility to bacitracin should be reported as presumptive identification of Group A streptococci. c. Final identification of Group A streptococci is made by additional tests including, biochemical, fluorescent antibody techniques, latex agglutination, or serological Lancefield grouping tests. 2. Direct observation of one out of one of the laboratory's incubating throat culture blood agar plate with a Bacitracin disc revealed an agar plate in the incubator with no indication of a CO2 environment. 3. Review of five out of five of the laboratory's final patient urine culture test reports found the following reported results: 06/10/2019 growth 07/05/2019 negative 10/03/2019 no growth 07/17 /2020 no growth 07/17/2020 no growth 4. The Laboratory Director confirmed the laboratory did not follow the manufacturer's instructions, the throat culture testing procedures did not include incubation in CO2 and the test results were not reported as presumptive. The interview occurred on 11/04/2020 at 10:20 AM. C; degrees Celsius CO2; carbon dioxide
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to include the review of quality control (QC) records and preventive maintenance records in the evaluation of the competency of testing personnel (TP) #2. All patient urine cultures and throat cultures performed from 04/04/2018 to 11/04 /2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Laboratory Procedures and Policies" manual, approved by the Laboratory Director and provided on the date of the inspection, did not find instructions to include the review of QC and preventive maintenance records in the evaluation of the competency of TP#2. 2. Review of the laboratory's Form CMS-209,

	approved and signed by the Laboratory Director on 11/01/2020, revealed two individuals, including the Laboratory Director, were indicated as TP and performed urine culture and throat culture testing procedures. 3. Review of the laboratory's 2019 and 2020 urine culture and throat culture testing competency assessment records for TP#2 did not find any documentation that indicated the review of QC and preventive maintenance records were included in the competency assessment of TP#2. 4. The Inspector requested the laboratory's 2019 and 2020 urine culture and throat culture testing competency assessment records for TP#2 that included the review of QC and preventive maintenance records from the Laboratory Director. The Laboratory Director stated that he conducted all QC procedures and the office staff monitored and documented all room, refrigerator, freezer and incubator temperatures. The Laboratory Director confirmed the laboratory did not document the competency of TP#2, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 11/04/2020 at 10:20 AM.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to include the assessment of problem solving skills in the evaluation of the competency of testing personnel (TP) #2. All patient urine cultures and throat cultures performed from 04/04/2018 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Laboratory Procedures and Policies" manual, approved by the Laboratory Director and provided on the date of the inspection, did not find instructions to include the assessment of problem solving skills in the evaluation of the competency of TP#2. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 11/01/2020, revealed two individuals, including the Laboratory Director, were indicated as TP and performed urine culture and throat culture testing procedures. 3. Review of the laboratory's 2019 and 2020 urine culture and throat culture testing competency assessment records for TP#2 did not find any documentation that indicated the assessment of problem solving skills were included in the competency assessment of TP#2. 4. The Inspector requested the laboratory's 2019 and 2020 urine culture and throat culture testing competency assessment records for TP#2 that included the assessment of problem solving skills from the Laboratory Director. The Laboratory Director confirmed the laboratory did not document the competency of TP#2, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 11/04/2020 at 10:20 AM.