Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0859826	04/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Kids Plus Pediatrics Pc	810 Clairton Blvd Ste 100, Pittsburgh, PA	

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
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 review of Quality Control records and interview with the Clinical Quality Coordinator (CQC), the laboratory failed to follow the manufacturer's instructions for a negative reactivity (no zone of inhibition) for Bacitracin Disks each lot/shipment of disks from 04/12/2020 to 04/12/2022. Findings include: 1. On the day of survey 04/12 /2022 at 02:25 pm, review of the quality control records revealed the laboratory used E. coli as a no zone of inhibition for Bacitracin disks. 2. HardyDisk Bacitracin Differentiation disks manufacturer's package insert states: "Streptococcus agalactiae (no zone of inhibition) should be use to monitor the accuracy of the disks" 3. The CQC confirmed the finding above on 04/12/2022 at 03:10 pm.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on lack of competency assessment (CA) records and interview with the Clinical Quality Coordinator (CQC), the Technical Consultant (TC) failed to assess the competency of 14 of 15 Testing Personnel (TP) who performed throat culture examinations in 2020. Finding Include: 1. On the day of survey, 04/12/2022 at 01:12 pm., The CQC could not provide CA records for 14 of 15 (CMS 209 Personnel #1,#2, #3, #4, #5, #6, #7, #8, #9, #10, #11, #12, #13, and #14) who performed throat culture examinations from 1/1/2020 to 12/31/2020. 2. The laboratory performed 849 throat cultures annually. 3. The CQC confirmed the findings above on 04/12/2022 at 03:10 p. m.