

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0967013	(X3) Date Survey Completed 06/24/2019
Name of Provider or Supplier Pediatric Associates Of Johns Creek Pc	Street Address, City, State 4310 Johns Creek Parkway, Suite 150, Suwanee, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 24, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to perform required sterility checks for bacteriology media. Refer to D5477 for details. This is a REPEAT DEFICIENCY.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on quality control (QC) document review and staff interview, the laboratory failed to perform required sterility checks for bacteriology media. Findings include: 1. Bacteriology QC document review revealed incubated sterility checks for Strep Select agar were not performed for 2017, 2018, and 2019 thus far. 2. An interview with Staff #2 in a conference room on 6/24/2019 at approximately 11:50 a.m. confirmed incubated sterility checks were not performed on Strep Select agar for the aforementioned dates. This is a REPEAT DEFICIENCY.