

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0925474	(X3) Date Survey Completed 03/10/2020
Name of Provider or Supplier Children's Medical Group Pc	Street Address, City, State 6918 Mcginnis Ferry Road, 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 March 10, 2020. 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:
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: Based on review of quality control (QC) documents and staff interview, the laboratory failed to check each batch of media for sterility as required. Findings include: 1. Review of (Streptococcus Select agar (SSA) QC logs revealed there was no sterility check documentation available at the time of survey for June through December 2018. 2. An interview with the laboratory coordinator in a medical office on 3/10/2020 at approximately 1:30 p.m. confirmed the lack of SSA sterility check documentation available at the time of survey for 2018 (June through December).</p>