

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0279039	(X3) Date Survey Completed 05/07/2018
Name of Provider or Supplier Sawgrass Pediatric Partners Llc	Street Address, City, State 9750 Nw 33rd St Ste 101, Coral Springs, FL	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to develop an Individualized Quality Control Plan (IQCP) for the performance of per lot or shipment quality control for the Strep Select Agar (SSA) plates. Findings included: Review of the laboratory's quality control procedure and the "Quality Assurance Log Sheet" for the SSA plates showed that the laboratory was accepting the manufacture's media quality control and not repeating the quality controls on the SSA plates with all the required organisms. The laboratory has some the parts of what is required in an IQCP, but failed to have a complete formal IQCP. During an interview on 5/11/18 at 12:25 PM, Laboratory Supervisor confirmed that the laboratory didn't have a formal IQCP for the SSA agar plates for the performance of per lot or shipment quality control.</p>