

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0296128	(X3) Date Survey Completed 05/30/2018
Name of Provider or Supplier Genesiscare Usa Of Florida, Llc	Street Address, City, State 1 S School Ave Ste 200, Sarasota, 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 with Testing Person #A, the laboratory failed to perform Bacteriology controls daily or establish an IQCP (Individualized Quality Control Plan) for 2 out of 2 years (2016-2018) reviewed. Findings Included: Review of QC (Quality Control) records revealed that QC was performed per the manufacturers instruction instead of daily. No IQCP was in place. Remel BactiDrop Spot Indol and BD Oxidase test kit - QC was performed every 6 months and when the lot number changed and a new shipment was received. Catalase-QC was performed when a new shipment or lot number of reagent was received. Kirby-bauer susceptibility testing-QC was performed weekly or before a new lot of disc or media was used. During an interview on 05/30/18 at 3:00 PM Testing Person #A confirmed that QC was not performed daily and there was no IQCP.</p>