

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2040074	(X3) Date Survey Completed 05/01/2018
Name of Provider or Supplier Harris Medical Services, Llc	Street Address, City, State 3328 Jenkins Rd, Ste 200, Chattanooga, TN	
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 lack of Quality Control documentation for Uricult media, lack of Individualized Quality Control Plan (IQCP) and interview with Primary Laboratory Person, the laboratory failed to have an IQCP procedure in place for Uricult Media since January 1, 2016. The findings include: 1. Lack of quality control documentation for new lot numbers and new shipments for Uricult media. 2. Lack of an IQCP procedure for Uricult Media since January 1, 2016. 3. Interview at approximately 12:00 p.m. May 1, 2018 with Primary Laboratory Person confirmed the laboratory did not have an IQCP in place for Uricult media since January 1, 2016. _____</p>