

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2132719	(X3) Date Survey Completed 03/12/2018
Name of Provider or Supplier Cquentia Ngs, Llc	Street Address, City, State 3742 Tyndale Drive, Memphis, 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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure titled "Respiratory Pathogen Panel", the laboratory's procedure manual and quality control (QC) records, and interview with the laboratory manager the laboratory failed to include a negative and positive control material at least once per day with patient testing in 2018. The findings include: 1. Observation of the laboratory on March 12, 2018 at 10:00 am revealed the GenMark ePlex instrument in use for patient testing for detection of respiratory pathogens. 2. Review of the laboratory's procedure titled "Respiratory Pathogen Panel" revealed the following statements "Positive and negative external controls should be tested with each new lot of reagents or monthly, whichever occurs first." "External controls utilized at CQuentia will be purchase-type controls." "These controls designations...are as follows: RPP-POSA, RPP-POSB, RPP-POSC, RPP-POSD, RPP-NEG." 3. Review of the laboratory's procedure manual revealed no Individualized Quality Control Plan "IQCP" for reduced frequency of quality control testing for the GenMark ePlex Respiratory Pathogen testing. 4. Review of the 2018 quality control records revealed the performance of quality control one time for each of the following cartridge lot numbers: 52968567, 53023395, 53009185, 53000303. 5. Interview with the laboratory manager on March 12, 2018 at 5:00 pm confirmed that the laboratory performs patient testing for respiratory pathogens using</p>

the GenMark ePlex instrument, does not perform negative and positive quality control each day of patient testing and does not have a IQCP for reduced frequency of QC testing.