

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0875492	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier North Little Rock Women's Clinic	Street Address, City, State 2524 Crestwood Road #5, North Little Rock, AR	
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: Review of the laboratory's Individualized Quality Control Plan (IQCP) for Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) testing performed on the Cepheid GeneXpert system, Cepheid GeneXpert manufacturer's requirement, observation, lack of documentation, and interview with laboratory staff determined that the laboratory failed to perform positive and negative quality control (QC) samples as required by the manufacturer and the IQCP. Findings follow: A) The laboratory's IQCP for CT and NG testing performed on the Cepheid GeneXpert system states "external controls should be performed using ZeptoMetrix NATrol CT/NG external run controls (NATrol CT positive, NATrol NG., and NATrol CT/NG negative control) at the following intervals: 1. On each new lot/shipment of cartridges or concurrently with placing them into use for patient testing, 2. Monthly, 3. After major system maintenance or software upgrade." B) The manufacturer's manual for NG/CT testing on the Cepheid GeneXpert system calls for positive and negative controls to be run monthly and with each new lot/shipment of cartridges. C) During a tour of the laboratory at 10:20 a.m. on 4/30/24, the surveyor noted that CT/NG cartridges currently in use was lot # 35104 and the box of cartridges was marked "QC run 1/5 /24". D) Upon request the laboratory was unable to provide documentation of QC</p>

results for cartridge Lot #'s 35104 and the only CT/NG QC available performed on 1/5/24 was for lot # 35329. E) Review of laboratory patient results revealed that CT/NG testing was performed and reported on patient # 1 (on a separate patient identification list) on 4/30/24. F) In an interview on 4/30/24 at 10:40 a.m., the laboratory staff member # 2 (on the form CMS 209) stated that QC was inadvertently performed on the wrong lot number of CT/NG cartridges and QC was not performed on lot # 35104 and should have been.