

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0919777	(X3) Date Survey Completed 11/21/2018
Name of Provider or Supplier Women's Clinic Of Forrest City	Street Address, City, State 902 Holiday Drive, Suite 102, Forrest City, 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Through a review of the Cepheid GeneXpert manufacturer's instruction, weekly external quality control documentation, and patient log , as well as interviews with laboratory staff, it was determined the laboratory failed to follow manufacturer's instructions, which resulted in no quality control on 24 of 34 days of testing, as evidenced by: D5449 - the laboratory failed to perform positive and negative controls each day of patient testing on the Cepheid GeneXpert.</p>
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: Through a review of the Cepheid GeneXpert manufacturer's instruction used as the</p>

lab procedure, weekly external quality control documentation, and patient log , as well as interviews with laboratory staff, it was determined the laboratory failed to perform positive and negative controls each day of patient testing. Survey findings include: A. The laboratory procedure titled "Cepheid GeneXpert Chlamydia/Gonorrhoeae" states, "Frequency of External Controls: One positive and one negative control will be run each day of patient testing." B. In an interview, at 10:31 a.m. on 11/21/2018, laboratory employee #3 (as listed on the form CMS-209) stated the procedure titled "Cepheid GeneXpert Chlamydia/Gonorrhoeae" was the manufacturer's instructions for use. C. A review of the Cepheid GeneXpert external quality control documentation for July, September, and November of 2018 revealed the laboratory performed external quality control weekly on the following days: 7/3/18, 7/11/2018, 7/18/2018, 7/25/2018, 7/31/2018, 9/4/2018, 9/10/2018, 9/24/2018, 11/5/2018, and 11/12/2018. D. Through a review of the Cepheid GeneXpert patient log for July, September, and November of 2018, it was determined patients were tested on the following days when quality control was not documented: 7/5/2018 (3 patients); 7/6/2018 (2 patients); 7/19/2018 (1 patient); 7/20/2018 (5 patients); 7/26/2018 (23 patients); 7/27/2018 (2 patients); 9/5/2018 (4 patients); 9/6/2018 (16 patients); 9/11/2018 (24 patients); 9/12/2018 (21 patients); 9/13/2018 (10 patients); 9/25/2018 (26 patients); 9/26/2018 (24 patients); 9/27/2018 (16 patients); 9/28/2018 (4 patients); 11/1/2018 (4 patients); 11/6/2018 (22 patients); 11/7/2018 (26 patients); 11/8/2018 (18 patients); 11/9/2018 (20 patients); 11/13/2018 (19 patients); 11/14/2018 (3 patients); 11/15/2018 (8 patients); and 11/16/2018 (8 patients). On 24 of 34 days of testing in July, September and November of 2018 patients were tested without external quality control. E. In an interview, at 10:31 a.m. on 11/21/2018, laboratory employee #3 (as listed on the form CMS-209) stated that external quality control was performed weekly instead of each day of patient testing. She further confirmed the laboratory did not have an IQCP for the Cepheid GeneXpert testing. This is a repeat deficiency from the survey conducted on 3/21/2017.