

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0874550	(X3) Date Survey Completed 02/05/2019
Name of Provider or Supplier Woman's Pavilion	Street Address, City, State #1 St Vincent Circle Suite 440, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: . Through a review of policy and procedure manual, Proficiency Test results of 2018, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to perform and document corrective actions that prevent recurrence of problems in the general laboratory systems. As evidenced by: A. A review of laboratory policy and procedure manual revealed the quality assessment procedure for Proficiency Testing assessment: " Corrective actions will be taken for unsatisfactory Proficiency Testing results and will be evaluated for effectiveness. A survey exception report is filed when Proficiency testing results are unacceptable." B. A review of Proficiency Testing records for second event of 2018 (one of three events) revealed the laboratory failed proficiency testing for Gardnerella Vaginalis with a score 60% and Urine Colony Count with a score of 50%. C. The surveyor requested documentation of corrective actions for the second Proficiency Testing event of 2018. No documentation was provided. D. In an interview on 2/5/2019 at 11: 30, laboratory personnel #3 (as listed on form CMS 209) confirmed that no corrective actions were performed for the second Proficiency Testing event of 2018.</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--</p>

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.

This STANDARD is not met as evidenced by:

. Through a review of Annual test volume worksheet, quality control data for the Quidel QuickVue Chlamydia, patient testing logs, lack of documentation, as well as interview with staff, it was determined the laboratory failed to perform a positive and negative controls on days when patients were analyzed. As evidence by: A. The laboratory utilizes the Quidel QuickVue Chlamydia test system to screen for the moderate complexity test of Chlamydia Antigen. A review of the Annual test volume worksheet revealed the laboratory performs 118 Chlamydia test annually. B. A review of the laboratory quality control policy for QuickVue Chlamydia test revealed "positive and negative controls should be tested with each lot or shipment of test materials." C. In an interview on 02/05/2019 at 1300, laboratory personnel #3 (as listed on form CMS 209) stated the laboratory did not develop an Individualized Quality Control Plan (IQCP) for Quickvue Chlamydia test. D. A review of quality control data for March, July and October of 2018 revealed on fourteen of thirty-one days in March, thirteen of thirty-one days in July and six of thirty-one days in October of 2018 the laboratory had no documentation of quality control. E. A review of the Chlamydia patient log for March 2018 revealed the following patients had Chlamydia testing performed and resulted on days with no quality control: on 3/12/18 patient #120272; patient # 020297; patient #072197; patient #022888; patient #111804; patient #020284 and patient #04085; on 3/13/2018 patient #043118; patient #121982; patient #062296; patient #021391; patient #092392 and patient # 100279; on 3/15/18 patient #100279; patient #040780 and patient #041002; on 3/16/18 patient #100185 and patient #071898; on 3/19/18 patient #080194, patient # 101993 and patient #092191; on 3/20/18 patient # 082084, patient # 111188 and patient # 013180; on 3/20 patient#022787; on 3/21/18 patient # 110182, patient # 031292, patient # 073182 and patient # 091698; on 3/26/18 patient # 012892, patient # 021802 and patient # 080888; on 3/27/18 patient #071193, patient # 042484, patient #120594 and patient # 12/24/64; on 3/28/18 patient # 012986 and patient # 100798; on 3/29/18 patient # 022898, patient # 022620, patient # 060398 and patient # 121490. F. A review of the Chlamydia patient testing log for July 2018 revealed the following patients had Chlamydia testing performed and resulted on days with no quality control: on 07/10/18 patient #012286; patient # 082989; patient #062189 and patient #120390; on 07/11/18 patient #071093; patient #102793; patient #022189 and on patient #030693; on 07/12/18 patient #120898; patient #092597; patient #071496 and patient #092392; on 7/16/18 patient #110691; on 7/17/18 patient #113091; on 7/18/18 patient #060893 and patient #031298; on 7/19/18 patient #042599 and patient #080277; on 7/24/18 patient #033162 and patient #112487; on 07/25/18 patient #122799; on 7/30/18 patient #050192 and patient # 051190. G. A review of the Chlamydia patient testing log for October 2018 revealed the following patients had Chlamydia testing performed and resulted on days with no quality control: on 10/6/2018 patient #041394; patient #080295; patient #101575; patient #101777 and patient #082902; on 10/18/18 patient #012295 and patient #100895; on 10/22/18 patient #030589 and patient #092392; on 10/23/18 patient #082789 and patient #021789; on 10/23/18 patient #082789; patient #090590 and patient #021789; on 10/25/18 patient #022996 and patient #022598; on 10/29/18 patient # 042197. H. In an interview on 02/05/2018 at 1330, laboratory personnel #3 (as listed on form CMS 209) confirmed patients were test without documentation of quality controls.