Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0874550	05/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Woman's Pavilion	#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	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: . Through a review of the Proficiency testing records for 2020, Survey Exception Reports, lack of documentation, and interviews with staff, it was determined the laboratory failed to prevent the recurrence of problems in the General Laboratory Systems. Survey findings follow: A. A review of the Proficiency testing records for 2020 Urine Colony Count proficiency testing results revealed for the first and second event of 2020 (two of two testing events) the laboratory received a score of 50% for the test Urine Colony Counts. B. A review of the Survey Exception Report for the first Urine Colony Count proficiency testing event of 2020 revealed the corrective actions: (1) All temperatures ranges was reviewed again for proper temperature checks: (2) Procedure for inoculation was reviewed: (3) techniques for reading colonies on plates was reviewed. C. A review of the Survey Exception report for the second Urine Colony Count proficiency testing event of 2020 revealed: "Techniques for Urine Colony Counts reviewed." D. The corrective actions taken by the laboratory in the first Urine Colony Count Proficiency testing event of 2020 failed to prevent the recurrence of problems identified in the second Proficiency testing event of 2020. E. In an interview on 05/25/2021 at 10:30, laboratory personnel #2 (as listed on form CMS 209) confirmed the corrective action taken failed to prevent the recurrence of failures in two of two Proficiency testing events.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	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. This CONDITION is not met as evidenced by: . Through a review of the Serum Pregnancy, Affirm and Chlamydia monthly 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 on the Affirm, Serum BHCG and Chlamydia tests. D5449 - the laboratory failed to perform positive and negative controls each day of patient testing on the Affirm, Serum BHCG and Chlamydia tests. This is a repeat deficiency from the survey performed on 2/5/2019.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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. This STANDARD is not met as evidenced by: . 1. Through a review of the policy and procedure manual, Quality Control (QC) and patient logs, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to perform positive and negative controls for the BD Affirm tests each day of patient testing. Survey findings follow: A. A review of the laboratory policy and procedure manual revealed the quality control protocol for the following test: BD Affirm: "Candida, Gardnerella and Trichomonas positive and negative controls will be performed with each new lot number B. A review of BD Affirm, quality control documentation for five of five months in 2020 and five of five months in 2021 revealed the laboratory performed a positive and negative control only on the opening of a new Lot number. C. A review of BD Affirm quality control and patient logs revealed: on 1/21/2020 a positive and negative controls were performed on BD Affirm Lot #9247926 expiration date 07/17/2020. On 1/22/2020 patient #112480, patient #010497, patient #031485, patient #012887, patient #042489: on 01 /23/2020 patient #101788, patient #092792; on 01/27/2020 patient #082497, patient #081393, patient #022488 and patient #112984; on 01/28/2020 patient #060985 and patient #092287; on 1/29/2020, patient #091186, patient #062787, patient #042480 and patient #020592 had BD Affirm tests performed and resulted without documentation of quality control. D. A review of BD Affirm quality control and patient logs revealed: on 02/06/2020 a positive and negative controls were performed on BD Affirm Lot #92206916 expiration date 06/30/2020. On 02/10/2020 patient #070697, patient #12898; on 2/11/2020 patient #08888 and patient #11995; on 2/12 /2020 patient #121888; on 2/13/2020 patient #101998 and patient #11294; on 2/17 /2020 patient #92779; on 2/18/2020 patient #12984, patient #6883, patient #12400 and patient #72495;on 2/19/2000 patient #112086; on 2/20/2020 patient #81289 and

patient #71194; on 2/25/2020 patient #42989, patient #11775 and patient #62579; on 2/26/2020 patient #122199, patient #71992, patient #62292, patient #7394 and patient #31897; on 2/27/2020 patient #814194; on 3/2/2020 patient #2187; on 3/3/2020 patient #71188, patient #53121, patient #81594; on 3/4/2020 patient #42990, patient #100174 and patient #1189 had BD Affirm tests performed and resulted without documentation of quality control. E. A review of BD Affirm quality control and patient logs revealed on 6/1/2020 a positive and negative controls were performed on BD Affirm Lot #0008354 expiration date 10/18/2020. On 6/3/2020 patient #82997, patient #92085, patient #72996 and patient #12288; on 6/4/20 patient #9486; on 6/8/2020 patient #112193; on 6/9/2020 patient #4599, patient #4599, patient#121292 and patient #1181; on 6/10/2020 patient#112790 and patient #51990; on 6/11/2020 patient #8998 and patient #11292; on 6/15/2020 patient #22189; on 06/16/2020 patient #110876, patient #71596 and patient #081085; on 6/17/20 patient #112392 and patient #82398; on 6/29/20 patient #12881 had BD Affirm tests performed and resulted without documentation of quality control. F. A review of BD Affirm quality control and patient logs revealed on 7/1/2020 a positive and negative controls were performed on BD Affirm Lot #00147912 expiration 11192020. On 7/2/2020 patient #031998 and patient #91698; on 7/6/2020 patient #52399, patient #92191 and patient #4780; on 7/7/20 patient #112486; on 7/8/2020 patient #8998, patient#81676, patient #102988 and patient #11292; on 7/9/2020 patient #11780 and patient #72996; on 7/13/2020 patient #62894 had BD Affirm tests performed and resulted without documentation of quality control. G. A review of BD Affirm quality control and patient logs revealed on 1/19/2021 a positive and negative controls were performed on BD Affirm Lot#0237521 expiration 3/19/2021. On 1/20/2021 patient #101788, patient #22285, patient #72996 and patient #121078; on 1/25/2021 patient #12782, patient #2606, patient #111593, patient #112984, patient #41493, patient #102605, patient #101097 and patient #31792; on 1/26/2021 patient #031792, patient #061494, patient #81602 and patient #111604 had BD Affirm tests performed and resulted without documentation of quality control. H. A review of BD Affirm quality control and patient logs revealed on 3/1/2021 a positive and negative controls were performed on BD Affirm Lot#0344118 expiration 12/14/2021. On 3/2/2021 patient #32305, patient # 62961, patient #122384, patient #11002, patient #121992 and patient #42989; on 3/3/2021 patient #81594, patient #11188, patient #32702, patient #91607 and patient #2699; on 3/8/21 patient #31097,patient #122195, patient #12984, patient #111694, patient #71294, patient #71294 and patient #122985; on 3/9/21 patient #82875, patient #8196, patient #102596, patient #101502, and patient #81602; on 3/10/21 patient #91520, and patient #100288; on 3/15/21 patient #12995; on 3/16/21 patient #31203, patient #3697, patient #112091, patient #42204 and patient #112790; on 3/22/21 patient #12984; on patient #21400, patient#111500 and patient#32784; on 3/29/21 patient #122496, patient #8/31/90, patient #8/7/79, and patient #7/1/91; on 3/30/21 patient #12399, patient #1298, patient #41989 and patient #8587; on 3/31/21 patient #11002, patient#51198 and patient #5105 had BD Affirm tests performed and resulted without documentation of quality control. I. A review of BD Affirm quality control and patient logs revealed on 4/15/2021 a positive and negative controls were performed on BD Affirm Lot#1033601 expiration date 12/2/61. On 4/5/21 patient #121293, patient #32899 and patient # 31998; on 4/6/21 patient #61599, patient #42301 and patient #101485; on 4/7/21 patient #13196, patient #12894, patient #71493 and patient #71493; on 4/8/21 patient #121791 and patient #112295; on 4/15/21 patient #11002, patient #3694 and patient #22809; on 4/19/21 patient #42801, patient #123193 and patient #92579; on 4/20/21 patient #122293, patient #112178, patient #1485, patient #61494 and patient #81287; on 4/22/21 patient #33163, patient #111094; on 4/26/21 patient #110888, patient#91490, patient #62182 and patient #2606 had BD Affirm tests performed and resulted without documentation of quality control. J. A review of

BD Affirm quality control and patient logs revealed in the month of May 2021(one of five months reviewed) there were no documentation of quality control and the following patients had BD Affirm test performed and resulted: on 5/3/21 patient #112391, patient #9196, patient #121202, patient #83002 and patient #83002; on 5/4 /21 patient #53120, patient #120898, patient #32899 and patient #91986; on 5/5/21 patient #31697, patient #121798 and patient #111604; on 5/7/21 patient #71294; on 5 /10/21 patient #61090, patient #42887, patient #123001 and patient #82084; on 5/11 /2021 patient #61595, patient#32493 and patient #4/6/99; on 5/12/21 patient #52793, patient #41788 and patient #5285. 2. Through a review of the policy and procedure manual, Quality Control (QC) and patient logs, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to perform positive and negative controls for the Quick-Vue Serum Pregnancy (B-HCG) tests each day of patient testing. Survey findings follow: A. A review of the laboratory policy and procedure manual revealed the quality control protocol for the following test: Quick-Vue Serum Pregnancy Test: "Controls will be performed with each new lot number both positive and negative." B. A review of the Quick-Vue Serum Pregnancy quality control documentation for eight of eight months in 2020 revealed the laboratory performed a positive and negative control only on the opening of a new Lot number of test kits. C. A review of Quick-Vue Serum Pregnancy quality control and patient logs revealed in the month of January 2020 (one of eight months reviewed) there were no documentation of quality controls and the following patients had serum pregnancy test performed and resulted: patient #0001 (as listed on patient identification worksheet), patient#0002, patient #0003, patient #0004, patient #0005, patient #0006, patient #0007, patient #0008, patient #0009, patient #0010, patient #0011, patient #0012, patient #0013, patient #0014 and patient #0015 and patient #0016. D. A review of Quick-Vue Serum Pregnancy quality control and patient logs revealed on 2/12/20 a positive and negative controls were performed on Serum Pregnancy Lot #HCG9082121 expiration date 7/31/21. On 2/03/20 patient #0017; on 2 /4/20 patient #0018; on 2/5/20 patient #0019 and patient #0020; on 2/6/20 patient #0021; on 2/10/20 patient #0022;on 2/13/20 patient #0023 and on 2/24/20 patient #0024 had serum pregnancy tests performed and resulted without documentation of quality control. E. A review of Quick-Vue Serum Pregnancy quality control and patient logs revealed in the month of March 2020 (three of eight months reviewed) there were no documentation of quality controls and the following patients had serum pregnancy test performed and resulted: patient #0024, patient #0025, patient #0026, patient #0027, patient #0028, patient #0029, patient #0030, patient 0031, patient #0032, patient #0033, patient #0034, patient #0035, patient #0036, patient #0037 and patient #0038. F. A review of Quick-Vue Serum Pregnancy quality control and patient logs revealed in the month of April 2020 (four of eight months reviewed) there were no documentation of quality controls and the following patients had serum pregnancy test performed and resulted: patient #0039, patient #0040, patient #0041 and patient #0042. G. A review of Quick-Vue Serum Pregnancy quality control and patient logs revealed on 5/4/20 a positive and negative control was performed on serum pregnancy lot #HCG9102115 expiration 10/31/21. On 5/5/20 patient #0043, patient #0044, patient #0045; on 5/11/20 patient #0046; on 5/12/20 patient #0047, patient #0048 and patient #0049; on 5/18 patient #0050 and patient #0051; on 5/18/20 patient #0051;on 5 /19/20 patient#0052 and patient #0053; on 5/27/20 patient #0054, patient #0055 and patient #0056 had serum pregnancy tests performed and resulted without documentation of quality control. H. A review of Quick-Vue Serum Pregnancy quality control and patient logs revealed in the month of August 2020 (six of eight months reviewed) there were no documentation of quality controls and the following patients had serum pregnancy test performed and resulted: patient #0056, patient #0057, patient #0058, patient #0059, patient #0060, patient #0061, patient #0062,

patient #0063, patient #0064, patient #0065, patient #0066, patient #0067, patient #0068, patient #0069, patient #0070 and patient #0071. I. A review of Quick-Vue Serum Pregnancy quality control and patient logs revealed in the month of September 2020 (seven of eight months reviewed) there were no documentation of quality controls and the following patients had serum pregnancy test performed and resulted: patient #0072, patient #0073, patient #0074, patient #0075, patient #0076, patient #0077 and patient #0078. J.A review of Quick-Vue Serum Pregnancy quality control and patient logs revealed in the month of October 2020 (eight of eight months reviewed) there were no documentation of quality controls and the following patients had serum pregnancy test performed and resulted: patient #0079, patient #0080, patient #0081 and patient #0082, patient #0083, patient #0084 and patient #0085. 3. Through a review of the policy and procedure manual, Quality Control (QC) and patient logs, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to perform positive and negative controls for the Quick-Vue Chlamydia tests each day of patient testing. Survey findings follow: A. A review of the laboratory policy and procedure manual revealed the quality control protocol for the following test: Quick-Vue Chlamydia Test: "Controls will be performed with each new lot number both positive and negative." B. A Quick-Vue Chlamydia quality control documentation for eight of eight months in 2020 revealed the laboratory performed a positive and negative control only on the opening of a new Lot number of test kits. C. A review of Quick-Vue Chlamydia quality control and patient logs revealed on 1/21/20 a positive and negative control was performed on Chlamydia lot #705430 expiration 4/30/20. On 1/22/20 patient #01497, patient #031485 and patient #72897; on 01/23/20 patient #101788; on 1/27/20 patient #82497, patient #81393; on 1/28/20 patient #6985, patient #92287, patient #91190, patient #62787; on 01/29/20 patient #42380, patient#2592; on 1/30/20 patient #22290 and patient #51780 had Chlamydia tests performed and resulted without documentation of quality control. D. A review of Quick-Vue Chlamydia quality control and patient logs revealed on 02/12/2020 a positive and negative control was performed on Chlamydia lot #705502 expiration 07/16/20. On 2/6/20 patient #72486, patient #42986 and patient #9985; on 02/11/20 patient #22290, patient #8888 and patient #21995; on 2/13/20 patient #123185 and patient #101993; on 2/17/20 patient #92779, patient #12989 and patient#2592; on 2/18/20 patient #12984, patient #6893, patient #12400 and patient #72495; on 1/30/20 patient #22290: on 2/19/20 patient #112086; on 2/20/20 patient #6496 and patient #71194; on 2/24/20 patient #11391; on 2/25/20 patient #42989 and patient #110775 had Chlamydia tests performed and resulted without documentation of quality control. E. A review of Quick-Vue Chlamydia quality control and patient logs revealed on 06/3/2020 a positive and negative control was performed on Chlamydia lot #706028 expiration 11/30/20. On 6 /4/20 patient #9480; on 6/8/20 patient #11293; on patient #4599, patient #121292, patient #1185; on 6/10/20 patient #112790, patient #51990; on patient #8998; patient #11292; on 6/15/20 patient #22189; on 6/16/20 patient #110876, patient #71596, patient #11085; on 6/17/20 patient #112392, patient #82398, patient #12792; on 6/18 /20 patient #122584, patient #121876 and on 6/22/20 patient #5791 had Chlamydia tests performed and resulted without documentation of quality control. F. A review of Quick-Vue Chlamydia quality control and patient logs revealed on 07/3/2020 a positive and negative control was performed on Chlamydia lot #705681 expiration 08 /28/20. On 7/6/20 patient #91191 and patient #41880; on 7/7/20 patient #112480; on 7 /8/20 patient #8998, patient #81876 and patient #11292; on 7/9/20 patient #11780 and patient #72990; on 7/15/20 patient #101788, patient #73184, patient #121992 and patient #2295 had Chlamydia tests performed and resulted without documentation of quality control. G. A review of Quick-Vue Chlamydia quality control and patient logs revealed on 08/4/2020 a positive and negative control was performed on Chlamydia

	lot #705985 expiration 01/01/21. On 8/5/20 patient #112260: on 8/10/20 patient #5796 and patient #31694; on 8/12/20 patient #103190 and patient #101269; on 8/17 /20 patient #72199, patient #91305, patient #9392, patient #32708, patient #12898 and patient #42403; on 8/24/20 patient #1795, patient #51081, patient #12502 and patient #11995; on 8/25/20 patient #22681, patient #111478, patient #122994 and patient #12097; on 8/26/20 patient #2699, patient #31100, patient #21489, patient #102884 and patient #112790; on 8/31/20 patient #102898, patient #31203, patient #82878, patient #80878, patient #22592 and patient #3378 had Chlamydia tests performed and resulted without documentation of quality control. H. A review of Quick-Vue Chlamydia quality control and patient logs revealed on 09/1/2020 a positive and negative control was performed on Chlamydia lot #706129 expiration 01/27/21. On 9 /2/20 patient #61372; on 9/29/20 patient #61892, patient #61892, patient #42197, and patient #102284; on 9/30/20 patient #71391, patient #112094, patient #1608, and patient #71392 had Chlamydia tests performed and resulted without documentation of quality control. I. A review of Quick-Vue Chlamydia quality control and patient logs revealed in the month of October 2020 (seven of eight months reviewed) there were no documentation of quality controls and the following patients had Chlamydia test performed and resulted: patient #11992, patient #21690, patient #2284, patient #111188, patient #121088, patient #112298, patient #11002, patient #8401, patient #92174, patient #31999, patient #3796, patient #102988, patient #32690, patient #61596, patient #11888, patient #101788, patient #12790, patient #22290, patient #112096, patient #10787, patient #22898, patient #122785, patient #3690, patient #22890 patient #31394, patient #31100, patient #72491, patient #4683, patient #12260, and patient # 41393 had Chlamydia tests performed and resulted without documentation of quality control. J. A review of Quick-Vue Chlamydia quality control and patient logs revealed on 11/16/2020 a positive and negative control was performed on Chlamydia lot #706027 expiration 01/30/21. On 11/17//20 patient #112274; on 11/18//20 patient #82466, patient #102693 and patient #7394; on 11/23 /20 patient #81720; patient #31394 and patient #12162; on 11/24/20 patient #1608121277, patient #12774 and patient #31792; on 11/25/20 patient #102296, patient #3898 and on 11/30/20 patient #4899, patient #83002 had Chlamydia tests performed and resulted without documentation of quality control. K. Surveyor requested an Individualized Quality Control Plan (IQCP) for the moderate complexity test BD Affirm, Quick-Vue Serum Pregnancy and Quick-Vue Chlamydia test. None was provided. K. In an interview on 5/25/2021 at 13:00, laboratory personnel #2 (as listed on CMS form 209) confirmed the laboratory were performing quality controls for the BD Affirm, Quick-Vue Serum Pregnancy and Quick-Vue Chlamydia test on each new lot of test kits. Laboratory personnel #2 also confirmed the laboratory did not develop an IQCP for the moderate complexity test systems performed by the laboratory. This is a repeated deficiency from the survey performed on 2/5/2019.