

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1001543	<b>(X3) Date Survey Completed</b>  03/06/2018
<b>Name of Provider or Supplier</b>  Woman's Health Group, Pllc	<b>Street Address, City, State</b>  7580 Fannin #330, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, direct observations, laboratory records, and confirmed in interview, the laboratory failed to monitor the storage temperature for the Quidel Quickvu hCG Urine test and Siemens Hema-Combistix urine strips. Findings were: 1. Review of the package insert for the Quidel Quickvue hCG Urine Test kit (1040603, 06/14) revealed "store the kit at room temperature 15 - 30 C, out of direct sunlight." 2. Review of the package insert for the Siemens hema-Combistix (TN30816A, Rev 05/10) revealed "store at temperatures between 15 - 30 C." 3. Direct observation of the nursing area revealed an opened box of Quidel Quickvue hCG Urine test kit. Direct observations of the facility restrooms revealed an opened bottle of Siemens Uristix (lot 708080, exp 08/31/19) with an opened date of 01 /04/18. 4. The laboratory was asked for the documentation of the environmental records for the nursing station and facility restrooms. No documentation was provided. 5. An interview with the lab director on 03/06/18 at 1030 hours in the break room confirmed the above findings. He was unaware the laboratory did not document the temperature.</p>

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing for 2016 and 2017 and confirmed in interview, the laboratory failed to participate and verify the accuracy of 1 of 6 events for the BD Affirm VP test for Gardnerella Vaginalis. Findings were: 1. Review of the 2016 and 2017 API proficiency testing records revealed 1 of 6 events when the laboratory did not receive a grade from API due to late enrollment and the laboratory had no documentation of the self-evaluation of the 2017 Microbiology 1st event. 2. Surveyor review of the 2017 Microbiology 1st event results revealed the laboratory had an unacceptable result for 1 of 5 specimens for Gardnerella Vaginalis. VP - 03 Gardnerella Vaginalis lab result - positive acceptable result - negative 3. An interview with the lab director on 03/06/18 at 1040 hours in the break room confirmed the above findings. He admitted he never looked at the results and just signed the proficiency testing pages.

**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:

Based on review of the American Proficiency Institute (API) proficiency testing for 2016 and 2017 and confirmed in interview, the quality assessment failed to identify the laboratory was not enrolled and did not perform a self-evaluation in 1 of 6 events for Gardnerella Vaginalis, Candida Sp, and Trichomonas vaginalis. Findings were: 1. Review of the 2016 and 2017 API proficiency testing records revealed 1 of 6 events when the laboratory did not receive a grade from API due to late enrollment and the laboratory had no documentation of the self-evaluation of the 2017 Microbiology 1st event for Gardnerella Vaginalis, Candida Sp and Trichomonas vaginalis. 2. The laboratory was asked for documentation of the self-evaluation of the above event. No documentation was provided. 3. An interview with the lab director on 03/06/18 at 1040 hours in the break room confirmed the above findings. He was unaware that he needed to perform a self-evaluation for testing events that were not scored. key: Candida Sp. - Candida species

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory proficiency testing records and confirmed in interview, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for the BD Affirm VP test for Gardnerella Vaginalis for all testing events of 2017. Findings were: 1. Review of the laboratory American Proficiency Institute proficiency testing records revealed the laboratory was not enrolled in proficiency testing for 2017 until 05/09/17. Microbiology first event was 02/2017 2. An interview with the testing person on 03/06/18 at 0930 hours confirmed the above findings. She stated that there were billing issues and the new office manager was unaware that the bill for API needed to be paid.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on review of the American Proficiency Institute (API) proficiency testing for 2016 and 2017 and confirmed in interview, the laboratory director failed to ensure accuracy of 1 of 6 events for the BD Affirm VP test. Refer to D5215