Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0918362	01/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
A Woman's View	915 Tate Boulevard Se, Suite 170, Hickory, NC	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of the Cepheid operator's manual, review of 2018 quality control logs, and laboratory director (LD) interview 1/3/19, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The laboratory began testing for Chlamydia (CT) and Gonorrhea (NG) on the Cepheid GenExpert analyzer in January 2017. Review of laboratory procedures and policies, and review of operator's manual for the Cepheid GenExpert revealed the procedures and operator's manual failed to include laboratory specific information for quality control, such as: what quality control material is used,

	the frequency for performance of quality control, the criteria used to determine acceptability of quality control results and the corrective actions to take if quality control results are unacceptable. For example: a. The laboratory procedure "CT/NG IN HOUSE (CEPHEID)" states "For procedure instructions for setup and testing on the Cepheid see the operator's manual on the Cepheid computer or the package inserts found in the green Cepheid binder." b. The operator's manual on the Cepheid computer states "6.3 External Quality Controls.....external controls may be used in accordance with local, state or federal accrediting organizations, as applicable..." c. The laboratory policy "QUALITY CONTROL" states "INTERNAL QUALITY CONTROL....Qualitative Controls: Qualitative controls must be run at least once per shift whenever patient samples are tested..." The policy also includes specific quality control information for each type of testing performed, but fails to include what is required for the Cepheid GenExpert. For example, the policy states ".... RAPID STREP A External positive and negative controls will be run with each new lot or new shipment of same lot. ..." Exit interview with LD at approximately 5:00 p.m. confirmed the procedures and operator's manual did not include specific information for quality control on the Cepheid GenExpert. She stated the frequency on the quality control is monthly and it is written in the Individual Quality Control Program (IQCP) for the Cepheid GenExpert. 2. The laboratory's "IN-HOUSE URINE CULTURES" procedure had not been updated to reflect the laboratory's current method. The procedure states "SUPPLIES/REAGENTS: CLED/EMB agar biplates ... 16. If there is growth on the EMB side of the bi-plate ...". During interview at approximately 11:05 a.m., the LD stated that they no longer use CLED/EMB biplates for urine cultures. She stated that they started using Maconkey/Blood agar biplates in November 2018, but the procedure had not been updated yet. 3. The procedure manual did not include the laboratory's procedure for media quality control on the Maconkey/Blood agar plates used for urine cultures. Review of 2018 media quality control logs revealed the laboratory documented a sterility check with each new lot number of media, and growth checks with quality control organisms (E. coli and Staph aureus) each day of testing. During interview at approximately 11:05 a.m., the LD confirmed that the procedure manual did not include a procedure for media quality control. 4. The laboratory's "RECORDING RESULTS" procedure had not been updated to reflect the laboratory's current LIS (laboratory information system). The procedure states "Patient results from the Medonic M-series, Seimens Dimension Expand Plus and the TOSOH are received into the LIS system, Apex. ..." The laboratory's current LIS (laboratory information system) is Orchard as indicated by other procedures in the procedure manual. For example, the laboratory's "IN-HOUSE URINE CULTURES" procedure states "... 15. Results should be entered in Orchard. ..." 5. The laboratory's "VAGINAL WETMOUNTS" procedure states on page 2 "... The 40x objective is used to identify the presence of white and red blood cells, quantity and type of bacteria present, clue cells, motile Trichomonas, yeasts, and fungal hyphae. ..." The procedure did not include the criteria used for interpretation of the results (present /absent; few/moderate/many; 1+/2+/3+, etc.). 6. The laboratory's "QUALITY CONTROL" policy had not been updated to reflect implementation of the IQCP (individualized quality control plan) for the BD Affirm VPIII. The policy states ".... BD AFFIRM...External positive and negative controls will be performed each day of use. ..." The laboratory's IQCP for the BD Affirm VPIII states "... Each test includes a positive and negative internal control on each PAC (Probe analysis card) ... These are tested with each patient specimen to ensure proper performance of the PAC ...Upon completion of IQCP, external QC will be done on each new shipment and new shipment of same lot. ..." Review of 2018 BD Affirm VPIII quality control logs revealed positive and negative external controls were tested with each new kit lot number or shipment.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and laboratory director (LD) interview 1/3/19, the laboratory failed to discard supplies that had exceeded their expiration dates. During a tour of the laboratory at approximately 5:00 p.m., surveyors observed the following expired supplies in the laboratory, available for use: 1. 7 boxes of BD Affirm VPIII Ambient Temperature Transport System, lot #6279779 with expiration date 01/21/2018 in a cabinet above the Affirm analyzer; 2. Siemens Dimension Clinical Chemistry System Chemistry Wash on the floor under the Millipore: a. 1 container of lot #56400019 with expiration date 10/23/2018; b. 2 containers of lot #56400020 with expiration date 10/24/2018; 3. 1 box of Quantimetrix Dropper Urinalysis Dipstick Control 1 and 2, lot #44070A with expiration date 08/2017 in the door of Refrigerator #1; 4. 3 bottles of BIO-RAD Lyphochek Immunoassay Plus Control, lot #40302 with expiration date 02 /28/2017 on the second shelf of the refrigerator. During interview at approximately 5: 10 p.m., the LD stated that the expired supplies were not being used.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, and review of 2017 and 2018 Millipore maintenance logs 1/3/19, the laboratory failed to follow manufacturer's instructions for maintenance of the Millipore water filtration system. The procedure for monitoring bacteria levels in water found in the Millipore User Manual states "To meet NCCLS requirements for the specification of bacteria count, periodic testing is recommended. ...NCCLS recommends the use of the Heterotrophic sampler count (HPC). ... To use the sampler, follow these steps: ... 2. sanitize the sampling port: Working from the inside out, wash the port with a 10% bleach solution. 3. Open the sampling port ... and let it run for at least one minute. 4. Pour a sample into the sampler case ... Insert the sampler ... 7. Incubate the sampler at 25 degrees C +/- 1 degree C for 48-72 hours. Total incubation time must be at least 48 hours. ..." The laboratory's "MILLIPORE CULTURE" procedure states "The water from the Millipore must be cultured monthly to check for growth. Procedure: 1. Dispense a few milliliters of Millipore water into a sterile cup from dispense valve on Millipore. 2. Use 1uL calibrated loop... 3. Streak biplate ... 4. Incubate biplate for 24 hours at 36-38 degrees C. 5. Inspect plate for growth after 24 hours incubation. ..." Review of 2017 and 2018 Millipore maintenance logs revealed the laboratory cultured the Millipore water once per month. Documentation indicated the cultures were set up one day and read the following day.
D5437	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's product inserts, review of 2016, 2017 and 2018 calibration records, and laboratory director (LD) interview 1/3/19, the laboratory failed to calibrate the Tosoh AIA-900 analyzer every 90 days as required. Findings: The laboratory performs the following tests on the Tosoh A1A-900 analyzer: Estradiol (E2), Follicle-Stimulating Hormone (FSH), Luteinizing Hormone (LHII) and Prolactin (PRL). Manufacturer's product inserts for Estradiol, FSH, LH, and Prolactin (ST A1A-Pack E2, ST AIA-PACK FSH, ST AIA PACK LH II, and ST AIA-PACK PRL) performed on the Tosoh AIA-900 analyzer state "... II. Calibration Procedure A) Calibration Curve The calibration curve is stable for up to 90 days. Calibration stability is monitored by quality control performance and is dependent on proper reagent handling and Tosoh AIA System maintenance according to the manufacturer's instructions. ..." 1. Review of the calibration records for FSH revealed the following: a. Calibration was performed 8/19/16; the calibration expired 11/17/16 and was not performed until 3/3/17. A period of approximately 106 days in which the calibration curve had expired and patients were tested. b. Calibration was performed 3/3/17; the calibration expired 6/1/17 and was not performed until 9/7/18. A period of approximately 463 days in which the calibration curve had expired and patient were tested. c. Calibration was performed 9/8/18; the calibration expired 12/7/18 and was not performed through time of survey 1/3/19. A period of approximately 27 days in which the calibration curve had expired and patients were tested. 2. Review of calibration records for LH revealed the following: a. Calibration was performed 9/30/16; the calibration expired 12/29/16 and was not performed until 3/3/17. A period of approximately 65 days in which the calibration curve had expired and patients were tested. b. Calibration was performed 3/3/17; the calibration expired 6/1/17 and was not performed until 8/7/17. A period of approximately 68 days in which the calibration curve had expired and patients were tested. c. Calibration was performed 8/7/17; the calibration expired 11/5/17 and was not performed until 1/26/18. A period of approximately 83 days in which the calibration curve had expired and patients were tested. d. Calibration was performed 1/26/18; the calibration expired 4/26/18 and was not performed until 6/7/18. A period of approximately 42 days in which calibration curve had expired and patients were tested. e. Calibration was performed 6/7/18; the calibration expired 9/5/18 and was not performed until 10/26/18. A period of approximately 51 days in which the calibration curve had expired and patients were tested. 3. Review of calibration records for PRL revealed the following: a. Calibration was performed 4/28/17; the calibration expired 7/27/17 and was not performed until 9/8/17. A period of approximately 43 days in which the calibration curve had expired and patients were tested. b. Calibration was performed 9/8/17; the calibration expired 12/7/17 and was not performed until 1/19/18. A period of approximately 43 days in

	which the calibration curve had expired and patients were tested. c. Calibration was performed 5/4/18; the calibration expired 8/2/18 and was not performed until 8/7/18. A period of approximately 5 days in which the calibration curve had expired and patients were tested. d. Calibration was performed 8/31/18; the calibration expired 11 /29/18 and was not performed through time of survey 1/3/19. A period of approximately 35 days in which the calibration curve had expired and patient were tested. During an interview at approximately 5:30 p.m. the LD stated that each reagent kit is consumed before it expires and before the 90 calibration period ends. The laboratory's focus is to ensure that those systems with calibration points of 3 or less are calibrated every 6 months.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of 2016, 2017, and 2018 laboratory records 01/03/19, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program (see D6021). 2. The laboratory director failed to ensure testing personnel had documented training for all testing performed (see D6029). 3. The laboratory director failed to ensure competency evaluation policies were established and followed (see D6030). 4. The laboratory director failed to ensure a complete and current procedure manual was available to all personnel for all aspects of the testing and reporting process (see D6031). 5. The laboratory director failed to failed to specify, in writing, which procedures each testing personnel (TP) is authorized to perform (see D6032).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan and review of 2016, 2017 and 2018 laboratory records 01/03/19, the laboratory director failed to ensure the laboratory's quality assessment program was maintained to identify and correct problems and prevent their recurrence to assure the quality of laboratory services provided. Review of laboratory policy "QUALITY ASSESSMENT PLAN" revealed "PROCEDURE.....Each month will include a quality assessment of factors which will help us accomplish the goals and statements listed above. The assessments will be reviewed monthly by the lab manager and the Medical Director." The laboratory performed monthly quality assessment activities, but the activities failed to identify

	problems identified during the survey. Examples: 1. Review of monthly quality assessment "PROCEDURE MANUAL REVIEW" for October 2017 and 2018 revealed "5. Are the procedures reflective of what is being performed in the lab?" The answer documented is "YES". "Evaluator" is initialed by testing personnel (TP) #3 and "Lab Director" is initialed by the laboratory director (LD). The monthly quality assessment failed to identify that the procedure manual was not complete and current (see D5403). 2. Review of monthly quality assessment "QUALITY CONTROL AND INSTRUMENTATION" for March 2017 and 2018 revealed "1. Are Calibrations performed according to manufacturer's guidelines and at least every 6 months?" The answer documented is "YES". "2. Is there documentation of each calibration?". The answer documented is "YES". "Evaluator" is initialed by TP #3 and "Lab Director" is initialed by the LD. The monthly quality assessment failed to identify that Tosoh AIA-900 calibrations were not performed at the frequency specified by the manufacturer (see D5437). 3. The laboratory's quality assessment policy also failed to identify and correct problems identified during the survey in the following areas: a. Expired supplies and controls (see D5417). b. Maintenance (see D5429). c. Testing personnel training (see D6029).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and laboratory director (LD) interview 01/03 /17, the laboratory director failed to ensure all testing personnel (TP) had documented training. Review of personnel records revealed TP #3 began testing on the Dimension Xpand and Tosoh A1A-900 chemistry analyzers in June of 2017. Review of personnel records for TP #3 revealed a 6 month competency assessment which included "Chemistry and Immunochemistry". The records failed to document training for the Dimension Xpand and Tosoh A1A-900 chemistry analyzers. Interview with LD at approximately 1:30 p.m. confirmed there was no documentation of training for TP #3 on the Dimension Xpand and Tosoh A1A-900 chemistry analyzers. She stated she had trained TP #3 but did not document the training.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to

	process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of personnel competency records and laboratory director (LD) interview 01/03/19, the laboratory director failed to ensure policies and procedures were established for the evaluation of testing personnel (TP) competency. 1. Review of laboratory procedure manual revealed no policy or procedure for the evaluation of TP competency Review of personnel records revealed the form "PERSONNEL COMPETENCY ASSESSMENT", which is used by the laboratory to document the competency evaluations of testing personnel. The "PERSONNEL COMPETENCY ASSESSMENT' form failed to establish a competency policy or procedure. Exit interview with laboratory director at approximately 5:00 p.m. confirmed the laboratory has no policy or procedure for the evaluation of TP competency. 2. Review of "PERSONNEL COMPETENCY ASSESSMENT" form revealed the form failed to include all moderate complexity testing performed by laboratory TP. The form failed to include the following: a. Urine cultures b. Chlamydia and Gonorrhea testing on the Cephid Gene Expert analyzer c. Gardnerella, Candida and Trichomonas testing on the BD Affirm analyzer. 3. Review of "PERSONNEL COMPETENCY ASSESSMENT" form revealed the form failed to include all 6 required components for competency assessment of TP. The form failed to include assessment of TP problem solving skills.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the deficiency cited at D5403 and review of the laboratory's policies and procedures 1/3/19, the laboratory director (technical consultant) failed to ensure a complete and current procedure manual was available to all personnel for all aspects of the testing and reporting process. Review of the laboratory's procedure manuals revealed the manuals were not complete and current for all aspects of the testing and reporting process (see D5403). The laboratory director also serves as the technical consultant. Review of laboratory policy "TECHNICAL CONSULTANT" revealed "Responsibilities...Maintain Procedure Manual revising any new procedures or removing any outdated procedures."
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of laboratory personnel records and laboratory director (LD) interview 01/03/19, the laboratory director failed to specify, in writing, which procedures each testing personnel (TP) is authorized to perform. Review of laboratory policy, "Laboratory Director" revealed ....." RESPONSIBILITIES....The responsibilities and duties of each consultant and testing personnel are specified in writing." Review of laboratory policy, "TESTING PERSONNEL" revealed a list of responsibilities for "Each individual performing tests..". The policy fails to specify which procedures each TP is authorized to perform. Review of laboratory procedure manual and personnel records revealed no documentation to indicate which procedures 3 of 3 TP were authorized to perform. Exit interview with LD at approximately 5:00 p.m. confirmed the laboratory had no documentation to indicate which procedures each TP were authorized to perform. She stated she was not aware that she needed to specify what test each TP could perform.