Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0918362	05/04/2022
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of hematology records, the absence of records, and interview with the TC (technical consultant) 5/4/22, the laboratory failed to retain background records for the Medonic M-series hematology analyzer from 1/4/19 to 2/24/22. Review of 2019, 2020, 2021, and 2022 hematology records revealed there were no background records available for the Medonic hematology analyzer. The laboratory director was able to print a background report during the survey, but the report did not include any backgrounds prior to 2/25/22. During interview at approximately 3:40 p. m., the TC stated that they don't routinely print backgrounds.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2019, 2020, 2021, and 2022 API (American Proficiency Institute) proficiency testing records, and interview with the TC (technical consultant) 5/4/22, the laboratory failed to ensure that all unacceptable and ungraded proficiency testng results were evaluated to determine the need for corrective action. Findings: The laboratory's "Proficiency

	Testing" procedure states "... 10. The Lab Manager will review the results, initial the Proficiency Survey Report Form, and initiate any corrective action(s) if needed. 11. The Lab Director and/or his Designee will review all Proficiency Test results and all corrective actions for unacceptable results. 12. All Proficiency Test reports must be reviewed and signed by the Lab Director. ... b. Passing results with grades less than 100% should be reviewed for cause of the failed result in the group. c. Failures must be thoroughly investigated and corrective actions documented. ... Document all corrective actions, attaching additional information if needed. d. All ungraded challenges must be reviewed against the Participant Summary to evaluate the lab's performance, with comments made on the result form indicating acceptability of results. ..." Review of 2019, 2020, 2021, and 2022 API proficiency testing results revealed the laboratory failed to document evaluation of all unacceptable and ungraded proficiency testing results. Examples: 1. On the 2019 2nd hematology event, the laboratory failed to document evaluation of the ungraded urobilinogen result for sample UA-04. The laboratory noted the expected result, but did not note any corrective action for their unacceptable result. 2. On the 2020 1st chemistry core event, the laboratory received a score of 80% for hCG (human chorionic gonadotropin). Sample HCG-02 was retested, but there was no documentation that the laboratory investigated to determine the cause of the unacceptable result. 3. On the 2021 1st chemistry core event, the laboratory received a score of 80% for TSH (thyroid stimulating hormone). Sample CH-02 was retested, but there was no documentation that the laboratory investigated to determine the cause of the unacceptable result. 4. On the 2022 1st hematology event, the laboratory failed to document evaluation of the ungraded urobilinogen result for sample UA-01. The laboratory noted "in consensus", but did not note any corrective action for their unacceptable result. During interview at approximately 5:30 p.m., the TC stated she was unaware that they needed to review ungraded results to determine whether the laboratory's result was consistent with the expected result or whether corrective action was needed.
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 procedures, review of laboratory records, and interview with the LD (laboratory director) 5/4/22, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. Review of laboratory procedure "BD Veritor COVID Antigen Test" revealed "The following is the procedure to be followed for reporting of (+) results for the BD Veritor COVID Antigen Test ...3. When the lab receives a positive Covid antigen test on the BD Veritor, they will immediately enter results into the LIS ...6. The phone nurse will then contact the local health department to notify them of the positive Covid antigen results along with any patient information necessary." Review of laboratory records revealed an electronic log of positive and negative SARS-CoV-2 results reported to the state. Interview with LD at approximately 4:00 p.m. confirmed the laboratory procedure for reporting SARS-CoV-2 test results is not current with the current procedure of reporting results both positive and negative results to the state and local health department via an online system. 2. The laboratory performs the following tests on the TOSOH A1A-900 analyzer: Estradiol (E2), Follicle-Stimulating Hormone (FSH), Luteinizing Hormone (LH), Prolactin (PRL) Progesterone, and Vitamins D and B12. Review of laboratory procedure manual revealed manufacturer's product inserts for "TOSOH A1A-Control Set", "TOSOH A1A-Calibrator Set" and "TOSOH A1A-Pretreatment Set" but no written procedure for performing Vitamin B12, Vitamin D, LH, FSH, Prolactin, Progesterone or Estradiol testing on the TOSOH A1A-900 analyzer. Interview with LD at approximately 3:15 p.m. confirmed the laboratory does not have a written procedure for performing Vitamin B12, Vitamin D, LH, FSH, Prolactin, Progesterone or Estradiol testing on the TOSOH A1A-900 analyzer and had been using the package inserts for performing testing.
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 review of manufacturer's product inserts, laboratory procedure manual, 2019, 2020, 2021, and 2022 calibration records, and LD (laboratory director) interview 5/4/22, the laboratory failed to calibrate the TOSOH analyzer as required by the manufacturer. Findings: The laboratory performs the following tests on the TOSOH A1A-900 analyzer: Estradiol (E2), Follicle-Stimulating Hormone (FSH), Luteinizing Hormone (LH), Prolactin (PRL) Progesterone, and Vitamins D and B12. For example: Manufacturer's product inserts for FSH (AIA-PACK FSH), 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. ..." Manufacturer's product inserts for Vitamin B12 (AIA- Pack B1)

	revealed, "The calibration curve for AIA-Pack B12 is stable for up to 30 days." Review of the laboratory procedure manual revealed "TOSOH chart" states "TEST: FSH ...CALIBRATION FREQUENCY ...EVERY 90 DAYS ..." "TEST: B12 ... CALIBRATION FREQUENCY ...EVERY 30 DAYS ..." 1. Review of the calibration records for FSH revealed calibration was performed 5/16/20; the calibration expired 6 /16/20 and was not performed until 7/2/20. A period of approximately 15 days in which the calibration curve had expired and 6 patients were tested during the expired calibration period. 2. Review of calibration records for Vitamin B12 revealed the following: a. Calibration was performed 2/21/19; the calibration expired 3/21/19 and was not performed until 4/8/19. A period of approximately 17 days in which the calibration curve had expired and 23 patients were run during the expired calibration period. b. Calibration was performed 7/31/19; the calibration expired 8/31/19 and was not performed until 9/11/19. A period of approximately 11 days in which the calibration curve had expired and 6 patients were run during the expired calibration period. During an interview at approximately 4:45 p.m., LD confirmed calibration for Vitamin B12 is due every 30 days and FSH is due every 90 days for the TOSOH per the manufacturer, and she has had trouble keeping up with when it was due in the past. This deficiency previously cited 1/3/19.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and records, review of random patient test reports, and interview with the laboratory director 5/4/22, the laboratory failed to ensure the reference ranges provided were accurate for the testing performed on the Dimension EXL 200 Chemistry analyzer. Findings: The laboratory began testing on the Dimension EXL 200 chemistry analyzer in April 2020. Review of the laboratory's procedures revealed a set of reference ranges for the Dimension analyzer, with a note that stated the ranges were being updated, and that the ranges in the Orchard LIS (laboratory information system) did not match the manufacturer's ranges in the Dimension EXL. For example, the laboratory's procedure manual listed the following reference ranges: AHDL(high density lipoprotein): 35-60mg/dL(milligrams per deciliter) Albumin: 3.4-5.0 g/dL(grams per deciliter) ALT(Alanine transaminase): 30-65U/L(Units per liter) BUN(Urea Nitrogen): 7-24mg/dL K(potassium: 3.6-5.2mmol/L (millimoles per Liter) 1. Review of the Dimension EXL analyzer printout and the patient test report for patient #1522212 revealed the manufacturer ranges in the analyzer did not match the ranges reported in the Orchard LIS. The patient's Dimension EXL analyzer printout revealed: AHDL: 40-60mg/dL Albumin: 3.4-5.0 g /dL ALT: 14-63U/L BUN: 7-18mg/dL K: 3.5-5.1mmol/L The patient test report from the Orchard LIS revealed: AHDL: 35-65mg/dL Albumin: 3.4-5.5g/dL ALT: 30-65U /L BUN: 7-24mg/dL K: 3.5-5.5mmol/L 2. Review of the Dimension EXL analyzer printout and patient test report for patient #1512724 revealed the A1c reference range listed as 4.3-6.4% which did not match the A1c reference range of 4.8-6.0% listed in the laboratory's procedure manual. At approximately 4:10 p.m., the laboratory director confirmed the reference ranges did not match. She stated she just realized the previous week that the ranges did not match and they were in the process of having them updated in Orchard to reflect the manufacturer's ranges.

D6020	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 the quality control program is 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 policies and procedures, review of 2019, 2020, 2021, and 2022 Medonic M-series hematology quality control records, review of the laboratory director job description, and interview with the laboratory director 5/4/22, the laboratory director failed to ensure the quality control program was established and maintained for hematology. Findings: Review of the laboratory's "QUALITY CONTROL PROGRAM" policy revealed "... Control Performance for Hematology (Medonic) ... 7. If any of the following conditions occur, the corrective action request form must be completed: a. One control is greater than +/- 3 SD (standard deviations) from the mean b. Two controls are greater than +/- SD from the mean c. One control is between 2-3 SD for four consecutive days or on one side (higher or lower) of mean for six consecutive days. ..." Review of 2019, 2020, 2021, and 2022 Levy-Jennings hematology quality control records revealed multiple days when controls were on one side of the mean for six consecutive days or more with no corrective action documented. Examples: 1. For lot #21905 (in use 6/24/19-9/23/19), all hemoglobin values for the high control were below the mean. 2. For lot #22011 (in use 12/16/20-3 /19/21), all hemoglobin values for the low control were below the mean. 3. For lot #22106 (in use 8/30/21-10/4/21), white blood cell count values were above the mean for multiple days: a. Low control above the mean for 14 consecutive days 9/1/21-9/21 /21; b. Normal control above the mean for 16 consecutive days 8/30/21-9/21/21; c. High control above the mean for 21 consecutive days 8/30/21-9/28/21. Review of the laboratory director's job description revealed the laboratory director "... Ensures that quality control and quality assurance programs are established and maintained to identify failures in quality ... " and "... Ensures that remedial actions are taken and documented when significant deviations from the lab's established performance characteristics are identified. ..." During interview at approximately 2:45 p.m., the laboratory director stated they do not use a corrective action request form. She confirmed there was no corrective action documented.
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 interview with the laboratory director 5/4 /22, the laboratory director failed to ensure that 2 of 3 TP(testing personnel #2 and #3) received appropriate training for all testing the TP perform. Findings: Review of personnel records revealed: 1. TP #2 was hired in June 2019 and had an initial competency completed 6/17/19. The competency evaluation form stated that TP #2 was evaluated for urine cultures, wet mounts, and urinalysis. The competency evaluation form stated under "reviewer's comment", "See training checklists for specific training". Review of the training checklists for TP#2 revealed there was no documentation of the training for urine cultures, wet mounts, and urine microscopic exam. 2. TP #3 was hired in January 2022 and had an initial competency completed 1 /26/22. The competency evaluation form stated that TP #3 was evaluated for urine cultures, but training for wet mounts and urine microscopic exam was still in progress. The "reviewer's comment" stated, "Training checklists completed." Review of the training checklists for TP#3 revealed there was no documentation of the training for urine cultures. At approximately 12:40 p.m., the laboratory director confirmed there was no documentation of training for urine cultures, wet mounts, and urine microscopic exam for TP #2 and no documentation of training for urine cultures for TP #3. She stated the TP received training, but no documentation of the training was completed.