Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403934	05/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
We Health Clinic, Pa	32 East First Street, Suite 300, Duluth, MN	

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 document review and interview with laboratory personnel, the laboratory failed to ensure a procedure describing the corrected reports process was included in the procedure manual. Findings are as follows: 1. The laboratory performed Rh factor testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 12:45 p.m. on 05/02/19. 2. A procedure describing the corrected test report process was not found in the Women's Health Center of Duluth, PA Procedure Manual on date

	of survey. 3. In an interview at 2:00 p.m. on 05/02/19, the LD indicated a process had been established for correcting test reports but a written procedure had not been generated.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation and interview with laboratory personnel, the laboratory failed to perform and document function checks (calibration) for 1 of 1 Min/Max digital thermometers from 2/28/18 to date of survey, 05/02/19. Findings are as follows: 1. The laboratory performed Rh factor testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 12:45 p.m. on 05/02/19. 2. A Lab Thermco Min /Max digital thermometer with serial number 2572 was observed as in use in the laboratory refrigerator during the tour. Control materials were stored in the refrigerator. 3. A manufacturer's calibration due date of 2/13 was indicated on the back of the Min/Max digital thermometer. The laboratory provided a calibration certificate which indicated the most recent calibration for the digital thermometer expired 02/28/19. 4. During an interview at 2:15 p.m. on 05/02/19, the LD confirmed the Min/Max digital thermometer calibration was overdue and indicated the vendor was scheduled to perform the calibration later in the year.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant failed to ensure 2 of 3 testing personnel (TP) in 2017 and 1 of 3 TP in 2018 were evaluated for test performance competency through assessment using previously analyzed Immunohematology specimens, blind samples, or proficiency testing samples at least annually. Findings are as follows: 1. The laboratory performed Rh factor testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 12:45 p.m. on 05/02/19. 2. Rh factor proficiency testing (PT) results were being used to evaluate testing personnel competency as indicated in the Training of New Lab Personnel procedure found in the Personnel Binder-Lab manual. Evaluation of PT documentation was not included on the 2017 and 2018 Personnel Assessment Program forms. 3. Laboratory records indicated 2 of 3 TP in 2017 and 1 of 3 TP in 2018 did not perform Rh factor PT. The laboratory was unable to provide

	additional documented evaluations of blind sample testing upon request. See below where "x" indicates proficiency testing was not performed. Rh Proficiency Testing Testing Personnel 1 2 3 2017 x x 2018 x 4. In an interview at 1:10 p.m. on 05/02/19, the LD verified all testing personnel routinely performed the Rh factor testing and confirmed PT for this testing was not completed by all staff in 2017 and 2018.