Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403934	03/02/2021
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to attest to the integration of proficiency testing samples into the routine patient workload on one occasion in 2019 and two occasions in 2020 . Findings are as follows: 1. The laboratory performed Rh factor testing as indicated on the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification Form CMS-116 and confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/02/21, at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The Laboratory Director (LD) and Testing Personnel (TP) were required to sign the attestation statements as established in the Proficiency Testing procedure located in the Laboratory Policy & Procedure manual. 4. The LD failed to attest to the integration of PT samples into the routine patient workload for 3 of 5 API PT events reviewed in the May 2019 through March 2021 timeframe. See below. Event Specialty missing attestation 2019-3 Immunohematology (No LD signature) 2020-1 Immunohematology (No LD signature) 2020-2 Immunohematology (No LD signature) 5. In an interview on 03/02/21 at 11:15 a.m., TP1 confirmed the above findings. .
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 05/02/19 to date of survey, 03/02/21. Findings are as follows: 1. The laboratory performed Rh factor testing as indicated on the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification Form CMS-116 and confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/02/21, at 10:05 a.m. 2. A Lab Thermco Min/Max digital thermometer with serial number 2447 was observed as in use in the laboratory refrigerator during the tour. Rh control materials were observed to be stored in the refrigerator. 3. A manufacturer's calibration due date of 2/18 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 02/28/18. 4. In an interview on 03/02/21 at 11:15 a.m., TP1 confirmed the above findings. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure quality control (QC) was performed each day of Rh testing. Findings are as follows: 1. The laboratory performed Rh factor testing as indicated on the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification Form CMS-116 and confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/02/21, at 10:05 a.m. 2. Eldon Rh testing kits were observed as present and available for use during a tour of the laboratory. 3. Performance of positive and negative QC each day of patient testing was established in the Rh Factor Control and Quality Assurance procedure found in the Laboratory Policy & Procedure manual. 4. QC was not performed as required on 3 days of patient testing between May 2019 and March 2021. Entries in the QC log and completed Rh QC cards on the back of the patient testing log were missing. 6 patient test results were released without the required QC performance. See below Date of testing Patients tested 11/04/20 3 11/12/20 1 11/20/20 2 5. In an interview on 03/02/21 at 11: 15 a.m., TP1 confirmed the above findings. .
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 document review and interview with laboratory personnel, the Laboratory Director failed to review and evaluate proficiency testing (PT) results one occasion in 2019 and three occasions in 2020 . Findings are as follows: 1. The laboratory performed Rh factor testing as indicated on the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification Form CMS-116 and confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/02/21, at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The results of the following PT events were not reviewed or evaluated by the laboratory. Event Specialty 2019-3 Immunohematology 2020-1 Immunohematology 2020-2 Immunohematology 2020-3 Immunohematology 4. In an interview on 03/02/21 at 11:15 a.m., TP1 confirmed the above findings. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Consultant failed to evaluate the competency of 1 of 4 testing personnel in 2020. Findings are as follows: 1. The laboratory performed Rh factor testing as indicated on the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification Form CMS-116 and confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/02/21, at 10:05 a.m. 2. The Approval of Laboratory Personnel procedure located in the Laboratory Policies and Procedures manual indicated personnel were to be evaluated semi-annually during the first year of employment and annually thereafter. 3. A 2020 competency assessment for TP1 was not found during review of the laboratory's records. The laboratory was unable to provide the document upon request. 4. In an interview on 03/02/21 at 11:15 a.m., TP1 confirmed the above findings. .