

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403934	(X3) Date Survey Completed 02/28/2023
Name of Provider or Supplier We Health Clinic, Pa	Street Address, City, State 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director (LD) failed to attest to the integration of proficiency testing samples into the routine patient workload on five of six occasions in 2021 and 2022. Findings are as follows: 1. The laboratory performed Immunohematology Rh factor testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 2:35 p.m. on 02/28/23. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The LD's signature was required on the attestation statements for all PT events as indicated in the Proficiency Testing section of the Quality Assurance Procedure found in the Laboratory Policy and Procedure Manual. 4. The Laboratory Director failed to sign the attestation statement for five of six API PT events reviewed from 2021 and 2022. See below. Event Specialty missing attestation 2021-2 Immunohematology 2021-3 Immunohematology 2022-1 Immunohematology 2022-2 Immunohematology 2022-3 Immunohematology 5. In an interview at 5:00 p.m. on 02/28/23, the TC confirmed the above finding. *This is a repeat deficiency. D2009 was previously cited during the 03/02/21 survey.* .</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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</p>

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 (LD) failed to review and evaluate proficiency testing (PT) results on five of six occasions in 2021 and 2022. Findings are as follows: 1. The laboratory performed Immunochemistry Rh factor testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 2:35 p.m. on 02/28/23. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The LD's review and evaluation of test results was required for all PT events as indicated in the Proficiency Testing section of the Quality Assurance Procedure found in the Laboratory Policy and Procedure Manual. 4. The Laboratory Director failed to review and evaluate test results for five of six API PT events from 2021 and 2022. See below. Event Specialty missing LD review 2021-2 Immunochemistry 2021-3 Immunochemistry 2022-1 Immunochemistry 2022-2 Immunochemistry 2022-3 Immunochemistry 5. In an interview at 5:00 p.m. on 02/28/23, the TC confirmed the above finding. *This is a repeat deficiency. D6018 was previously cited during the 03 /02/21 survey.* .

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 document review and interview with laboratory personnel, the Laboratory Director (LD) failed to ensure the established quality assessment program was followed to ensure the quality of laboratory services provided in 2021 and 2022. Findings are as follows: 1. The laboratory performed Immunochemistry Rh factor testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 2:35 p.m. on 02/28/23. 2. Annual quality assurance (QA) review of proficiency testing, personnel requirements, and pre-analytical, analytical, and post-analytical criteria was required as established in the Quality Assurance Procedure found in the Laboratory Policy and Procedure Manual. 3. Annual QA review documentation for 2021 and 2022 was not found in laboratory records. The laboratory was unable to provide this documentation upon request. The most recent annual QA review found was completed on 05/11/18. 4. In an interview at 5:05 p.m. on 02/28/23, the TC confirmed the above finding.