

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408612	(X3) Date Survey Completed 09/10/2024
Name of Provider or Supplier First Care Health Center	Street Address, City, State 115 Vivian St, Park River, ND	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy/procedure review, the laboratory failed to perform a positive and negative control each day of patient testing for Helicobacter pylori (H. pylori) antigen tests for 8 of 9 patient testing days (04/11, 04/24, 04/30, 06/21, 07/12, 07/25, 07/27, and 08/02) since the start of a new test method in April 2024. The laboratory performed eight H. pylori antigen tests on days with no quality control (QC) performance in April-August 2024. Findings include: 1. Reviewed on 09/10/24, the patient testing records for H. pylori antigen indicated performance of one patient test using the TechLab H. pylori Quik Chek test kit on the following days in April-August 2024: 04/11, 04/24, 04/30, 05/31, 06/21, 07/12, 07/25, 07/27, and 08/02. 2. Reviewed on 09/10/24, the April-August 2024 QC records for H. pylori antigen failed to include evidence of the performance of positive and negative controls on the following patient testing days: 04/11, 04/24, 04/30, 06/21, 07/12, 07/25, 07/27, and 08/02. 3. During interview at 8:55 a.m. on 09/10/24, a technical supervisor (#1) confirmed the laboratory failed to perform QC each day of patient testing for H. pylori antigen since the lab started using a new test method in April 2024. 4. Reviewed on 09/10/24, the policy/procedure "H. pylori Antigen," dated 07/2023, stated, ". . . Procedure: . . . Classified as moderately complex . . . Quality Control - . . . External Quality control - . . . a positive and negative external control is</p>

performed when opening a new kit and monthly. . . ." The policy/procedure failed to require the performance of a positive and negative external control each day of patient testing.