Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393107	(X3) Date Survey Completed 05/08/2019
Name of Provider or Supplier Prairie Clinic	Street Address, City, State 112 Helen St, Sauk City, WI	

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 surveyor review of laboratory procedures and interview with the laboratory supervisor, the laboratory has not ensured the procedure for Helicobacter Pylori (H. pylori) testing limits the patient specimen to whole blood. Findings include: 1. Interview with the laboratory supervisor on May 8, 2019 at 10:45 AM revealed that H. pylori testing is performed as a waived test in the laboratory. 2. Review of the laboratory procedure for "QuickVue H. pylori gII Procedure" Version #1, shows acceptable patient specimen types as serum, plasma, or whole blood. 3. Further interview with the laboratory supervisor confirmed the procedure does not include

	specimen limitation to whole blood which is required to limit the testing process to waived complexity. This is a repeat deficiency previously cited June 2, 2015.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of information on patient testing work sheets, the NextGen electronic health record (EHR), and interview with the laboratory supervisor, two of two patient test reports reviewed did not indicate the specimen source for KOH or Wet Prep testing. Findings include: 1. Review of patient testing work sheets for KOH and Wet Prep testing show that patient one (PT 1) had a KOH test performed on May 2, 2019. The specimen source was "mouth". Patient two (PT 2) had a Wet Prep and KOH performed on May 1, 2019. The specimen source was "vaginal". 2. Observation of the NextGen EHR patient test reports on May 8, 2019 at 11:45 AM shows that no specimen source was provided for KOH and Wet Prep tests performed on PT 1 and PT 2. 3. Interview with the laboratory supervisor on May 8, 2019 at 11:45 AM confirmed the laboratory does not report the specimen source on the NextGen EHR reports for KOH and Wet Prep testing. This was a repeat deficiency previously cited May 22, 2007 and May 24, 2011.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of competency assessment records and interview with the laboratory supervisor, competency evaluation of three of three testing personnel listed on the Center for Medicare and Medicaid Services (CMS)-209 Form was not evaluated in 2017 or 2018 by the technical consultant. Findings include: 1. Review of competency assessment records show that the technical consultant did not evaluate the competency for three of three testing personnel listed on the CMS-209 Form for 2017 and 2018. 2. Interview with the laboratory supervisor on May 8, 2019 at 09:30 AM confirmed the technical consultant did not evaluate testing personnel competency for non-waived testing in 2017 or 2018.