Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0394447	03/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kaukauna Clinic Sc	305 E 12th St, Kaukauna, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing records and laboratory procedures and interview with the laboratory supervisor, the laboratory performed but did not have a procedure for fern testing. Findings include: 1. Review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing results for the Provider Performed Microscopy modules in 2019 and 2020 showed the laboratory reported results for fern testing for four of four events. 2. Review of the laboratory procedure manual showed no evidence of a procedure for fern testing. 3. Interview with the laboratory supervisor (staff A) on March 26, 2021 at 10:20 AM confirmed the laboratory performs rare fern tests and confirmed the laboratory did not have a procedure for the examination.
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 "Leukocyte Differential Counts" procedure does not include a requirement for referral of high complexity differentials with abnormal cells or morphology. Findings include: 1. Review of the "Leukocyte Differential Counts" procedure showed the procedure included instructions for identifying abnormal red cell and white cell morphology. The procedure states "Slides will be referred to a Pathologist to examine and (sic) the discretion of the technologist and/or attending physician". 2. Interview with the laboratory supervisor (staff A) on March 26, 2021 at 10:20 AM confirmed the laboratory's procedure did not require referral of differentials with abnormal cells or morphology, which the laboratory was not qualified to report.