Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396494	02/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hirsch Clinic-Vmh	407 S Main St Ste 400, Viroqua, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor observation of the urinalysis testing area and interview with testing personnel (staff A), handwritten results of urinalysis microscopic testing were not retained after entry in the laboratory information system (LIS). Findings include: 1. Observation of the urinalysis testing section in the laboratory on February 4, 2019 at 10:45 AM revealed no computer for data entry near the microscope. No written records of microscopic urinalysis results were present. 2. Interview with testing personnel, staff A, on February 4, 2019 at 10:45 AM revealed test results may be written down until the results are entered in the LIS. Further interview confirmed the laboratory did not retain the written test results after entry in the LIS.
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: Item 1: Based on surveyor review of the KOH (Potassium Hydroxide Test) Procedure and interview with the technical consultant, the laboratory procedure did not define the required frequency for control testing. Findings include: 1. Review of the KOH procedure showed testing of Candida albicans is required for quality control. The procedure did not define the required frequency of quality control testing. 2. Interview with the technical consultant on February 4, 2019 at 2:15 PM confirmed the KOH procedure did not define the required frequency of quality control testing. Item 2: Based on surveyor review of the hCG (human Chorionic Gonadotropin) procedure and interview with the technical consultant, the procedure does not provide specimen handling instructions for serum and does not specify the type of quality control material or the frequency of testing serum controls. Findings include: 1. Review of the "Sure-Vue hCG STAT test" procedure showed no instructions for serum specimen handling, including specimen collection, labeling, storage, preservation, transportation, and processing of serum samples for testing. Additionally, the procedure does not require testing of serum controls and does not define the required frequency of testing controls when serum patient samples are tested. 2. Interview with the technical consultant on February 4, 2019 at 1:30 PM confirmed the procedure for HCG testing did not include instructions for handling serum samples for testing and did not identify the quality control requirements that apply when the laboratory tests serum patient samples.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of sample collection tubes in two of the three phlebotomy stations and interview with the technical consultant, three of three sodium heparin tubes in one of the two areas reviewed had expired on January 31, 2019 and were available for use. Findings include: 1. Observation of collection tubes available for use at one phlebotomy station on February 4, 2019 at 2:15 PM showed three of three available sodium heparin tubes had expired on January 31, 2019 (lot number 7256989). 2. Interview with the technical consultant on February 4, 2019 at 2:15 PM confirmed the three sodium heparin tubes were expired and that they were available for specimen collection.
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 technical consultant, the technical consultant did not evaluate the competency of seven of seven testing personnel who could perform serum hCG (human chorionic gonadotropin) testing. Findings include: 1. Review of competency assessment records showed no evaluation of testing personnel competency in performing serum hCG testing. 2. Interview with the technical consultant on February 4, 2019 at 11:45 AM confirmed the technical consultant has not evaluated testing personnel competency in performing serum pregnancy testing for the seven testing personnel.