

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396494	(X3) Date Survey Completed 03/07/2023
Name of Provider or Supplier Hirsch Clinic-Vmh	Street Address, City, State 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical consultant, two of two procedures reviewed did not include the laboratory's reference intervals (normal ranges). Findings include: 1. Review of the potassium hydroxide (KOH) procedure, 'KOH Prep for Fungal Elements', and the procedure for the hematology analyzer, 'KX-21N', showed no reference ranges or normal values included in the procedures. Review of the procedure manual showed no evidence of a separate procedure that included reference ranges for the hematology analyzer or KOH testing. 2. Interview with the technical consultant on March 7, 2023 at 10:45</p>

AM confirmed the laboratory's procedures did not include reference ranges for KOH testing or testing performed on the KX-21N hematology analyzer. This is a repeat deficiency previously cited on February 4, 2019 and February 15, 2011.

D5409

PROCEDURE MANUAL
CFR(s): 493.1251(e)

The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and interview with the technical consultant, one of one discontinued procedure was not maintained with the date the test was discontinued. Findings include: 1. Interview with the technical consultant on March 7, 2023 at 11:00 AM confirmed the serum hCG (human Chorionic Gonadotropin) test was discontinued in the laboratory as of January 1, 2023. 2. Review of the procedure for the serum hCG test showed staff had not identified the procedure as discontinued. 3. Further interview with the technical consultant on March 7, 2023 at 11:00 AM confirmed staff did not mark the serum hCG procedure as discontinued and did not maintain the procedure with the date of discontinuance.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on surveyor review of competence evaluation records for testing personnel that were testing for more than two years and interview with the technical consultant, the technical consultant did not document annual competence evaluations in 2021 or 2022 for one of two testing personnel reviewed. Findings include: 1. Review of documented competence evaluation records for two testing personnel who were performing testing for more than two years at this laboratory showed no documented annual competence evaluation for one of the two personnel (staff A) in 2021 or 2022. 2. Interview with the technical consultant on March 7, 2023 at 9:30 AM confirmed there were no documented competence evaluation records for staff A at this laboratory in 2021 or 2022 and confirmed staff A had performed testing during 2021 and 2022.