Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393663	08/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ghc-Scw Capitol Clinic	675 W Washington Ave, Madison, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of procedures and laboratory proficiency testing (PT) records and interview with the technical consultant, the laboratory did not verify the accuracy of the post vasectomy semen analysis motility testing twice annually in two of the last two years. Findings include: 1. Review of the "Semen Analysis - Post Vasectomy" procedure, effective date 6/8/2023, showed testing personnel evaluate patient post vasectomy semen samples for the presence of spermatozoa and for motility. 2. Review of PT records from 2024 and 2025 showed no evidence the laboratory evaluated PT samples for spermatozoa motility. 3. Interview with the technical consultant on August 26, 2025, at 11:40 AM, confirmed the laboratory did evaluate post vasectomy semen samples for motility and that the laboratory did not verify the accuracy twice annually of the spermatozoa motility evaluation included in the post vasectomy semen analysis.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains,

	and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 procedure review and interview with the technical consultant, for one of one test procedures reviewed, the laboratory did not include step-by-step information for reporting the findings of a microscopic evaluation of a post vasectomy semen collection. Findings include: 1. Review of the procedure "Semen Analysis - Post Vasectomy" test procedure effective 6/8/2023, revealed that the procedure did not include instructions on how many fields to evaluate, whether quantity of spermatozoa reported is per each field of view or per slide, and how to report results if the sample is centrifuged. 2. Interview with the technical consultant on August 26, 2025, at 11:50 AM, confirmed that the procedure did not include step-by-step information for reporting the evaluation of a post vasectomy semen collection.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of individualized quality control plans (IQCPs) and interview with the technical consultant, three of three IQCPs in place did not specify the type of external quality control materials used for the five tests covered by the IQCPs. The laboratory had IQCPs in place for infectious mononucleosis and serum pregnancy kit testing, and for troponin-I, b-type natriuretic peptide (BNP), and d-dimer testing performed on the Triage analyzer. Findings include: 1. Review of the three IQCPs revealed that the laboratory did not specify the type of external control materials used for the five tests in the IQCPs. 2. Interview with the technical consultant on August 26, 2025, at 1:15 PM, confirmed that the IQCPs did not include specific information about the type of external quality control materials used for infectious mononucleosis and serum pregnancy kit testing, and for troponin-I, BNP, and d-dimer testing performed on the Triage analyzer.