Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0397019	07/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Burnett Medical Center	257 W St George Ave, Grantsburg, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and competence evaluations and interview with the Technical Consultant, the policies and procedures did not address evaluation of consultant competence and the laboratory had not documented the evaluation of the competence of one of one General Supervisor in performed the responsibilities of a general supervisor. Findings include: 1. Review of laboratory procedures showed no evidence the laboratory had established a procedure for evaluation of the general supervisor in performing their responsibilities. 2. Review of competence evaluations showed no evidence the laboratory evaluated the General Supervisor's competence. 3. Interview with the Technical Consultant on July 17, 2024, at 10:00 AM confirmed the laboratory had not documented the evaluation of the performance of the General Supervisor's responsibilities and confirmed the procedures did not address evaluation of consultant competence.
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 Technical Consultant, one of one laboratory procedure for performing a complete urinalysis did not include step-by-step instructions for preparing the urine sample for microscopic examination or for performing the microscopic exam. Findings include: 1. Review of the 'Urinalysis Complete' procedure showed the procedure included expected microscopic results and reporting ranges. Further review of the procedure showed no instructions for evaluating the sample microscopically or for preparing the sample for microscopic analysis. 2. Interview with the Technical Consultant on July 18, 2024, at 10:45 AM confirmed the procedure did not include step-by-step instructions for preparing and evaluating the microscopic examination of the urine sample.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of test system verification studies and interview with the Technical Consultant, the laboratory did not document the verification of reference ranges to ensure the ranges were appropriate for the laboratory's patient population for two of two new tests reviewed. Findings include: 1. Review of verification studies for the Beta hydroxybutyrate test and the Gem Premier 5000 analyzer showed no evidence the laboratory evaluated the manufacturer's reference ranges for use with the laboratory's patient population. 2. Interview with the Technical Consultant on July 18, 2024, at 10:45 AM confirmed the laboratory did not document the evaluation of reference ranges with the verification studies for the Beta hydroxybutyrate test or the Gem Premier 5000 analyzer.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and interview with the Technical Consultant, the laboratory did not calibrate the Innovance D-dimer test every six months once in the last two years. Findings include: 1. Review of the laboratory's 'Innovance D-dimer Procedure' showed the D dimer test required calibration every six months or with a new lot of reagents. 2. Review of calibration records for the D dimer test showed the laboratory calibrated the test on January 24, 2023. The records showed the laboratory next calibrated the test on September 5, 2023. 3. Interview with the Technical Consultant on July 18, 2024, at 1:50 PM confirmed the laboratory did not calibrate the assay every six months as required.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and individualized quality control plans (IQCP) and interview with the General Supervisor, the laboratory did not check each batch of blood culture media for its ability to support growth in the last two of two years and did not develop an IQCP. Findings include: 1. Review of laboratory procedure, 'Quality Control of Commercially Prepared Media' revealed the laboratory limited its quality control process for blood culture bottles was to a visual check before use and retention of the Quality Assurance certificates from the manufacturer. 2. Review of IQCP showed no evidence of an IQCP for blood culture bottle media. 3. Interview with the General Supervisor on July 18, 2024, at 12:00 PM confirmed the laboratory had not checked each batch of blood culture media for its ability to support growth in the last two years and had not developed an IQCP for media bottles.