Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396996	(X3) Date Survey Completed 02/26/2025
Name of Provider or Supplier Cumberland Memorial Hospital	**Street Address, City, State** 1705 16th Ave, Cumberland, 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 personnel records, Laboratory Personnel Report (CLIA) (Form CMS-209), and procedures and interview with the Laboratory Manager (Staff A), the laboratory did not develop procedures or document evaluation of four of four employees performing clinical consultant, technical consultant, technical supervisor, and / or general supervisor responsibilities in the laboratory. Findings include: 1. Review of personnel records showed no competence evaluations of the clinical consultant, technical consultant, technical supervisor, or general supervisor responsibilities that the director had delegated to staff members or consultants. 2. Review of the Form CMS-209 submitted for this survey showed four staff members or consultants (Staff A, B, C, and D) had responsibilities in addition to that of testing personnel. 3. Review of procedures showed no written procedure for evaluating competence of personnel delegated responsibilities of the clinical consultant, technical consultant, technical supervisor, or general supervisor in performing those responsibilities. 4. Interview with Staff A on February 25, 2025, at 12:15 AM confirmed competence of staff performing clinical consultant, technical consultant, technical supervisor, or general supervisor responsibilities had not been documented and confirmed procedures had not been developed to evaluate staff competence in the performance of these responsibilities.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)

	(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) and laboratory records and interview with the Laboratory Manager (Staff A), the laboratory did not evaluate the accuracy of their potassium hydroxide (KOH) test for the presence or absence of yeast or fungi in dermatology samples in the last two of two years. Findings include: 1. Review of PT records showed no evidence the laboratory enrolled in PT for KOH testing of dermatology samples. 2. Review of laboratory quality records showed no evidence of twice annual evaluation of accuracy of KOH testing of dermatology samples. 3. Interview with Staff A on February 25, 2025, at 12:20 PM confirmed the laboratory performed KOH testing on dermatology samples but did not evaluate the accuracy of the KOH test on dermatology samples twice annually in 2023 or 2024.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 procedures and interview with the Laboratory Manager (Staff A), the laboratory procedure manual did not include a procedure for potassium hydroxide (KOH) testing for specimens from dermatology sources. Findings include: 1. Review of the "Wet Prep / KOH" procedure showed the procedure addressed the use of KOH in evaluating urogenital specimens. The procedure did not include instructions for KOH testing of hair, nail, or skin samples and did not identify hair, nail, or skin as acceptable samples for the test procedure. 2. Interview with Staff A on February 26, 2025, at 11:30 AM confirmed the laboratory did not have a written procedure for performing or reporting KOH testing performed on dermatology samples.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation of frozen supplies, review of temperature logs, and

	interview with the Laboratory Manager (Staff A), the laboratory did not define freezer storage conditions that were consistent with the manufacturer's instructions for one of one freezer in the laboratory. Findings include: 1. Observation of the contents of the laboratory freezer on February 26, 2025, at 3:45 PM showed staff stored Siemens Cardiac, Anemia and Thyroid calibrators and Film Array Gastrointestinal Panel controls in the freezer. The identified calibrators and control boxes showed the manufacturer required storage between negative 15 to negative 25 degrees C (Celsius). The freezer temperature at 3:50 PM on February 26, 2025, was negative 28.9 degrees. 2. Review of temperature monitoring logs showed the laboratory's acceptable freezer temperature range was less than negative 20 degrees C. 3. Interview with Staff A on February 26, 2025, at 3:50 PM confirmed the Siemens calibrators and the Film Array controls were not stored in a manner consistent with the manufacturer's instructions and confirmed the laboratory's defined acceptable temperature range was not consistent with the manufacturer's instructions for storage for these items.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on surveyor observation of the biological safety cabinet (BSC) in the laboratory and interview with the Laboratory Manager (Staff A), the laboratory had not ensured the certification (including function checks) for one of one BSC were completed annually as required. Findings include: 1. Observation of the Esco Sentinel Gold BSC in the laboratory on February 26, 2025, at 12:45 PM showed the certification of the BSC was due in January 2025. The record on the BSC showed performance of the last certification on January 25, 2024. 2. Interview with Staff A on February 26, 2025, at 12:45 PM confirmed the certification and function checks were past due and not completed as required.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Laboratory

	Manager (Staff A), the laboratory did not record the source of dermal samples received for potassium hydroxide (KOH) testing for seven of ten KOH tests performed since October 2024. Findings include: 1. Review of the 'Result Activity Report' for KOH testing (Procedure code KOHP) showed records for ten samples tested from October 29, 2024, through February 26, 2025. Only three of the ten records specified the sample source. 2. Email interview with Staff A on February 28, 2025, at 8:42 AM confirmed staff had not reported the specimen source with the KOH test results from dermatology specimens.