| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 52D0396909 | 05/20/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Tri-County Memorial Hospital | 18601 Lincoln St, Whitehall, 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<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and procedures and interview with the laboratory manager (Staff A), the director did not delegate the responsibility for testing personnel (TP) competence assessment to six of seven TP that performed assessments in 2025 and did not ensure policies were developed to assess the performance of the additional delegated responsibilities. Findings include: 1. Review of competence evaluation records for seven TP showed Staff A through G performed direct observations of TP in 2025 to evaluate competence. 2. Review of laboratory records showed no evidence that the director delegated the responsibility for competence evaluation to staff B through G or that these personnel were assessed to ensure they effectively performed the competence evaluations. 3. Review of relevant sections of the 'Quality Assurance for Laboratory Testing, Lab-0135' procedure (effective and approved date, February 4, 2026) showed no mechanism for assessing staff with delegated duties other than testing personnel responsibilities. 4. Interview with Staff A on May 19, 2026, at 2:00 PM confirmed the director did not delegate in writing the responsibility for performing direct observation competence evaluations to Staff B through G, and confirmed the competency assessment portions of the 'Quality Assurance for Laboratory Testing' procedure did not address evaluation of additional delegated responsibilities. |
| **D5403** | PROCEDURE MANUAL<br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the laboratory's procedures and interview with the laboratory manager (Staff A), one of one test procedure for bacteriology culture set up failed to include steps the laboratory follows for handling culture media plates once placed into the incubator. Findings include: 1. Review of policy, 'Culture Setup and Rejection Criteria, Lab-3000' effective August 19, 2025, revealed the procedure did not contain steps to describe how the laboratory handles culture media plates after the plates are placed into the incubator, including how long the plates are kept at the laboratory before being transported, how frequently media plates are taken by courier to the reference laboratory, and packing instructions for transportation. 2. Interview with Staff A on May 20, 2026, at 2:00 PM, confirmed the procedure did not contain steps for handling culture media plates once placed into the incubator. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Item 1: Based on surveyor review of the laboratory's records, procedures, and interview with the laboratory manager (Staff A), the laboratory director approved one of one procedure in the chemistry section that contained information about tests not offered at this laboratory. Findings include: 1. Review of the laboratory's test verification records revealed the laboratory started performing total protein testing from a urine sample on January 20, 2026. 2. Review of the policy, 'Total Protein (Urine/CSF) - Roche/Hitachi cobas c system, Lab-4385' approved by the laboratory director March 4, 2026, revealed the procedure was applicable to this laboratory and included information for performing total protein testing on a cerebral spinal fluid (CSF) sample. 3. Interview with Staff A on May 19, 2026, at 3:25 PM confirmed the laboratory did not perform total protein testing on a CSF sample and confirmed the procedure approved by the laboratory director contained information about |

| | |
|---|---|
| | performing total protein test on a CSF sample that was not relevant for the laboratory. Item 2: Based on surveyor review of the laboratory's procedures and interview with the laboratory manager (Staff A), the laboratory director did not approve one of one microbiology section procedures when the laboratory changed how it performs respiratory culture media set ups. Findings include: 1. Review of the policy, 'Culture Setup and Rejection Criteria, Lab-3000' revealed attachment, 'Affiliate Culture Setup Workaid' that provided guidance on how to plate each culture type. Respiratory culture setups included adding a "P disk" to the blood agar media plate. 2. Observation in the laboratory on May 20, 2026, at 10:25 AM revealed no evidence the laboratory stocked P disks. 3. Interview with Staff A on May 20, 2026, at 10:25 AM confirmed the laboratory did not stock P disks. Further interview with Staff A revealed the laboratory stopped adding P disks to the blood agar plate during respiratory culture setup over five years ago and confirmed the information in the procedure approved by the laboratory director did not reflect current practice. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the individualized quality control plan (IQCP) and interview with the laboratory manager (Staff A), the laboratory's IQCP for one of one test system for Clostridioides difficile (C. diff) did not specify the type of controls used. Findings include: 1. Review of the IQCP for the Alere Quik Check Complete - C diff test system showed the IQCP did not define the type of positive or negative external control required. 2. Interview with Staff A on May 20, 2026, at 10:00 AM confirmed the IQCP did not identify the type of the required positive and negative control for the test system. |
| **D6080** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(c)<br><br>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and interview with the laboratory manager (Staff A), the laboratory director did not document an onsite visit every six |

| | |
|---|---|
| | months after one of the last three visits. Findings include: 1. Review of 'Laboratory Director Site Visit Checklist' records showed the director completed visits on March 3 and October 6, 2025, and March 2, 2026. 2. Interview with Staff A on May 19, 2026, at 12:50 PM confirmed the director did not document a visit to the laboratory within six months of the March 3, 2025, visit. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the individualized quality control plan (IQCP) and procedure, observation in the laboratory, and interview with the laboratory manager, the director did not ensure the laboratory's IQCP and procedure for one of one test system for Clostridioides (previously Clostridium) difficile (C. diff) was specific for the test system in use. Findings include: 1. Review of the IQCP for the C. diff test system showed the IQCP was for the Alere Quik Chek Complete - C. Diff test. 2. Review of the procedure, 'Clostridium difficile Antigen and Toxin A&B Assay - Regional, Lab-8461', showed the procedure was specific for the Alere C. DIFF QUIK CHEK COMPLETE test kit. 3. Observation on May 20, 2026, at 10:15 AM of the C. diff test in the laboratory showed the kit was TECHLAB C. DIFF QUIK CHEK COMPLETE. 4. Interview with the laboratory manager on May 20, 2026, at 10:00 AM confirmed the manufacturer of the test kit had changed and the IQCP and procedure did not reflect the current test kit. |
| **D6177** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1495(b)(3)<br><br>(b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;<br><br>This STANDARD is not met as evidenced by:<br>Item 1: Based on surveyor review of the individualized quality control plan (IQCP) and laboratory records in the information system, observation of a test kit in the laboratory, and interview with testing personnel (Staff E), testing personnel did not document quality control activities including the lot number and expiration date as required in the IQCP for the Clostridioides (previously Clostridium) difficile (C. diff) test kit. Findings include: 1. Observation of the C. diff test kit in the laboratory on May 20, 2026, at 10:15 AM showed testing personnel had opened the kit on February 26, 2026. The kit showed lot number 0925017, expiration date July 1, 2027. 2. Review of laboratory records in the EPIC Beaker system showed testing personnel recorded control results for the C. diff test kit on February 26, 2026. The record did not include the lot number or expiration date. 3. Review of the IQCP, 'Alere Quik Chek Complete - C. Diff' revealed testing personnel were required to "document the lot numbers and expiration dates in the laboratory testing records". 4. Interview with Staff E on May 20, 2026, at 10:15 AM confirmed testing personnel did not document the lot number and expiration date of the C. diff test when they tested the controls and confirmed the lot number and expiration date were not recorded elsewhere in the laboratory records. 52883 Item 2: Based on surveyor review of quality control records |

| | |
|---|---|
| | and interview with a testing personnel (Staff B), while performing quality control (QC) testing on the serum pregnancy test kit, testing personnel failed to document kit lot number and expiration date on three out of seven QC records from March to May 2026. Findings include: 1. Review of quality control records recorded in EPIC Beaker laboratory information system revealed testing personnel performed QC on the serum pregnancy test kit seven times between March 3, 2026 to May 14, 2026. Testing personnel failed to document kit lot number and expiration date on the QC entries for April 1, 2026, April 6, 2026, and May 14, 2026. 2. Interview with Staff B on May 20, 2026, at 12:20 PM confirmed testing personnel should include kit lot number and expiration date when documenting QC activities for the serum pregnancy test kit, and confirmed testing personnel failed to do so for the three of seven entries. |