

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0679419	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier Columbus Community Hospital	Street Address, City, State 4508 38th Street, Suite 168, Columbus, NE	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's Actim Prom package insert, review of the laboratory's Individualized Quality Control Plan (IQCP), lack of documentation, and interview with the lab manager and lab assistant manager the laboratory failed to monitor and document the temperature of one out of two locations where Actim Prom tests are stored. Findings are: 1. Review of the Actim Prom package insert revealed kits should be stored at 2 to 25 degrees Celsius. 2. Review of the laboratory's IQCP for Actim Prom indicated "Daily monitoring of storage temperatures." 3. Actim Prom test kit in use was stored at the nurses station. No documentation of daily monitoring of temperatures from the nurses station was presented at time of survey. 4. Interview with the laboratory manager and assistant laboratory manager on 9/18/2024 at 10:10 AM confirmed the laboratory did not monitor temperatures at the nurses station.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

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 review of laboratory test reports and interview with the lab manager and assistant lab manager the laboratory failed to have the test report date on twelve out of twelve laboratory test reports. Findings are: 1. Review of twelve laboratory test reports, including seven chemistry, three hematology and two bacteriology, revealed the laboratory test reports did not include a test report date. 2. Interview with the lab manager and assistant lab manager on 9/18/2024 at 2:17 PM , confirmed the laboratory test reports did not include a test report date.