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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>04D0642400 | <b>(X3) Date Survey Completed</b><br><br>03/05/2025 |
| <b>Name of Provider or Supplier</b><br><br>Mercy Hospital Ozark  | <b>Street Address, City, State</b><br><br>801 West River Street, Ozark, AR |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based upon observation, review of manufacturer's package inserts, and interview, the laboratory failed to maintain required storage conditions for Biorad Liquicheck Immunoassay Plus chemistry controls. Findings follow: 1) During a tour of the laboratory on 3/5/25 at 09:45 a.m., the surveyor observed 14 boxes of Biorad Liquicheck Immunoassay Plus chemistry control material, lot # 85361 expiration date 2025-05-31 in a freezer with no accumulated frost apparent. 2) Review of the manufacturer's package insert for Biorad Liquicheck Immunoassay controls revealed "For optimum performance, avoid storing this product in a frost-free freezer". 3) In an interview on 3/5/25 at 09:45 a.m., the laboratory staff member (# 2 on form CMS 209) confirmed that the freezer identified above was frost-free.</p> |