

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 28D0668791	<b>(X3) Date Survey Completed</b> 07/30/2024
<b>Name of Provider or Supplier</b> Osmond General Hospital	<b>Street Address, City, State</b> 402 North Maple Street, Osmond, NE	
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>
<b>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's 2023 and 2024 American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of genital culture procedure, and interview with the laboratory manager, revealed the laboratory failed to perform proficiency testing in the same manner as it tests patient specimens for microbiology genital culture proficiency testing event 1 - 2023. 1. Surveyor review of bacteriology worksheet for genital culture event 1 - 2023 revealed the laboratory performed a genital culture gram stain and set up the culture on 2/13/2023. 2. On 7/30/2024 at 1:12 PM interview with the laboratory manager confirmed the laboratory did not have a procedure for genital cultures. Laboratory manager indicated genital cultures are sent out for testing. 3. On 7/30/2024 at 1:12 PM interview with the laboratory manager confirmed the laboratory did not perform genital culture PT event 1 - 2023 the same manner as it tests genital culture patient specimens.</p>
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p>

For 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on review of laboratory's maintenance procedure, blood bank centrifuge maintenance reports, and interview with the laboratory manager, the laboratory failed to follow procedures for performing centrifuge speed check on the blood bank centrifuge from 9/21/2022 - 7/30/2024. 1. Review of the laboratory's maintenance procedure for centrifuges indicate "Quarterly tachng - Check speed (RPM) by tachometer." 2. Review of the blood bank centrifuge maintenance reports revealed the laboratory performed a speed check on the blood bank centrifuge on 9/21/2022, 9/11/2023, and 3/8/2024 from 9/21/2022 - 7/30/2024. 3. On 7/30/2024 at 1:12 PM interview with the laboratory manager confirmed that the laboratory did not follow quarterly tachng on the blood bank centrifuge as indicated on the laboratory's maintenance procedure.