

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0642122	(X3) Date Survey Completed 02/06/2025
Name of Provider or Supplier Howard Memorial Hospital	Street Address, City, State 130 Medical Circle, Nashville, AR	
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>(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: Based upon observation, review of temperature records, lack of documentation and interview the laboratory failed to monitor the temperature on each day of operation in two of four rooms in which supplies with storage temperature requirements were stored. . Findings follow: A) During a tour of the laboratory on 2/4/25 at 12:34 p.m., the surveyor observed four rooms (main laboratory, Office, storage room and respiratory therapy blood gas lab) containing laboratory items with a temperature storage requirement. B) A review of the laboratory's temperature records revealed that no room temperatures were recorded for the office or storage room for the year 2024. C) During a tour of the laboratory on 2/6/25 at 09:00 a.m. the surveyor observed 2 cases of Biofire Bacti 2 Panels lot# 2404824 expiration date 2025-10-31 and 3 cases of Biofire Respiratory Panel 2.1 lot # 2397724 expiration date 2026-04-30 with a storage temperature requirement of 18 degrees to 25 degrees Centigrade (C) in the office. D) During a tour of the laboratory on 2/6/25 at 09:15 a.m. the surveyor observed 26 boxes of Biorad IH-Card ABO/D Blood Grouping Reagent Lot # 9350010 expiration date 2025-09-11 with a storage temperature requirement of 18 - 25 degrees C in the storage room. D) Upon request, the laboratory could not present the temperature records for the office and the storage room in which the supplies</p>

identified above were stored. E) In an interview on 2/6/25 at 09:20 a.m., the laboratory staff member (# 2 on form CMS 209) confirmed that temperature records for the office or storage room were not recorded.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Through review of package inserts, observation, and interview it was determined that the laboratory did not change expiration dates on control materials after opening as required by manufacturer. Finding follow: A) Review of the package insert for Coulter 6C Hematology controls revealed that the product expires in 16 days after vial is opened and put into use and the expiration dates should be changed as required after opening. B) During a tour of the laboratory on 2/5/25 at 3:35 p.m.the surveyor observed a plastic container with three vials of Coulter 6C hematology controls , lot #'s 923175770, 933185770 and 943195770 expiration date 2025-02-28. The vials did not have new expiration dates or dates put into use indicated on the testing materials or the container and were identified as the controls currently in use. C) In an interview on 2/5/25 at 13:45 p.m. laboratory staff member (number 2 on form CMS 209) confirmed that no amended expiration date or date when put into use were written on the vials or container.

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 upon review of six randomly selected medical records for microbiology reports and interviews with laboratory staff, determined the laboratory test report failed to include required information (specimen source and specimen time of receipt) for six of the six reports reviewed. Survey findings include: A) Review of the final microbiology reports (four urinary tract cultures and two wound cultures) for six patients chosen at random (numbers one through six on a separate patient identification list) revealed that none of the reports listed the source of the specimen or the time received in the laboratory . B) In an interview, at 08:45 a.m. on 2/6/25, the laboratory staff member (# 2 as listed on the form CMS-209) stated the source was identified on the information system (CPSI). Upon request, the source of the specimen

could not be found on CPSI. The laboratory staff member (# 2 on form CMS 209) confirmed that the source was not identified on the final report, could not be found on CPSI, and if it was on CPSI medical providers from outside Howard Memorial Hospital system would not have access to the specimen source or time specimen was received in the laboratory.