

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0310091	(X3) Date Survey Completed 06/23/2025
Name of Provider or Supplier Memorial Health Partners Foundation, Inc	Street Address, City, State 605 Glenwood Dr, Suite 404, Chattanooga, TN	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of patient test reports, review of laboratory procedure, and staff interview, the laboratory failed to ensure the procedure for the Complete Blood Count: Whole Blood on the Sysmex XN-450/XN-430 Automated Hematology Analyzer was approved by the laboratory director before patient testing began on 08/16/2024. The findings include: 1. Observation of the laboratory on 06/23/2025 at 9:30 a.m. revealed the Sysmex XN 430 Automated Hematology Analyzer (Serial Number 11097) used for patient testing. This instrument was new since the last survey date. 2. A review of patient test reports revealed that the first Complete Blood Count (CBC) from the Sysmex XN 430 was performed on 08/16/2024 for patient sample number 533010. 3. A review of the laboratory procedure for the Sysmex XN 430 revealed that the laboratory director approved the procedure on 09/26/2024. 4. The laboratory technical consultant and compliance coordinator confirmed during an interview on 06/23/2025 at 2:15 p.m., the laboratory director did not approve the procedure for the Sysmex XN 430 CBC instrument before patient testing, which began on 08/16/2024. .</p>
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</p>

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.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory policy and procedure manual and a staff interview, the laboratory failed to define criteria for essential laboratory conditions when it did not have an approved policy or procedure for temperature and humidity monitoring available on the day of the survey, 06/23/2025. The findings include: 1. A review of the laboratory's policy and procedure manuals revealed no policy defining the laboratory's temperature and humidity monitoring criteria. 2. The technical consultant and compliance coordinator confirmed the survey findings in an interview on 06/23/2025 at 2:15 p.m. .

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, lack of documentation, and staff interviews, the laboratory director failed to ensure that the Sysmex XN 430 Automated Hematology Analyzer, which has been used for Complete Blood Count (CBC) patient testing since 08/16/2024, had been evaluated before use. The findings include: 1. Observation of the laboratory on 06/23/2025 at 8:45 a.m. revealed a Sysmex XN 430 (Serial Number 11097) used for patient testing. 2. No approved instrument validation records were available for review on the survey day, 06/23/2025. 3. The laboratory technical consultant and compliance coordinator confirmed in an interview on 06/23/2025 at 2:15 p.m. that no approved performance verification records were available.