

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0975370	(X3) Date Survey Completed 03/10/2026
Name of Provider or Supplier Memorialcare Miller	Street Address, City, State 2801 Atlantic Ave, Long Beach, CA	
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
D0000	An onsite validation survey was conducted on 03/10/2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
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: I. Based on laboratory observation, review of instrument operator manual, and interview with the Laboratory Quality Manager, the laboratory failed to define, record and monitor room temperature and humidity ranges based on instrument manufacturer's requirements for two of two years (2024 and 2025). Findings: 1. During a tour of laboratory room 3-662 on 03/10/2026 at 3:20 PM, the following instrument was observed in use for Complete Blood Count (CBC) testing: Sysmex XN-1000 Equipment Assesst ID: 45575 2. A review of the Sysmex Operator's Manual indicated the following environmental specifications required for operation of the instrument: Ambient Temperature Range: 15 to 30C Humidity Range: 20% to 85% 3. In an interview on 03/10/2026 at 3:25 PM, the Laboratory Quality Manager confirmed the laboratory failed to define an acceptable room temperature and humidity ranges based on the manufacturer's requirements and there was no room temperature and humidity records for monitoring in laboratory room 3-662, for years 2024 and 2025.</p>

II. Based on laboratory observation, review of instrument operator manual, review of room humidity records, and interview with the Laboratory Quality Manager, the laboratory failed to define acceptable room humidity range based on instrument manufacturer's requirements for 31 of 31 days in January 2025. Findings: 1. During a tour of Sysmex Bench area of the laboratory on 03/10/2026 at 3:40 PM, the following instrument was observed in use for Complete Blood Count (CBC) testing: Sysmex XN-1000 Equipment Asset ID: 12310 2. A review of the Sysmex Operator's Manual indicated the following environmental specification required for operation of the instrument: Humidity Range: 20% to 85% 3. In an interview 03/10/2026 at 3:50 PM, the Laboratory Quality Manager confirmed the laboratory failed to define an acceptable room humidity range for the Sysmex Bench area based on the instrument manufacturer's requirement for 31 of 31 days in January 2025.

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 on review of final test reports and interview with the Laboratory Quality Manager, the laboratory failed to include the name and address of the laboratory where testing was completed for four of four final test reports. Findings: 1. The following four randomly selected final test reports revealed no name and address of the laboratory that performed the testing: Order # 587534352 Collection Date: 02/25/2026 Test: CBC with auto differential, reflex manual differential if indicated Order # 588239682 Collection Date: 02/28/2026 Test: CBC with auto differential, reflex manual differential if indicated Order # 588238704 Collection Date: 02/28/2026 Test: Urinalysis with microscopic Order # 589244360 Collection Date: 03/09/2026 Test: Urine microscopic only 2. In an interview on 03/10/2026 at 3:00 PM, the Laboratory Quality Manager confirmed the final test reports listed above did not include the name and address of the laboratory that completed the testing, Long Beach Memorial Medical Center.