

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1093121	(X3) Date Survey Completed 05/04/2026
Name of Provider or Supplier Millennium Medical Management Llc	Street Address, City, State 7955 Spyglass Hill Rd Ste A, Melbourne, FL	
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 announced CLIA recertification survey was conducted at Millennium Medical Management LLC on April 20, 2026 to May 4, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D6033 493.1409 Condition: Technical Consultant - Moderate Complexity
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of calibration records and interview, the laboratory failed to perform calibration verification for the Horiba Micro 60 hematology analyzer at least every six months in 2025 for the calibration records reviewed from 01/02/2024 to 04/15/2026. (See D5439)</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to</p>

verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of allegation of compliance, calibration records, and interview, the laboratory failed to perform calibration verification for the Horiba Micro 60 hematology analyzer at least every six months in 2025 for the calibration records review from 01/02/2024 to 04/15/2026. This is a repeat deficiency from recertification survey performed on 12/27/2023. Findings: 1. Review of the allegation of compliance (signed by the Laboratory Director on) stated "The lab consultant and Lab Director will be responsible for making sure that calibration is completed every 6 months, using the manual calendar and the Outlook email reminder. They will also use the monthly document sheet to check for calibration results if present, and if due, can investigate." 1. Review of calibration records for the hematology analyzer revealed calibrations were performed on 01/02/2024, 07/26/2024, 12/19/2024, 05/09/2025, 05/19/2025, and 04/15/2026. 2. Review of the document titled Corrective Action Plan for Missed Horiba Micros 60 Calibration in Late 2025 noted, the Horiba Representative and Technical Consultant A on 05/10/2025 "Calibrated the instrument. This would have made the next calibration due in November 2025." The document also noted, the 2025 wall calendar was overlooked and the email notifications that were set up failed. 3. During an interview on 04/20/2026 at 12:53 PM, Technical Consultant B stated the calibration due at the end of 2025 was missed.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview, Technical Consultant A (who is also the Laboratory Director) and Technical Consultant B failed to ensure verification for the Horiba Micro 60 hematology analyzer calibration was performed at least every six months for once in 2025 for the calibration records review from 01/02/2024 to 04/15/2026. (See D6040)

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

(b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of

each test and test system;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Technical Consultant A (who is also the Laboratory Director) and Technical Consultant B failed to ensure the verification for the Horiba Micro 60 hematology analyzer calibration was performed at least every six months for once in 2025 for the calibration records review from 01/02/2024 to 04/15/2026. Findings included: 1. The laboratory failed to perform calibration verification for the Horiba Micro 60 hematology analyzer at least every six months in 2025 for the calibration records review from 01/02/2024 to 04/15/2026. (See D5439)