

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1093121	(X3) Date Survey Completed 12/27/2023
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	Recertification survey was conducted from December 13, 2023 to December 27, 2023. Millennium Medical Management LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, proficiency testing policy, and interview, the laboratory failed to ensure the attestation form for specialty of Hematology was signed by Testing Personnel for 2 (2023 2nd and 3rd) of 6 events (2022 1st, 2nd and 3rd; 2023 1st, 2nd and 3rd). Findings: Review of the attestation for American Association of Bioanalysts (AAB) noted, "The undersigned analyst attests that samples were tested in the same manner as patient samples." Review of the laboratory's policy titled, Proficiency testing noted, "This attestation document is signed by the analyst, technical consultant and laboratory director" Review of the AAB PT records showed the attestation statements were not signed by the Testing Personnel for the specialties of specialty of Hematology for 2 2023 2nd and 3rd event. On 12/13/2023 at 2:00 PM, Testing Personnel B confirmed the attestations were not signed by the Testing Personnel.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems</p>

activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of temperature logs, and interview, the laboratory failed to maintain documentation of the Laboratory Temperature Logs for 1 (May 2022) of 20 months (May 2022 to December 2023) reviewed. Findings: Review of the Laboratory Temperature Logs revealed the month of May 2022 was missing. On 12/13/2023 at 5:18 PM, the Laboratory Consultant stated she did not know where the May 2022 temperature log was located.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

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.

This CONDITION is not met as evidenced by:

Based on observation, review of temperature logs, and interview, the laboratory failed to document corrective actions when refrigerator temperatures were not within the acceptable temperature range of 2 to 8 degrees Celsius (C) from 06/01/2022 to 12/27/2023. (See D5781).

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 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:

	<p>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 for two out of two years, (2022 to 2023). Findings: Review of calibration records for the hematology analyzer revealed the only record of calibration being performed was 03/03/2023. On 12/13/2023 at 2:57 PM, the Laboratory Consultant stated she was unable to locate the calibration records and was unable to re-print them from the analyzer.</p>
<p>D5781</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of temperature logs, and interview, the laboratory failed to document corrective actions for refrigerator temperatures not within the acceptable temperature range of 2 to 8 degrees Celsius (C) from 06/01/2022 to 12/27/2023. This is a repeat deficiency from the initial survey on 04/08/2022. Findings: On 12/13/2023 at 2:00 PM, the Horiba Medical Minotrol 16 Whole Blood Hematology Controls were observed in the laboratory refrigerator. The hematology control box instructions noted to store the controls at "2 - 8 degrees C." Review of the "Laboratory Temperature Log" showed the temperatures were out of range or not recorded for the following dates: 07/05/2022 temperature 1.1 degrees C 07/12/2022 temperature 1.8 degrees C 09/15/2022 temperature 8.1 degrees C 11/29/2022 temperature 1.3 degrees C 11/30/2022 temperature 1.7 degrees C 02/28/2023 no temperature was recorded 03/03/2023 no temperature was recorded 03/09/2023 no temperature was recorded 03/30/2023 temperature 1.4 degrees C 04/05/2023 temperature 1.5 degrees C On 12/28/2022 at 3:55 PM, the Laboratory Consultant stated there was no corrective action documented for the temperatures that were out of range.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observation, review of temperature logs and interview, the Laboratory Director failed to ensure the laboratory documented corrective actions when the refrigerator temperatures were not within the acceptable temperature range of 2 to 8 degrees Celsius (C) from 06/01/2022 to 12/27/2023 (See D6020).</p>

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, review of temperature logs, and interview, the Laboratory Director failed to ensure the laboratory documented corrective actions when the refrigerator temperatures were not within the acceptable temperature range of 2 to 8 degrees Celsius (C) from 06/01/2022 to 12/27/2023. Findings: The Laboratory Director failed to ensure the laboratory documented corrective actions when the refrigerator temperatures were not within the acceptable temperature range of 2 to 8 degrees Celsius (C) from 06/01/2022 to 12/27/2023 (See D5781).