

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2136510	<b>(X3) Date Survey Completed</b>  06/12/2024
<b>Name of Provider or Supplier</b>  Mays Medical Wellness, Llc	<b>Street Address, City, State</b>  3964 Goodman Rd E Ste 128, Southaven, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3037</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing event records and confirmation with Technical Consultant/Lab Director (TC/LD), the laboratory failed to retain all proficiency records to include but not limited to results, attestation statements, submitted results and analyzer printouts for four of four proficiency testing events. Findings include: 1. Review of 3rd event of 2022, 1st and 3rd events for 2023 and 1st event for 2024 proficiency testing records revealed the laboratory did not retain the following: a. Report sheets and submitted result sheets for 3rd event of 2023. (1 of 5 events report sheets not retained) b. Attestation statement for 3rd event of 2023. (1 of 5 events attestation statements not retained) c. Analyzer printouts for 3rd event of 2022. (1 of 5 events analyzer printouts not retained) d. Proficiency graded results for 3rd event of 2022, 1st and 3rd events of 2023 and 1st event of 2024. (4 of 4 graded results not retained.) 2. Interview with TC/LD on 6/12/2024 at 1:00 p.m. confirmed that the listed proficiency records were not retained after completion of each proficiency event.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in</p>

electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the laboratory temperature records and interview with the Technical Consultant/Lab Director (TC/LD), the laboratory failed to monitor and document 22 of 22 months of the laboratory room temperature where hematology testing was performed. Findings include: 1. Beckman Coulter DxH 500 manufacturer's instructions require: a. DxH 500 rinse and diluent should be stored at temperature of 4-32 degrees Celsius(C). b. Operating specifications for the DxH 500 hematology analyzer require a room temperature of 18-32 degrees Celsius(C). c. Quality control and calibration materials for the DxH 500 must be allowed to come to room temperature before testing. 2. Review of the laboratory room temperature logs from 8/15/2022 through 6/12/2024 revealed the room temperature was not documented as monitored for 22 of 22 months. 3. The TC/LD confirmed in an interview on 6/12/2024 at 10:00 a.m., the laboratory room temperature was not documented as monitored where hematology testing was performed.

**D6041**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing records, the Centers for Medicare and Medicaid Services (CMS)database Casper report 0155D and interview with the Technical Consultant/Lab Director (TC/LD), the technical consultant failed to ensure the laboratory participated in an HHS approved proficiency testing (PT) program for (complete blood count) CBC performed on the Beckman Coulter DxH 500 for the 3rd event of 2023. The laboratory failed to participate in 1 of 6 proficiency testing events. Findings include: 1. Review of the laboratory proficiency records for 8 /10/2022 through 6/12/2024, and the CMS database Casper Report 0155D proficiency report, confirmed the laboratory did not perform or participate in proficiency testing for CBC's for the 3rd event of 2023. The laboratory did not participate in 1of 6 proficiency events. 2. The TC/LD confirmed in an interview on 6/12/2024 at 12:00 p. m. that the laboratory did not participate in the 3rd proficiency event of 2023 for hematology testing (CBC). THIS IS A REPEAT DEFICIENCY

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on surveyor review of proficiency testing records and interview with the Technical Consultant/Lab Director (TC/LD), the technical consultant (TC) failed to document review for four of four graded proficiency test events. Findings Include: 1.

Review of proficiency records from 2022 through 2024, revealed there was no documented review of proficiency graded test results for the 3rd event of 2022, 1st and 3rd events of 2023 or 1st event of 2024. The TC did not review for four of four graded proficiency results returned to the laboratory. 2. Interview with the TC/LD on 6/12/2024 at 12:30 p.m. confirmed there was no documentation available on the day of survey of review of these records by the TC.