

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2136510	<b>(X3) Date Survey Completed</b>  08/10/2022
<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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter AcT Diff 4C quality control (QC) records from 2/5/2021 until 8/10/2022, the AcT Diff ES QC manufacturer assay sheets, patient CBC (complete blood count) logs and an interview with the laboratory director /technical consultant (LD/TC) at 12:00 p.m. on 8/10/22, the laboratory failed to follow the manufacturer's instructions for the open expiration date requirement from 3/2/22 through 3/17/22. Findings include: 1. Review of the Beckman Coulter AcT Diff 4C control records from 2/5/21 through 8/10/22 revealed the following hematology controls (low normal, high) were tested 3/2/22 through 3/17/22 which exceeds the manufacturer's expiration date: Low Control lot number 069100 exp date 2/28/22 Normal lot number 079100 exp date 2/28/22 High lot number 089100 exp date 2/28/22 2. Review of three patient CBC logs on 8/10/22 revealed approximately 121 patient samples were tested between 3/2/22 and 3/17/22 when 3 expired levels of quality control were used. 3. The LD/TC in an interview at 12:00 p.m. on 8/10/22 confirmed that 121 patient CBC samples were tested between 3/2/22 and 3/17/22 when all 3 levels of QC (low,normal,high) had exceeded the manufacturer's expiration date.</p>
<b>D6019</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on the Centers for Medicare and Medicaid Services (CMS) data proficiency testing (PT) report, review of the laboratory's PT records from 2021 and 2022 and lack of documentation of corrective action, the laboratory director failed to ensure an approved corrective action plan was followed when the proficiency testing results for CBC (complete blood count) were unacceptable. Findings Include: 1. Review of the CMS data system report for proficiency testing indicated hematology was graded at 0% for the 2nd events of 2021 and the 2nd event of 2022. 2. Review of the facility's proficiency testing records also indicated hematology was graded at 0% on the 2nd event of 2021 and the 2nd event of 2022. 3. There was no documentation of corrective action for either the 2nd event of 2021 or the 2nd event of 2022.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on review of laboratory testing personnel (TP) records available on 8/10/22, the CMS (Centers for Medicare and Medicaid Services) 209 form and interview with the technical consultant/laboratory director (TC/LD), the laboratory director had not ensured that all testing personnel as listed on the CMS 209 personnel form had received the appropriate documented training prior to performing CBC (complete blood count) testing on the AcT Diff hematology analyzer. Findings Include: 1. Based on review of laboratory personnel records and lack of training documentation available the day of survey, testing personnel #1 - #5 had no initial training for moderate complexity CBC testing prior to performing testing on patients. TP #1 - hire date - 8/21 TP #2 - hire date - 7/21 TP #3 - hire date - 1/22 TP #4 - hire date - 7/21 TP #5 - hire date - 3/22 2. The TC/LD in an interview at 12:30 p.m. on 8/10/22 confirmed that no initial training for CBC testing had been documented for TP #1 - #5 prior to testing patients.

**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, Centers of Medicare and Medicaid Services proficiency testing report and interview with the technical consultant/Laboratory Director (TC/LD) at 11:00 a.m. on 8/10/22, the TC failed to ensure the laboratory participated in an HHS approved proficiency testing (PT) program for CBC (complete blood Count) performed on the Beckman Coulter AcT Diff hematology analyzer for the 2nd event of 2021 and the second event of 2022. Findings include: 1. Review of the laboratory proficiency records for 2021 and 2022 and the CMS database report revealed no proficiency testing was reported for the 2nd event of 2021 and the 2nd event of 2022. 2. The TC/LD in an interview on 8/10/22 at 11:00 am confirmed the laboratory did not participate in the 2nd event of 2021 and the 2nd event of 2022 for hematology testing (CBC).

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel records from 2/5/21 through 8/10/22, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with the laboratory director/technical consultant (LD/TC), the TC failed to evaluate and document the performance of TP #1, TP#2 and TP#4 at least semiannually during the first year of employment. Findings include: 1. Review of the laboratory personnel records indicated that there were no 6 month evaluations for TP #1, TP#2 or TP#4 available for review on the day of survey. TP#1 hire date 8/21 - due February 2022 TP#2 hire date 7/21 - due January 2022 TP#4 hire date 7/21 - due January 2022 2. The LD/TC confirmed in an interview at 12:30 p.m. on 8/10/22 that there was no 6 month evaluation/competency performed on TP #1, TP #2 and TP #4 during the first year of performing moderate complexity testing.