| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 25D2136510 | 02/05/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mays Medical Wellness, Llc | 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.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records for the 1st, 2nd and 3rd events of 2019 and 2020, the (CMS) Centers for Medicare & Medicaid Services 209 personnel form and confirmation by laboratory testing personnel (TP) and technical consultant (TC) at 11:00 am on the day of survey 2/5/21, the laboratory failed to rotate proficiency testing samples among testing personnel who routinely test CBC (complete blood counts) on patient samples. Findings include: 1. Review of proficiency records since the last survey, revealed the 1st and 2nd events of 2019 were performed by TP #1 and the 3rd event of 2019 and all 3 events of 2020 were all performed by the TC. 2. The TC confirmed that CBC testing is routinely performed by TP#1 and TP#2. 3. In an interview at 11:00 a.m. on the day of survey, the TC and TP#1 confirmed that TP#1 performed both 1st and 2nd proficiency test events for 2019 and the TC performed the 3rd event of 2019 and all events in 2020. The proficiency testing events must be performed by testing personnel who routinely test patients. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) |

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| | Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the AcT Diff hematology calibration records from last survey through the survey on 2/5/21 and interview with testing personnel (TP) #1 and the laboratory technical consultant (TC) listed on the CMS (Center for Medicare & Medicaid Services) form at 12:00 p.m., the laboratory failed to perform calibration on CBC (complete blood count) on the AcT Diff hematology analyzer every 6 months as required by the manufacturer. Findings include: 1. Interview with TP #1 and the TC at 12:00 p.m. on 2/5/21 confirmed AcT Diff CBC (complete blood count) calibrations were not performed every 6 months as evidenced by the calibration records available the day of survey. 2. Review of the AcT Diff calibration records from 1/3/19 through the day of survey revealed calibrations were performed on 1/3/19, and again on 2/20/20. This exceeds the 6 month calibration requirement of the manufacturer. |