

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2158677	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier Ms Medical Associates, Llc	Street Address, City, State 8 Front St, Belmont, 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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) 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Cell Dyn Emerald hematology analyzer records including quality control, maintenance, and calibration records from 9/2/2021 through 4/19/2023 and confirmation with testing personnel (TP) #1 (as listed on the Centers for Medicare and Medicaid Services 209 Personnel form) at 10:00 a.m. on 4/19/2023, the laboratory failed to perform calibration on CBC (complete blood count) performed on the Cell Dyn Emerald every 6 months as required by the manufacturer for 2 of 3 six-month periods. Findings include: 1. Review of the Cell Dyn Emerald calibration records revealed calibration was performed on 8/22/2021, 4/3/2022, 8/14/2022, and 4/12/2023. 2. Two of three of these calibration time frames exceeded the 6 month mandatory calibration requirement of the manufacturer. 2. Interview with the TP #1 at 10:00 a.m. on 4/19/2023 confirmed CBC calibrations were not performed every 6 months for 2 of 3 six-month periods.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</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 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing records, Centers of Medicare and Medicaid Services (CMS) database proficiency testing CASPER report 0155D and confirmation with TP #1 at 1:00 p.m. on 4/19/2023, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program for CBC (complete blood count) performed on the Abbott Emerald hematology analyzer for 1 of 4 testing events between 9/2/2021 and 4/19/2023. Findings include: 1. Review of the CMS database proficiency testing CASPER Report 0155D revealed no scores for CBC for the first event of 2022. 2. Review of the laboratory proficiency records from 9/2/2021 through 4/19/2023 revealed no evidence of proficiency testing participation for the 1st event of 2022. The laboratory did not enroll in 1 of 4 proficiency events since 9/2/2021. 3. TP #1 confirmed in an interview at 1:00 p.m. on 4/19/2023 that the laboratory director did not ensure the laboratory was enrolled in proficiency testing for CBC for the 1st event of 2022. THIS IS A REPEAT DEFICIENCY

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 from 09/02/2021, Centers of Medicare and Medicaid Services database proficiency testing CASPER report 0155D, and confirmation by Testing Personnel (TP) #1 at 1:00 p.m. on 4/19/2023, the technical consultant (TC) failed to ensure the laboratory participated in an HHS approved proficiency testing (PT) program for CBC (complete blood Count) performed on the Cell Dyn Emerald hematology analyzer for 1 of 4 events. Findings include: 1. Review of the laboratory proficiency records from 9/02/2021 through 4/19/2023 and the CMS database CASPER Report 0155D proficiency report revealed no proficiency testing was reported for the 1st event of 2022. The laboratory did not participate in 1 of 4 proficiency events since 9/2/2021. 2. TP #1 confirmed in an interview at 1:00 p.m. on 4/19/2023 that the laboratory did not participate in the 1st proficiency 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 surveyor review of testing personnel records since 9/2/2021, including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with TP#1 at 2:00 p.m. on 4/19/2023, the technical consultant (TC) failed to evaluate and document the performance of TP #1 - #6 at least semiannually during the first year of moderate complexity testing. Findings include: 1. Review of the laboratory personnel records indicated that there were no 6-month evaluations available for TP #1 through TP#6. TP #1 initial training date 12/30/2021 - 6 month evaluation due June 2022 TP #2 initial training date 12/30/2021 - 6 month evaluation due June 2022 TP #3 initial training date 12/30/2021 - 6 month evaluation due June 2022 TP #4 initial training date 12/30/2021 - 6 month evaluation due June 2022 TP #5 initial training date 12/30/2021 - 6 month evaluation due June 2022 TP #6 initial training date 12/30/2021 - 6 month evaluation due June 2022 2. TP #1 confirmed in an interview at 2:00 p.m. on 4/19/2023 that no 6 month evaluation/competency was performed on TP #1, #2, #3, #4, #5 or #6 during the first year while performing moderate complexity testing.