

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2029494	(X3) Date Survey Completed 08/02/2023
Name of Provider or Supplier Mms Medical Clinical Vicksburg	Street Address, City, State 4204 Clay St, Vicksburg, 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
D5413	<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 electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory temperature records from 11/24/2021 through 8/1/2023, interview with the technical consultant (TC) at 11:00 a.m. on 8/2/2023, and lack of documentation of room temperature values from December 2021 through December 2022, the laboratory failed to monitor and document 13 of 20 months of the laboratory room temperature where hematology testing was performed. Findings include: 1. Boule Medonic M Series manufacturer's instructions require: a. The Medonic M Series rinse and diluent should be stored between 4 - 35 degrees Celsius (C). b. Operating specifications for the Medonic M Series hematology analyzer require a room temperature of 18 - 32 degrees C. c. Quality control and calibration materials for the Medonic M Series must be allowed to come to room temperature before testing. 2. Review of the laboratory room temperature logs from 11/24/2021 through 8/2/2023 revealed the room temperature was not documented as monitored for 13 of 20 months from December 2021 through December 2022. 3. The TC, in an interview at 11:00 a.m. on 8/2/2023, confirmed the laboratory room temperature was not documented as monitored from December 2021 through December 2022 in the room where hematology testing was performed.</p>
D5429	MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the preventive maintenance logs for the Medonic M Series hematology analyzer from 11/24/2021 through 8/1/2023, interview with the technical consultant (TC) on 8/2/2023 at 11:00 a.m. and lack of documented maintenance for March, June, July, August, September, October, November, and December 2022, the laboratory failed to perform and document monthly maintenance for 8 of 20 months as defined by the manufacturer. Findings include: 1. Review of preventive maintenance logs for the Medonic M Series hematology analyzer from 11/24/2021 through 8/2/2023 revealed the monthly maintenance procedure "Monthly Cleaning and Clot Prevention" was not documented as performed for 8 of 20 months reviewed including March, June, July, August, September, October, November and December 2022. 2. An interview with the TC on 8/2/2023 at 11:00 a.m. confirmed the monthly maintenance procedure was not documented as performed for 8 out of 20 months reviewed.

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 preventive maintenance logs for the Medonic M Series hematology analyzer and temperature, cleaning, and centrifuge logs for the area where hematology testing is performed from 11/24/2021 through 8/2/2023, the technical consultant (TC) failed to document review of preventive maintenance for 2 of 20 months, and temperature (room, refrigerator), counter cleaning, and centrifuge logs for 13 of 20 months from December 2021 through December 2022 for the evaluation of the competency of testing personnel. Findings Include: 1. Review of Medonic M Series preventive maintenance from 11/24/2021 through 8/2/2023 revealed no documentation of review by the TC for 2 of 20 months (December 2021, January 2022). a. Medonic M Series monthly maintenance includes: hypochlorite and clot prevention - enzymatic 2. Review of the laboratory temperature logs (room, refrigerator), counter cleaning logs, and centrifuge logs from 11/24/2021 through 8/2/2023 revealed the TC did not document review for 13 of 20 months (December 2021 through December 2022).

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 laboratory personnel records from 11/24/2021 through 8/1/2023, including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel competency evaluations, and interview with the current technical consultant (TC) at 12:30 p.m. on 8/2/2023, the technical consultant (TC) failed to evaluate and document the performance of testing personnel (TP) #3 (1 of 3 new TP since 11/24/2021) at least semiannually during the first year of moderate complexity testing. Findings include: 1. Review of the laboratory personnel records indicated that TP #3 was initially trained on 10/11/2021. 2. There was no 6-month competency evaluation available for review on TP #3 (due in April 2022). 3. The TC confirmed in an interview at 12:30 p.m. on 8/2/2023 that there was no 6-month competency evaluation documented as performed on TP #3 during the first year of performing moderate complexity testing (1 of 3 6-month competency evaluations due).

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of testing personnel (TP) records, including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and laboratory personnel competency evaluations, and interview with the technical consultant (TC) at 12:30 p.m. on 8/2/2023, the former technical consultant failed to evaluate the competency annually for 1 of 6 testing personnel listed on the CMS 209 form. Findings include: 1. The surveyor reviewed personnel records from 11/24/2021 through 8/2/2023 including competency evaluations and the CMS-209 personnel form. 2. There were no annual competency evaluations for TP #5, responsible for moderate complexity testing, available for review from 11/24/2021 through 8/1/2023. 3. The TC confirmed in an interview at 12:30 p.m. on 8/2/2023 that no annual competency evaluations had been documented as performed for TP #5 from 11/24/2021 through 8/1/2023 (for 1 of 6 testing personnel).