

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2018114	(X3) Date Survey Completed 12/27/2022
Name of Provider or Supplier Mea Medical Clinic-Spillway	Street Address, City, State 106 Lake Vista Place, Brandon, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of preventive maintenance logs for the CDS Medonic hematology analyzer from 3/30/2021 through 12/31/2021 and 6/1/2022 through 11/30/2022 and lack of documentation of daily maintenance for five months, monthly maintenance for ten months, and six-month maintenance from 3/30/2021 until 5/27/2022, the laboratory failed to perform and document maintenance as defined by the manufacturer, with at least the frequency specified by the manufacturer. Findings include: Review of preventive maintenance logs for the CDS Medonic hematology analyzer since the last survey on 3/30/2021 revealed no documentation of the following maintenance procedures for the months listed: (1) Daily maintenance procedure "Clean Probe with alcohol" for the months of January through May 2022. (2) Monthly maintenance procedures "Monthly Cleaning" and "Clot Prevention" for the months of July, August, September, November, and December of 2021 and January, March, April, June, and July of 2022. (3) Six-month maintenance "Boule Cleaning Kit Procedure" from 3/30/2021 until 5/27/2022.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Quality Assessment (QA) Plan and review of quality assessment documentation since the last survey on 3/30/2021, the laboratory failed to follow its written policy for performing a weekly chart review of test results from 3/30/2021 until a new Quality Assessment Plan was implemented on 10/1/2022. Findings include: Review of the laboratory's Quality Assessment (QA) Plan in the laboratory procedure manual revealed the "Relationship of Patient Information to Patient Test Results" policy states, "Our laboratory will do one chart review a week to ensure efficiency. The laboratory testing personnel will pull one chart a week to monitor the relationship of the test results to other test results, the relationship of test results to diagnosis, and the distribution of test results." There was no documentation available on the day of the survey, 12/27/2022, of a weekly chart review for the eighteen months from 3/30/2021 until 10/1/2022.

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 personnel records since the last survey on 3/30/2021, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with the technical consultant on 12/27/2022 at 2:30 p.m., the laboratory director failed to ensure that, prior to testing patients' specimens, Testing Personnel #4 and #5 had received the appropriate training for moderate complexity testing and had demonstrated performance of all testing operations reliably to provide and report accurate results. Findings include: Review of personnel records since the last survey on 3/30/2021 and the CMS 209 personnel form revealed the laboratory director failed to ensure that Testing Personnel #4, date of hire 8/20/2021, and Testing Personnel #5, date of hire 8/27/2021, received appropriate training for performing moderate complexity testing prior to testing patients' specimens. In an interview on 12/27/2022 at 2:30 p.m., the technical consultant confirmed there was no documentation of training available for Testing Personnel #4 and #5.

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 review of preventive maintenance logs for the CDS Medonic hematology

analyzer from 3/30/2021 through 12/31/2021 and from 6/1/2022 through 11/30/2022 and lack of documentation of review by the technical consultant, the technical consultant failed to document review of the CDS Medonic preventive maintenance logs for April through December of 2021 and June through August of 2022, until the current technical consultant was hired on 10/1/22. There was also no documentation to indicate that the previous technical consultant detected a lack of documentation of daily maintenance on the CDS Medonic hematology analyzer from 1/1/2022 through 5/31/2022. Findings include: Review of preventive maintenance logs for the CDS Medonic hematology analyzer from 3/30/2021 through 12/31/2021 and 6/1/2022 through 11/30/2022 revealed no documentation of review by the technical consultant for twelve months, for the evaluation of the competency of the staff, until the current technical consultant was hired on 10/1/2022. There was also no documentation to indicate that the previous technical consultant detected a lack of documentation of daily maintenance on the CDS Medonic hematology analyzer from 1/1/2022 through 5/31/2022. Refer to D5429 (Failure to document daily, monthly, and six-month maintenance.)

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 personnel records since the last survey on 3/30/2021, the CMS 209 personnel form, and lack of documentation of competency assessments, the technical consultant failed to evaluate and document the performance of Testing Personnel #4, date of hire 8/20/2021, and #5, date of hire 8/27/2021, at least semiannually, during the first year these individuals tested patient specimens. Findings include: Review of personnel records since the last survey on 3/30/2021 and the CMS 209 personnel form revealed the technical consultant failed to evaluate and document the performance of Testing Personnel #4, date of hire 8/20/2021, and Testing #5, date of hire 8/27/2021, responsible for moderate complexity testing, at least semiannually during the first year these individuals tested patient specimens.

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 personnel records since the last survey on 3/30/2021, the CMS 209 personnel form, and lack of documentation of competency assessments, the technical consultant failed to evaluate and document the performance of Testing Personnel #5, date of hire 8/27/2021, at least annually, after the first year. Findings include: Review of personnel records since the last survey on 3/30/2021 and the CMS

209 personnel form revealed the technical consultant failed to evaluate and document the performance of Testing Personnel #5, who was responsible for moderate complexity testing, at least annually since this individual's date of hire on 8/27/2021.