

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0925214	(X3) Date Survey Completed 03/06/2023
Name of Provider or Supplier Mea Primary Care Plus	Street Address, City, State 7300 Siwell Road, Byram, 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 Clinical Diagnostics Solutions (CDS) Medonic hematology analyzer since 7/22/2021, interview with the technical consultant on 3/6/2023 at 11:50 a.m., and lack of documentation of six-month maintenance between 5/18/2022 and 3/6/2023 and monthly maintenance for seventeen of nineteen months reviewed, the laboratory failed to perform and document maintenance as defined by the manufacturer, with at least the frequency specified by the manufacturer. Findings include: 1. Review of preventive maintenance logs for the CDS Medonic hematology analyzer from 7/23/2021 through 3/6/2023 revealed the six-month maintenance procedure "Boule Cleaning Kit Procedure" was not documented, as performed, for nine months from 5/18/2022 through 3/6/2023. 2. Review of preventive maintenance logs for the CDS Medonic hematology analyzer from 7/23/2021 through 3/6/2023 revealed the monthly maintenance procedure "Monthly Cleaning and Clot Prevention" was not documented, as performed, for the following seventeen of nineteen months reviewed: August, September, October, November, and December of 2021; January, March, April, June, July, August, September, October, November, and December of 2022; and January and February of 2023. In an interview on 3/6/2023 at 11:50 a.m., the technical consultant confirmed the six-month maintenance procedure was not documented as performed, from 5/18/2022 through 3/6/2023, and the monthly maintenance procedures were not documented for the seventeen months listed.</p>
D5437	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

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.

This STANDARD is not met as evidenced by:

Based on review of the CDS M-Series Hematology Analyzer Procedure Manual, calibration records for the CDS Medonic hematology analyzer from 7/23/2021 through 3/6/2023, and interview with the technical consultant on 3/6/2023 at 11:40 a. m., the laboratory failed to perform calibration with at least the frequency recommended by the manufacturer from 7/23/2021 until 5/18/2022. Findings include: 1. Review of the CDS M-Series Hematology Analyzer Procedure Manual revealed the calibration procedure states, "Calibration must be performed upon setup of the instrument and then at a minimum of every six months." 2. Review of calibration records for the CDS Medonic hematology analyzer from 7/23/2021 through 3/6/2023 revealed calibration was not performed for ten months, from 7/23/2021 until 5/18 /2022. 3. In an interview on 3/6/2023 at 11:40 a.m., the technical consultant confirmed that calibration was not performed for a ten month period from 7/23/2021 until 5/18 /2022.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of patient complete blood count (CBC) results in electronic medical records and interview with the technical consultant on 3/6/2023 at 1:00 p.m., the laboratory failed to maintain a record system that included the identity of the personnel who performed CBC testing for five of the five patient results reviewed. Findings include: 1. Review of patient complete blood count (CBC) results in their electronic medical records revealed no documentation of the identity of the testing personnel who performed CBC testing for five of five patient results reviewed. 2. In an interview on 3/6/2023 at 1:00 p.m., the technical consultant stated that there was no documentation of the testing personnel for these five CBC results.

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 7/22/2021, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and lack of documentation of training, the laboratory director failed to ensure that, prior to testing patients' specimens, Testing Personnel (TP) #5 and #7, listed on the CMS 209 personnel form, received the appropriate training for moderate complexity testing and demonstrated performance of all testing operations reliably to provide and report accurate results. Findings include: 1. Review of personnel records and the CMS 209 personnel form revealed that TP #5 and TP #7 began moderate complexity testing without documented training for moderate complexity testing. a. There was no documentation of training available for Testing Personnel #5, responsible for moderate complexity testing since 11/16/2021, until training was performed and documented by the new/current technical consultant on 2/21/2023. TP #5 performed moderate complexity testing without documented training for 17 months. b. There was no documentation of training available for Testing Personnel #7, responsible for moderate complexity testing since 7/25/2022, until training was performed and documented by the new/current technical consultant on 2/20/2023. TP #7 performed moderate complexity testing without documented training for 7 months. 2. The laboratory director failed to ensure that Testing Personnel #5, date of hire 11/16/2021, and Testing Personnel #7, date of hire 7/25/2022, received appropriate training for performing moderate complexity testing prior to testing patients' specimens.

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, including temperature logs, and quality control results for the CDS Medonic hematology analyzer from 7/23/2021 through 3/6/2023, the technical consultant failed to document review of CDS Medonic preventive maintenance logs, temperature logs, and quality control results for six months, from July through December 2021, of the twenty months reviewed, for the evaluation of the competency of the staff. Findings include: Review of preventive maintenance logs, including temperature logs, and quality control results for the CDS Medonic hematology analyzer from 7/23/2021 through 3/6/2023 revealed no documentation of review by the technical consultant of preventive maintenance logs, temperature logs, and quality control results for six of twenty months reviewed, from July 2021 through December 2021, for the evaluation of the competency of the staff.

Refer to D5429 (Failure to document CDS Medonic hematology analyzer 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 7/22/2021, the CMS 209 personnel form, and lack of documentation of a semiannual competency assessment, the technical consultant failed to evaluate and document the performance of Testing Personnel #5, date of hire 11/16/2021, at least semiannually during the first year this individual tested patient specimens. Findings include: Review of personnel records since the last survey on 7/22/2021 and the CMS 209 personnel form revealed no documentation of a semiannual competency assessment for Testing Personnel #5, listed on the CMS 209 personnel form, from date of hire on 11/16/2021 through the first year this individual 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 7/22/2021, the CMS 209 personnel form, and lack of documentation of competency assessments, the former technical consultant failed to evaluate and document the performance for 6 of 10 Testing Personnel (#1, #3, #6, #8, #9, and #10), listed on the CMS 209 personnel form, at least annually. Findings include: 1. Review of personnel records since the last survey on 7/22/2021 and the CMS 209 personnel form revealed the former technical consultant failed to evaluate and document the performance for 2 of 10 Testing Personnel (#6 and #8), who were responsible for moderate complexity testing, since the last survey on 7/22/2021. 2. Review of personnel records since the last survey on 7/22/2021 and the CMS 209 personnel form revealed the former technical consultant failed to evaluate and document the performance of 4 of 10 Testing Personnel (#1, #3, #9, and #10), who were responsible for moderate complexity testing, at least annually from 7/22/2021 until the current technical consultant performed competency assessments for these testing personnel on 2/21/2023.