

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 25D0956590 | (X3) Date Survey Completed 05/01/2024 |
| Name of Provider or Supplier Careplus Madison Family Medicine | Street Address, City, State 7732 Old Canton Rd, Madison, 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 |
|---------------------------|---|
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of written laboratory policy and procedure manual and interview with the clinic office manager and testing personnel (TP), the laboratory failed to establish and maintain a written procedure manual for all laboratory testing, to include collecting specimens, performing CBC (Complete Blood Count) testing with the hematology analyzer, or reporting patient test results since the last survey. Findings include: 1. There was no policy and procedure manual available the day of survey, for collecting, performing moderate or waived tests, or reporting test results performed by testing personnel in the laboratory. 2. The laboratory uses the Boule Medonic hematology analyzer to perform CBC testing. The laboratory has an annual volume of 3500 patient samples for CBC and approximately 1000 are waived tests performed. 3. The office manager and testing personnel confirmed in an interview on 5/1/2024 at 10:30 a.m. that there was no written laboratory policy and procedure available, approved and signed by the laboratory director.</p> |
| D6015 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <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</p> |

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 interview with office manager, 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 Boule Medonic hematology analyzer for 1 of 7 testing events. Findings include: 1. Review of the CMS database proficiency testing CASPER report 0155D revealed no scores for CBC for the first event of 2024. 2. Review of the laboratory proficiency records from 1/27/2022 through 5/1/2024, revealed no evidence of proficiency testing participation for the 1st event of 2024. 3. The office manager confirmed in an interview on 5/1/2024 at 12:00 p.m. that the laboratory was not enrolled in proficiency testing for CBC for the 1st event of 2024.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of a written quality control procedure appropriate for the testing performed and interview with the office manager and testing personnel, the laboratory director did not ensure the laboratory had available a quality control policy manual which should include established parameters for acceptable levels of analytic performance for testing performed on the Boule Medonic hematology analyzer. Findings include: 1. Based on review of the laboratory records, the laboratory did not have available a Quality Control policy that included: A. The levels of control and type of calibration material to be performed B. The frequency of control and calibration performance C. The criteria for determining the acceptability of control results D. The corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability 2. Interview with the office manager and testing personnel on 5/1/2024 at 10:30 a.m., confirmed the written laboratory procedure manual which contained the quality control policy was not available the day of survey.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interviews with the office manager and testing personnel (TP), the laboratory director failed to ensure a comprehensive QA (quality assessment) program designed to monitor and evaluate the overall quality of the total testing process (general laboratory, preanalytic, analytic and postanalytic systems) was established, maintained and available the day of survey to assure the quality of the laboratory services provided. Findings include: A. The laboratory director had not ensured the laboratory had a written QA program available the day of survey for review, that included the practices or issues related to the following when applicable to the test procedure: 1. Patient confidentiality. 2. Specimen integrity. 3. Complaint investigations. 4. Communications. 5. Personnel competency (education, training, evaluation). 6. Proficiency testing or QA activities. 7. Specimen submission, handling, and referral. 8. Establishment and verification of method performance specifications. 9. Control procedures. 10. Review and documentation of the effectiveness of corrective actions taken to resolve problems. 11. Monitoring and evaluating the accuracy and completeness of the laboratory test reports. 12. Performance and periodic review of quality control, proficiency testing, and patient results. 13. Specifications of which qualified personnel will conduct QA reviews and how often these reviews will be conducted, systems and retention of QA records. 14. Revision of policies and procedures necessary to prevent recurrence of problems. 15. Discussion of laboratory QA reviews with appropriate testing personnel. 16. Documentation of QA activities. B. The office manager and testing personnel confirmed on 5/1/2024 at 10:30 a.m., that the laboratory procedure manual which contained a Quality Assessment (QA) program/policy established for the laboratory to follow and maintain, was not available on the day of survey.

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 laboratory testing personnel (TP) records, the CMS (Centers for Medicare and Medicaid Services) 209 form and interview with the office manager and TP, the laboratory director had not ensured that one of one testing personnel as listed on the CMS 209 personnel form had received the appropriate documented training prior to performing and reporting all testing in the laboratory to include CBC (complete blood count) testing on the Medonic hematology analyzer. Findings Include: 1. Review of laboratory personnel records and lack of training documentation available the day of survey, the TP had no initial training for moderate complexity CBC testing prior to performing testing on patients. One of one testing personnel did not have initial laboratory training. 2. Interview with the office manager and testing personnel on 5/1/2024 at 3:00 p.m. confirmed the personnel records containing initial

laboratory training was not available for review the day of survey. According to the office manager, the TP was hired in July of 2023.

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, Centers of Medicare and Medicaid Services (CMS) database proficiency testing CASPER report 0155D and interview with the office manager, the technical consultant failed to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program for CBC (complete blood count) performed on the Boule Medonic hematology analyzer for 1 of 7 testing events. Findings include: 1. Review of the CMS database proficiency testing CASPER report 0155D revealed no scores for CBC for the first event of 2024. 2. Review of the laboratory proficiency records from 1/27/2022 through 5/1/2024, revealed no evidence of proficiency testing participation for the 1st event of 2024. 3. The office manager confirmed in an interview on 5/1/2024 at 12:00 p.m. that the laboratory was not enrolled in proficiency testing for CBC for the 1st event of 2024.

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 moderate testing records and interview with the office manager, the technical consultant (TC) failed to document review of Medonic calibrations, quality controls, maintenance and temperature logs from 1/28/2022 through 5/1/2024. Findings Include: 1. There was no review documented by the TC for the following records: a. Laboratory Temperature Logs (room, refrigerator, freezer, humidity) (8 of 8 months) b. Medonic M Series calibration from 2/17/2022 through 2/7/2024. (6 of 6 calibrations) c. Medonic M Series quality controls from 7/18/2023 through 5/1/2024 (10 of 10 months) d. Medonic M Series maintenance (daily, monthly, 6 month) from 1/2023 through 5/2023 (5 of 5 months) 2. Interview with the office manager on 5/1/2024 at 3:00 p.m. confirmed there was no available documentation of review of these records by a technical consultant.

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 laboratory personnel records, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with the office manager, the technical consultant (TC) failed to evaluate and document the performance of one of one testing personnel at least semiannually during the first year of moderate complexity testing. Findings include: 1. Review of the laboratory personnel records only indicated the testing personnel education and license. There was no 6 month semiannual evaluation available for review the day of survey. 3. The office manager confirmed in an interview on 5/1/2024 at 3:00 p.m., there was no personnel file containing the 6 month evaluation/competency on the testing personnel. The testing personnel obtained employment and laboratory testing in July of 2023. 4. The TC failed to document 6 month competency evaluation on one of one new testing personnel.