Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1098724	04/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Careplus Reservoir Family Medicine	1220 North Shore Pkwy Ste A, 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	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 an interview with the technical consultant at 11:15 a.m. on 4/27/2023 and review of preventive maintenance logs for the CDS Medonic M-Series hematology analyzer from 10/21/2021 through 4/27/2023, the laboratory failed to perform and document maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer for 12 of 18 months for monthly maintenance and 3 of 3 six-month periods for semi-annual maintenance. Findings include: 1) Review of preventive maintenance logs for the CDS Medonic M-series hematology analyzer from 10/21/2021 through 4/27/2023 revealed no documentation of the following maintenance procedures for the months listed: a) Monthly maintenance procedures "Monthly Cleaning" and "Clot Prevention" were not documented as performed for 12 of 18 months (March, April, May, June, July, August, September, October, November, December of 2022 and January and February of 2023). b) Six-month maintenance "Boule Cleaning Kit Procedure" was not documented as performed for 3 of 3 six-month periods between November of 2021 and February of 2023. 2) The technical consultant confirmed in an interview at 11:15 a.m. on 4/27/2023 the maintenance procedures were not documented as performed for the specified months.
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 Medonic M-Series Hematology Analyzer Procedure Manual, calibration records for the CDS Medonic hematology analyzer since the last survey on 10/21/2021, and interview with the technical consultant on 4/27/2023 at 12:20 p.m., the laboratory failed to perform calibration at a minimum of every six months, as recommended by the manufacturer, from 4/29/2022 until 3/2/2023 for two of two six-month periods. Findings include: 1. Review of the CDS Medonic 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 4/29/2022 through 3/2/2023 revealed calibration was not performed for twelve months, from 4/29/2022 until 3/2/2023. Calibration was not performed for two of two six-month periods reviewed. 3. The technical consultant confirmed in an interview on 4/27/2023 at 12:20 p.m. the calibration was not performed at a minimum of every six months as recommended by the manufacturer.