Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2160281	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Mrh Med Grp-Verona Family Medicine & Urgent Care	**Street Address, City, State** 5024 Raymond Ave, Tupelo, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's specifications for the Clinical Diagnostic Solutions (CDS) Medonic hematology analyzer, laboratory temperature records since the last survey on 9/3/2021, and interview with the technical consultant on 3/23/2023 at 1:00 p.m., the laboratory failed to follow the manufacturer's instructions for operation of the CDS Medonic hematology analyzer at the proper temperature and humidity for sixteen of nineteen months reviewed. Findings include: 1. Review of manufacturer's specifications for the CDS Medonic hematology analyzer revealed the operating temperature is 18 - 32 degrees Celsius (64 - 90 degrees Fahrenheit) and the humidity should be 80 percent or below. 2. Review of laboratory temperature records since the last survey on 9/3/2021 revealed no documentation of room temperature and humidity for sixteen of nineteen months for the room in which patient complete blood count (CBC) testing was performed on the CDS Medonic hematology analyzer from 9/3 /2021 until 1/19/2023, to ensure the proper operating temperature and humidity was maintained. 3. In an interview on 3/23/2023 at 1:00 p.m., the technical consultant stated there was no documentation of room temperature and humidity from the last survey on 9/3/2021 until 1/19/2023.
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 preventive maintenance logs for the CDS Medonic hematology analyzer from 9/3/2021 through 3/23/2023 and lack of documentation of preventive maintenance for six months from November 2021 through April 2022, the laboratory failed to perform and document daily and monthly maintenance for six of nineteen months and six-month maintenance for eleven of nineteen months. Findings include: 1. Review of preventive maintenance logs for the CDS Medonic hematology analyzer since the last survey on 9/3/2021 through 3/23/2023 revealed no documentation of the following daily and monthly maintenance procedures for six months, from November 2021 through April 2022, of the nineteen months reviewed. a. Daily maintenance procedure "Clean Probe with alcohol." Daily maintenance was not performed for six of nineteen months (182 days) reviewed. b. Monthly maintenance procedures "Monthly Cleaning" and "Clot Prevention." Monthly maintenance was not performed for six of nineteen months reviewed. 2. Review of preventive maintenance logs for the CDS Medonic hematology analyzer since the last survey on 9/3/2021 through 3/23 /2023 revealed no documentation of the following six-month maintenance procedure for eleven months, from 9/3/2021 until 8/8/2022. a. Six-month maintenance "Boule Cleaning Kit Procedure." Six-month maintenance was not performed for one of one six-month periods during the timeframe reviewed.
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 since the last survey on 9/3/2021, and interview with the technical consultant on 3/23/2023 at 12:10 p.m., the laboratory failed to perform calibration at a minimum of every six months, as recommended by the manufacturer, from 9/3/2021 until 1/17/2023 for three of three six-month periods. 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 9/3/2021 through 3/23/2023 revealed calibration was not performed for sixteen months, from 9/3/2021 until 1/17/2023. Calibration was not performed for three of three six-month periods reviewed. 3. In an interview on 3/23/2023 at 12:10 p.m., the

	technical consultant confirmed that calibration was not performed since the last survey on 9/3/2021 until 1/17/2023.
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's proficiency testing (PT) records since the last survey on 9/3/2021, the Centers for Medicare and Medicaid Services (CMS) data system CASPER Report 0155D, and interview with the current technical consultant on 3/23/2023 at 10:30 a.m., the former technical consultant failed to ensure that the laboratory participated in a Health and Human Services (HHS) approved proficiency testing program for complete blood count (CBC) testing for one of three PT events for 2021 (2021-3rd event) and failed to enroll the laboratory in an HHS approved PT program for the year of 2022. Findings include: 1. Review of the laboratory's PT records since the last survey on 9/3/2021 revealed no documentation of the performance of PT for the third hematology event of 2021 and no PT records for the year of 2022. 2. There was no documentation of the performance of PT after the second event of 2021 on 8/2/2021 until the first event of 2023 on 3/9/23. a. Review of the CMS data system CASPER Report 0155D revealed a score of zero for the third hematology PT event of 2021 for failure to participate (one of three events in 2021). b. Review of the CMS data system CASPER Report 0155D revealed no scores for three of three hematology PT events in 2022. 3. In an interview on 3/23/2023 at 10:30 a.m., the current technical consultant confirmed that hematology PT was not performed for the third event of 2021 and stated the former technical consultant failed to enroll the laboratory in an HHS approved proficiency testing program for CBC testing for the year of 2022.