

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2160281	<b>(X3) Date Survey Completed</b>  08/22/2019
<b>Name of Provider or Supplier</b>  Mrh Med Grp-Verona Family Medicine & Urgent Care	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and confirmation with technical consultant (TC) at 2:00 pm on the day of survey, 8/22/19, the laboratory did not have available written approved procedures for venipuncture, capillary (fingerstick), and urine collections. Findings include: A. Review of the laboratory procedure manual revealed the lack of the following procedures: 1. Written procedure for blood collection to include venipuncture and capillary (fingerstick) collections. 2. Written procedure for urine collections on male and female patients. B. The TC confirmed</p>

during an interview at 2:00 pm on the day of survey that there were no procedures for venipuncture, capillary (fingerstick), and urine collections included in the laboratory procedure manual.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of laboratory records since the Boule Medonic M Series installation on 1/24/19 and confirmation with laboratory Technical Consultant (TC) at 3:00 pm on the day of survey, 8/22/19, the laboratory failed to monitor and document the temperatures of the laboratory room and refrigerator. Findings include: 1. Observation of the laboratory room where hematology testing was performed revealed no thermometer to monitor the room temperature for optimal performance of the Boule Medonic hematology analyzer. 2. No refrigerator temperature logs were available for review. 3. Boule Medonic manufacturer's instructions require: a) The Medonic rinse and diluent should be stored at a temperature range of 4-35 degrees Celsius (C). b) The Medonic hematology analyzer instrument operating specifications require a room temperature of 18-32 degrees C. c) The Medonic QC (quality control) and calibration material must be stored at 2 - 10 degrees C. QC and Calibration materials must be allowed to come to room temperature before testing. d) The refrigerator storage requirement for samples is 2-10 degrees C. 3. Interview with the laboratory TC at 3:00 pm on the day of survey confirmed no room or refrigerator temperatures were being monitored and documented.

**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 the Boule Medonic M Series hematology analyzer maintenance records from installation on 1/24/19 until survey on 8/22/19 and interview with the laboratory Technical Consultant (TC) at 3:30 pm on 8/22/19, the laboratory failed to document as performed the daily, monthly and semi-annual maintenance as required by the manufacturer. Findings include: A. Review of the Medonic M Series manual revealed that the following maintenance is required by the manufacturer: 1. Daily- Check reagent levels, Check printer paper, Perform a background count, Quality Control, Clean probe(s) with alcohol 2. Monthly - Monthly Cleaning (Hypochlorite), Clot Prevention (Enzymatic) 3. Six Month - Boule Cleaning Kit Procedure B. Review of the monthly Maintenance record indicated that the maintenance (daily, monthly, six

month) other than daily Quality control had not been documented as performed on the hematology analyzer since installation on 1/24/19. C. Interview with the TC at 3:30 pm on 8/22/19 confirmed maintenance was not documented as performed on the Boule Medonic M.