

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0670422	<b>(X3) Date Survey Completed</b>  09/24/2025
<b>Name of Provider or Supplier</b>  Selma Doctors Clinic	<b>Street Address, City, State</b>  509 Parkman Avenue, Selma, AL	
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>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) and an interview with the Technical Consultant (TC) and Testing Personnel 1 (TP1), the laboratory failed to attain satisfactory scores for the Hematocrit (HCT) and Mean Corpuscular Volume (MCV) testing. The surveyor noted one of the six events from 2023-2025 had unsuccessful performance evaluation. The findings include: 1. A review of the WSLH PT records revealed the laboratory received unsatisfactory scores for the HCT (0%) and MCV (60%) in the 2025 Heme Reg 1 Event. 2. During the exit conference on 09-24-2025 at 1:30 PM, TC and TP1 confirmed the above findings.</p>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on reviews of Hematology Daily Logs, the Medonic M-Series maintenance logs, and by direct observation during the laboratory tour, the laboratory failed to ensure, A) the Room and Refrigerator Temperatures (RRT) and the Humidity were documented each day of patient testing (Refer to D5413), B) the daily Medonic M-Series maintenance was documented (Refer to D5415), C) the new expiration date was documented on the Quality Control vials after opening (Refer to D5429).

**D5413**

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

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 a review of the Hematology Daily Logs, the patient history testing data and an interview with the Technical Consultant (TC) and the Testing Personnel 1 (TP1), the laboratory failed to document the Room and Refrigerator Temperatures (RRT) and the Humidity each day of patient testing. The surveyor noted no RRT and Humidity readings were recorded for one of the 30 days in November 2024, two of the 31 days in July 2025 and one of the 31 days in August 2025. The findings include: 1) A review of the Hematology Daily Logs and patient history testing data revealed the laboratory had no documentation of the RRT and Humidity for the following days. A) November 27, 2024 had 8 patients testing performed. B) July 2, 2025, and July 30, 2025 had 16 patients testing performed. C) August 29, 2025 had 17 patients testing performed. 2. A further review of the Hematology Daily Logs indicated the following specified ranges: A) Room Temperature of 22-30 degrees Celsius B) Refrigerator Temperature of 2-8 degrees Celsius C) Humidity of 20-60 Percent 3) During exit conference on 09-24-2025 at 1:30 PM, TC and TP1 confirmed the above findings.

**D5415**

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

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation, a review of the Complete Blood Count (CBC) Quality Control (QC) package insert, and an interview with the Testing Consultant (TC) and Testing Personnel 1 (TP1), the laboratory failed to write the new expiration date on the QC vials after opening. The surveyor noted three of three QC vials currently in use were missing the open date stability information, the date opened with the new expiration date. The findings include: 1. During the laboratory tour on 09-24-2025 at

approximately 8:35 AM the surveyor observed the testing personnel had not recorded the open date stability information on the CBC QC vials, Lot number 22505-31, Expiration 10-14-2025. 2. A review of the Boule QC package insert revealed a 14 day open-tube stability requirement. 4. TC and TP1 confirmed the above findings during the exit conference on 09-24-2025 at 1:30 PM.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

(a)(1) 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 reviews of the Medonic M-Series maintenance logs and User Manual, patient testing records, and an interview with the Technical Consultant (TC) and Testing Personnel 1 (TP1), the laboratory failed to document the daily maintenance procedure prior to patient testing for one of the 31 days in March 2024. The findings include: 1. A review of the Medonic M-Series maintenance logs revealed the laboratory had not documented the daily analyzer maintenance for March 28, 2024. 2. A review of the Medonic M-Series User Manual revealed the following instruction on Section 8.1 page 64, Daily Cleaning Procedure. 3. A review of the patient testing records revealed 15 patients were performed on March 28, 2024. 4. During the exit conference on 09-24-2025 at 1:30PM, the TC and TP1 confirmed the above findings.