

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1063889	<b>(X3) Date Survey Completed</b>  07/31/2025
<b>Name of Provider or Supplier</b>  Middle Creek Medical Center	<b>Street Address, City, State</b>  4810 Bell Hill Road, Bessemer, 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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Complete Blood Count (CBC) Quality Control (QC) records for the Sysmex XP-300 analyzer, patient records, and an interview with the Technical Consultant (TC), the laboratory utilized expired QC materials prior to patient testing. The surveyor noted the three levels of expired CBC QC were used for two days from September - December 2023, affecting sixteen patients. The findings include: 1. Reviews of the CBC QC and the patient records revealed the laboratory utilized three levels of CBC QC after the expiration dates as follows. A) Sysmex QC Lot 31640710-712, Expiration 09-20-2023, used on 09-21-2023 before testing ten patients. B) Sysmex QC Lot 32480710-712, Expiration 12-13-2023, used on 12-14-2023 before testing six patients. 2. During the exit conference on 07-31-2025 at 2:37 PM, the TC confirmed the above findings.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Hematology Sysmex XP-300 maintenance records, the Sysmex XP-300 Instructions For Use, and an interview with the Technical Consultant,</p>

the laboratory failed to document the manufacturer's required quarterly maintenance. The surveyor noted maintenance due two out of eight quarters in 2023-2025 were not documented. The findings include: 1. A review of the Sysmex XP-300 Maintenance Hematology log maintenance records revealed no documentation of quarterly (every 3 months) maintenance for the following periods: (A) February 2024 - July 2024 (B) January 2025 - July 2025. 2. A review of the Sysmex XP-300 Instructions For Use in section 12, page 12-12, under Clean SRV, revealed the following instructions, "... When the main power switch is turned ON, and if either the counter value exceeds 4,500, or if 3 months have passed since the last maintenance, a message will appear prompting the operator to perform periodic maintenance (SRV cleaning) ...". 3. During the exit conference on 07-31-2025 at 2:37 PM, the TC confirmed the above findings.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

(b)(9) 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 a review of personnel evaluation records and an interview with the Technical Consultant (TC), the TC failed to assess and document the semi-annual competency for two of the eleven Testing Personnel (TP) responsible for moderate complexity testing during the first year of patient testing in 2025. The findings include: 1. A review of personnel records for TP listed on the CMS-209 Form (Laboratory Personnel Report) revealed the TC failed to perform and document the semi-annual competency assessment for TP9 and TP10 in 2025. 2. The TC confirmed the above findings during the exit conference on 07-31-2025 at 2:37 PM.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:  
Based on a review of personnel evaluation records and an interview with the Technical Consultant (TC), the TC failed to assess and document the annual competency for one of the eleven Testing Personnel (TP) responsible for moderate complexity testing from 2024-2025. The findings include: 1. A review of personnel records for TP listed on the CMS-209 Form (Laboratory Personnel Report) revealed the TC failed to perform and document the annual competency assessment for TP3 from 2024-2025. 2. The TC confirmed the above findings during the exit conference on 07-31-2025 at 2:37 PM.