| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D2026234 | 04/30/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Medcenter Demopolis Pc | 705 Highway 80 West, Demopolis, AL | |

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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and an interview with the Testing Personnel 1 (TP1), the laboratory failed to ensure the TP (analyst) signed the attestation statements for six of the six PT events reviewed in 2024-2026. The findings include: 1. A review of the AAB-MLE PT records revealed the TP (analyst) failed to sign the attestation statements for the following PT events: a) 2024 M2-M3 Events (Hematology and Microscopy) b) 2025 M1-M3 Events (Hematology and Microscopy) c) 2026 M1 Event (Hematology and Microscopy) 2. TP1 confirmed the above findings during exit conference on 04-30-2026 at 2:30 PM. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of the Beckman Coulter (BC) DxH 500 Hematology analyzer maintenance records and an interview with the Testing Personnel 1 (TP1), the laboratory failed to perform the annual maintenance, as per the manufacturer's instructions. The surveyor noted two of the three possible annual maintenances from |

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| | 2024-2026 had no documentation. The findings include: 1. A review of the BC DxH 500 Hematology analyzer maintenance records revealed the BC DxH 500 analyzer had no documentation of the annual maintenance from 2024-2026. 2. A further review of the BC DxH 500 Hematology analyzer maintenance log form revealed the following annual requirements. A) Yearly (Lubricating Pistons) B) Yearly or every 18,000 cycles (Replace Rinsing Head O-Ring) 3. TP1 confirmed these findings during the exit conference on 04-30-2026 at 2:30 PM. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of personnel records listed on the CMS 209 Form (Laboratory Personnel Report) and an interview with Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to specify in writing which of the LD's duties and responsibilities were assigned to a designee. The surveyor noted there was no documentation for the delegation of responsibilities from the date of the last survey, 05-16-2024, to the date of the current survey, 04-30-2026. The findings include: 1. A review of personnel records revealed the LD had no documentation authorizing a qualified designee to perform TP competency assessments in all phases of the laboratory testing process. 2. TP1 confirmed the above findings during exit conference on 04-30-2026 at 2:30 PM. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of the 2024-2026 Hematology Quality Control (QC) records for the Beckman Coulter (BC) DxH 550 analyzer, the laboratory Policy and Procedure (P&P) manual and an interview with the Testing Personnel 1 (TP1), the laboratory failed to ensure a written policy defining and guiding TP what process to follow when QC values were outside established limits after several runs. The surveyor noted four of the five months reviewed from 2024 through 2026 had QC reruns of up to 5 times or more prior to patient testing. The findings include: 1. A review of the BC DxH 550 QC records revealed Hematology QC were performed several times, up to 5 or more, until all parameters were within acceptable limits without documentation of corrective action. 2. Further review of the QC records revealed TC had written "OK" next to the multiple QC runs for the following months. A) August 2024 (Hematocrit) B) February 2025 (Platelet, Mean Platelet Volume [MPV]) C) October 2025 (Platelet) D) March |

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| | 2026 (Red Blood Cell, Hematocrit, Hemoglobin) 3. A review of the P&P manual revealed no written policy and procedure for TP to follow and document the troubleshooting process when the QC failed several times (more than 2-3 reruns) prior to patient testing. 4. TP1 confirmed the above findings during the exit conference on 04-30-2026 at 2:30 PM. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the personnel records, and an interview with the Testing Personnel (TP1), the Technical Consultant (TC) failed to assess and document the annual competency of the TP listed on the CMS 209 (Laboratory Personnel Report) responsible for the moderate complexity testing. The surveyor noted 12 of the 16 TP had no documentation of the annual competency assessments. The findings include: 1. A review of the TP records performing Complete Blood Count (CBC) and Microscopy (Urine Sediments and Wet Preparation) testing revealed the TC had not documented the annual competency assessment for TP5-16. 2. A further review of the personnel records for TP5 and TP6 revealed the TC had not checked the competency assessment requirements listed on the form but had signed their evaluation forms as the "Trainee". 2. TP1 confirmed the above findings during the exit conference on 04-30-2026 at 2:30 PM. |