| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>01D2126498 | **(X3) Date Survey Completed**<br><br>07/29/2025 |
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| **Name of Provider or Supplier**<br><br>Medcenter Primary Care Pc | **Street Address, City, State**<br><br>4960 Rice Mine Road Ne Suite 10, Tuscaloosa, 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 Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the Laboratory Director (or designee) and laboratory testing analysts failed to sign the attestation statements for ten of twelve events reviewed in 2023 through 2025. The findings include: 1. A review of the MLE PT records revealed the no signature by the previous Laboratory Director (or designee) or the testing analyst on attestation statements for the following surveys: a) 2023 Chemistry M3 and Non-Chemistry M3. b) 2024 Chemistry M1 and Non-Chemistry M1. c) 2024 Chemistry M2 and Non-Chemistry M2. d) 2024 Chemistry M3 and Non-Chemistry M3. e) 2025 Chemistry M1. f) 2025 Chemistry M2. 2. During an interview on 7/29/25, at 1:45 PM, Testing Personnel #1 confirmed the above findings. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(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 |

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| | reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the temperature records, the Beckman Coulter DxH 520 Hematology analyzer user manual, DxH 500 Series Quality Control package insert, and an interview with Testing Personnel #1, the Laboratory failed to document temperatures for the refrigerator in which Hematology QC was stored and room temperature and humidity in which the DxH 520 Hematology analyzer is stored. This was noted for 23 days of 91 days reviewed in April through June 2025. The findings include: 1. A review of the temperature records revealed the laboratory failed to document temperatures for the refrigerator, room temperature, and humidity for the Beckman Coulter DxH 500 series Controls and Beckman Coulter DxH 520 Hematology analyzer for the following days: a) April 2025: 4/3, 4/6, 4/7, 4/9, 4/10, 4 /18, 4/22, 4/26, and 4/29. b) May 2025: 5/26 - 5/29. c) June 2025: 6/3, 6/10, 6/11, 6 /14, 6/17 - 6/19, 6/23, 6/28, and 6/30. 2. A review of the Beckman Coulter DxH 520 Hematology analyzer user manual revealed, "Optimal requirements: Room temperature 16-30 degrees Celsius, Humidity less than 80%." 3. A review of the Beckman Coulter DxH 500 series Quality Control package insert revealed, "Store at 2-8 degrees Celsius." 4. During an interview on 7/29/25, at 1:45 PM, Testing Personnel #1 confirmed the above findings. |
| **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 a review of the Hematology maintenance records, Hematology maintenance procedure, and an interview with Testing Personnel #1, the Laboratory failed to document monthly maintenance on the Beckman Coulter DxH 520 Hematology analyzer as per the manufacturer's requirements. This was noted for 8 months of 18 months reviewed in 2024 and 2025. The findings include: 1. A review of the Beckman Coulter DxH 520 Hematology analyzer records revealed no documentation of monthly maintenance for the following dates: a) 2024: April, May, July, August. b) 2025: March through June. 2. A review of the Beckman Coulter DxH 520 Hematology analyzer maintenance procedure revealed, "Clean WBC bath filter." 3. During an interview on 7/29/2025, at 1:45 PM, Testing Personnel #1 confirmed the above findings. |