| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D1064250 | 09/05/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| After Hours Clinic Sumiton | 292 Bryan Road, Sumiton, 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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| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel (TP) #1, the laboratory failed to retain the instrument printouts for one of six 2021 - 2023 API surveys reviewed. The findings include: 1. A review of the API PT records revealed the laboratory failed to retain the CBC (Complete Blood Count) instrument prints for API 2022 Event #2. 2. During an interview on 9/05/2023 at 2:00 PM, the above noted findings were reviewed and confirmed with Testing Personnel #1. TP #1 explained she was on emergency leave mid-2022, and the survey was performed by a previous employee "who just didn't care". . |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of proficiency testing (PT) records and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to implement procedures to ensure proficiency testing failures were effectively investigated, with corrective actions documented and implemented to prevent possible recurrence. This |

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| | was noted on three of six 2021-2023 Hematology surveys. The findings include: 1. A review of the 2021-2023 API (American Proficiency Institute) Hematology PT records revealed the following: A) 2022-Event #2: WBC (White Blood Cells), RBC (Red Blood Cells), Hemoglobin, Hematocrit and WBC Differential each with failing scores of 60%, resulting in an overall failing score of 66% for the specialty of Hematology. The laboratory was unable to investigate these failures because the testing personnel had failed to retain the instrument CBC (Complete Blood Count) printouts and the PT specimens. (Refer to D3037.) However, there was no evidence the laboratory had implemented corrective actions and training for the testing personnel in PT retention requirements. B) 2022-Event #3 performed on 11/30/2022: MCH (Mean Corpuscular Hemoglobin) with a failing score of 20%. There was no evidence the laboratory had noted and investigated the severe negative bias on the survey in MCH or other RBC parameters, Hemoglobin and MCHC (Mean Corpuscular Hemoglobin Concentration). The surveyor further noted the laboratory failed to document reviews of quality controls (QC), calibrations and other factors. The surveyor noted on 11/30/2022, RBC, Hematocrit, and MCH were outside acceptable limits on the High QC. In addition, a calibration was performed on the Medonic M Series Hematology analyzer two days earlier using an expired calibrator. (Refer to D5413.) C) 2023-Event #1: Monocyte% with a failing score of 0%, resulting in an overall failing score of 66% for WBC Differential. A review of the PT records revealed the testing personnel had entered the absolute values for Lymphocytes, instead of the Monocyte% values. However, there was no evidence the laboratory had implemented procedures to ensure PT results were checked for clerical errors before submission, and testing personnel were trained to understand which results should be entered for the WBC Differential. 2. During reviews of the PT records with Testing Personnel #1 on 9/5/2023 between 2:00-2:55 PM, TP #1 confirmed the laboratory did not have a step-by-step mechanism or procedure to investigate PT failures and results less than 100% to determine the causes of problems and prevent recurrence. . |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Medonic M Series Hematology records and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure testing personnel checked expiration dates and did not use an expired calibration kit when calibrating the instrument. This was noted on one of eight 2022 calibrations. The findings include: 1. A review of Medonic M Series calibration records revealed an expired calibrator (Lot # 22208-24; Expiry: 11/25/2022) was used to calibrate the instrument on 11/28/2023. The surveyor noted concerns due to failures and biases in the Red Blood Cell (RBC) parameters on a proficiency testing survey performed two days later on 11/30/2023, which the laboratory failed to adequately investigate. (Refer to D5291.) 2. During an interview on 9/05/2023 at 4:20 PM, the above noted findings were reviewed and confirmed with Testing Personnel #1. TP #1 explained the calibration was performed by a previous employee "who just didn't care". . |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a) |

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| | Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Medonic M-Series Hematology analyzer calibration records, the Medonic Procedure Manual and an interview with Testing Personnel (TP) #1, the laboratory failed to perform a calibration at least every six months as per manufacturer's instructions in 2023. The laboratory failed to perform and document one of one calibrations due the first half of 2023. The findings include: 1. A review of the Medonic Hematology records revealed the last calibration performed was on 12/14/2022; there was no documentation of a calibration performed in 2023. 2. A review of the Medonic M-Series and the Quick Reference Card revealed written instructions specifying calibrations should be performed every six months. 3. During an interview on 9/05/2023 at 5:26 PM, the surveyor asked how often the Medonic should be calibrated; Testing Personnel #1 stated the CDS Technician told her the instrument should be calibration every six months. TP #1 confirmed the analyzer had not been calibrated in 2023, and the calibration was already three months late. . |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of a patient's final report and an interview with Testing Personnel #1, the laboratory failed to ensure the name and address of the laboratory performing the test was included on the EHR (Electronic Health Record) report. The laboratory name and address are two of eight required parameters on a patient CBC (Complete Blood Count) report. The findings include: 1. During the post-analytical review, the surveyor requested a copy of a final patient report. Testing Personnel #1 provided a CBC report from a patient's chart in the MedConnect EHR. However, the name and address of the main laboratory in Jasper were at the top of the report. 2. During an interview on 9/5/2023 at 6:05 PM, Testing Personnel #1 confirmed the CBC had been performed on site at this laboratory in Sumiton, however the Jasper laboratory's name and address were on the report. . |

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| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of Proficiency Testing (PT), Hematology records and interviews with Testing Personnel #1, the Technical Consultant (also the Laboratory Director) failed to provide technical and scientific supervision and oversight for the laboratory since the previous survey on 8/4/2021. The findings include: 1. A review of laboratory records revealed a lack of technical and scientific oversight and direction contributed to the following deficiencies: A) failure to ensure in proficiency (PT) testing records were complete and retained for at least two years (Refer to D3037.) B) failure to implement procedures to ensure proficiency testing failures were effectively investigated, with corrective actions documented and implemented to prevent recurrence (Refer to D5291.) C) failure to ensure testing personnel checked expiration dates and did not use an expired calibration kit when calibrating the Medonic M Series Hematology analyzer (Refer to D5417.) D) failure to ensure the Medonic M Series Hematology analyzer was calibrated every six months as per the manufacturer's instructions (Refer to D5437.) 2. During the exit summation and interview on 9/05 /2023 at 6:15 PM, the surveyor reviewed the above concerns found during the survey with Testing Personnel #1; the surveyor explained many of the problems noted indicated a lack of technical oversight and direction of the laboratory by a qualified Technical Consultant. SURVEYOR ID #32558 Licensure and Certification Surveyor |