Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0862701	05/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Afterhours Clinic Inc	1800 Birmingham Ave, Jasper, 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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on a review of Medonic M Series Hematology records, and an interview with Testing Personnel #1, the laboratory failed to retain the instrument printouts for patient CBC's (Complete Blood Counts) since the previous survey on 7/20/2021. The surveyor noted five days in 2022-2023 when Quality Controls (QC) run in the CP/OT (Cap Piercer/ Open Tube) mode were outside acceptable limits, however there were no instrument printouts retained to prove no patient CBC's were run in the CP/OT mode on these five days. The findings include: 1. A review of Medonic M Series Hematology records revealed three days in 2022 and two days in 2023 when QC run in the CP/OT mode was unacceptable. [Refer to D5481.] 2. A review of patient records revealed the laboratory had not saved the instrument printouts which specified the mode in which the CBC specimens were run. 3. During an interview on 5/25/2023 at 1:55 PM, the surveyor confirmed the laboratory had saved an electronic copy of the CBC printout in the patient's Electronic Medical Record until 2021. However, when the Medonic was interfaced, the lab stopped scanning the printout. The laboratory had no other mechanism to document the mode in which patient CBC's were run on days when QC was outside acceptable parameters. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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.

This STANDARD is not met as evidenced by:
Based on a review of the API (American Proficiency Institute) Hematology proficiency testing (PT) records, and interviews with Testing Personnel #1, the surveyor determined the laboratory failed to perform effective Quality Assurance (QA) reviews of the PT results to ensure the causes of unsuccessful PT performance (any scores less that 100 percent) were determined, and implement corrective measures to prevent recurrence. The laboratory further failed to implement QA reviews to ensure all required documentation for each survey was complete. This was noted on four out of five 2021-2022 PT surveys. The findings include: 1. A review of API PT records revealed the following: A) 2021 Hematology Event #3: i) Scores: Red Blood Cell (RBC), Hemoglobin and MPV (Mean Platelet Volume) each with a score of 80%, resulting in a score of 93% for this event. ii) Lab's Corrective Action: "Upon review of the results they [the results submitted] are reported as they printed in our office. Next time will run samples twice". iii) Interview: During an interview on 5/25 /2023 at 10:20 AM, Testing Personnel #1 confirmed she had performed a clerical review. The surveyor then asked if the laboratory ran patients twice; Testing Personnel #1 confirmed they did not, and the surveyor then explained their corrective action could not be to run PT samples twice. The surveyor then pointed out the SDI (Standard Deviation Index) on the PT evaluation, which showed a severe negative bias for RBC's and Hemoglobin on all five PT specimens. [This resulted in one out of five specimens actually failing PT.] The laboratory failed to notice the biases or realize the significance, and implement/document an investigation with possible corrective actions to alleviate the trends. B) 2022 Hematology Event #1: i) Scores: WBC (White Blood Cell) Differential with a failing score of 0%, resulting in a score of 83% for this event. ii) Lab's Corrective Action: "Monthly cleaning done ...with clot prevention and new controls ran..." iii) Interview: See 2022 Hematology Event #2 interview C) 2022 Hematology Event #2: i) Scores: WBC Differential with a failing score of 73%, resulting in a score of 95% for this event. ii) Lab's Corrective Action written in response to the deficiencies cited on 9/14/2023 due to unsuccessful participation. However, the surveyor noted the laboratory had not specified the actual cause of the failures. iii) Interview: During an interview on 5/25/2023 at 11:10 AM, the surveyor asked if the laboratory had determined the cause of the original WBC Differential failure for Hematology Event #1; Testing Personnel #1 was unsure until the surveyor pointed out the laboratory had entered the absolute values for the WBC Differential, instead of the % values as required by API. Because the laboratory failed to recognize the error and implement training on the correct entry of the differential results, Testing Personnel #4 made the same error on 2022 Event #2. Thus the laboratory had a Condition deficiency due to unsuccessful participation (written by the CLIA Supervisor on 9/14/2022). iv) In addition, the laboratory failed to retain the instrument printouts for 2022 Hematology Event #2. During the interview above, Testing Personnel #1 confirmed there were no instrument printouts for review. D) 2022 Hematology Event #3 with a score of 80% for MCV (Mean Corpuscular Volume); there was no corrective action documented. 2. During the exit summation on 5/25/2023 at 2:00 PM, the surveyor reviewed the above concerns and lack of procedure to investigate scores less than 100%. In addition, there was no evidence of technical supervision and direction for the staff to ensure the actual causes of the failures were determined, and a lack of instruction on how to implement measures to prevent recurrence. The laboratory further failed to implement QA reviews to ensure

	all documents (instrument printouts) were present and ensure all results less than 100% had documenation of corrective actions. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Medonic M Series Hematology records, and an interview with Testing Personnel #1, the laboratory failed to: 1) ensure at least two levels of Quality Control (QC) were within acceptable ranges in both modes [CP/OT (Cap Piercer/ Open Tube) and MC (Micro Container)] each day of patient testing and reporting of results, or 2) retain the instrument printouts for patient Complete Blood Counts (CBC's) or implement another mechanism to document no patient specimens were run in the CP/OT mode when QC was outside acceptable limits. The surveyor noted five days in 2022-2023 when QC run in the CP/OT mode was unacceptable, however the laboratory had no record to prove no patient CBC's were run in the CP/OT mode on these five days. The findings include: 1. A review of 2022-2023 Medonic M Series Hematology records revealed five days of patient CBC testing and reporting when QC run in the CP/OT mode was unacceptable, as follows: A) 6/22/2022: Normal and High QC unacceptable; 57 patient CBC's performed B) 6/27/2022: Normal and High QC unacceptable; 55 patient CBC's performed C) 12/14/2022: Normal and High QC unacceptable; 83 patient CBC's performed D) 2/21/2023: Normal and High QC unacceptable; 78 patient CBC's performed E) 2/28/2023: Normal and High QC unacceptable; 78 patient CBC's performed 2. During an interview on 5/25/2023 at 1: 10 PM Testing Personnel #1 confirmed the above days of unacceptable QC, and provided the total number of patient CBC's performed. Testing Personnel #1 further stated most patient CBC's were collected via fingerstick and run in the MC mode. However, the surveyor explained laboratory must have a method to document the mode in which patient CBC's were run to ensure patient testing was not affected on days when the CP/OT mode QC was unacceptable. .
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on reviews of the Proficiency Testing records, Hematology records, and interviews with Testing Personnel #1, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to provide technical and scientific oversight and direction for the laboratory when: (I) Proficiency Testing performance was unsuccessful (any scores less that 100 percent), and failed to ensure the causes of the failures were determined so corrective measures could be implemented to prevent recurrence. (II) Quality Controls were not within acceptable ranges in the CP/OT (Cap Piercer/ Open Tube) mode each day of patient testing and reporting of results, and failed to ensure there was documentation no patient specimens were run in the CP/OT

	mode when QC was outside acceptable limits. This occurred from the date of the previous survey on 7/20/2021 to the day of the current survey. The findings include: 1. Refer to D5291 and D5481. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of personnel files and an interview with Testing Personnel #1, the Technical Consultant (also the Laboratory Director) failed to ensure one of one new testing personnel provided educational credentials before performing patient CBC (Complete Blood Count) testing. The findings include: 1. A review of employee files of testing personnel listed on the Form CMS-209 (Laboratory Personnel Report) revealed Testing Personnel #6 was trained to perform CBC's on 7/10/2021, however, the file had no documentation of the employee's educational credentials. 2. During a review of the file and an interview on 5/25/2023 at 9:55 AM, Testing Personnel #1 stated she had asked for the documentation. Testing Personnel #6 had stated her high school diploma was destroyed in a house fire, but had made no attempt to obtain any other records, such as a high school transcript from the school she attended. SURVEYOR ID# 32558 Licensure and Certification Surveyor