Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0862701	12/19/2018
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 the laboratory test menu, the post-analytical laboratory procedures, a review of quality control and patient results reports, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to implement a mechanism to ensure instrument printouts which specified the mode in which the patient CBC (Complete Blood Count) was run, were retained for at least two years. The findings include: 1. On 12/19/2018 at approximately 8:45 AM, during the entrance tour of the laboratory, the surveyor reviewed the moderate-complexity testing procedures. TP #1 included on the test menu CBC's performed on the Medonic M Series Hematology analyzer, and stated the instrument was not interfaced with the Medisys Electronic Medical Record (EMR) system. 2. A review of the Medonic M Series Hematology analyzer procedures revealed patients CBC's (Complete Blood Counts) may be tested in the MC (Microtainer) mode or the OT/CP (Open Tube/Cap Piercing) mode. The procedures required performance of quality controls (QC) in both modes with at least two levels within acceptable ranges in each mode before patient testing began. A review of the QC results and cumulative results log revealed four days of patient testing when QC was outside acceptable ranges in one mode. (Refer to D5481.) 3. On 12/19/2018 at 2:53 PM, the surveyor reviewed the above noted findings with TP #1 who confirmed the cumulative patient log did not specify whether the patient testing was performed in the MC or OT/CP mode; only the instrument printout documented this information. When the surveyor asked for instrument printouts from patient CBC's performed on the days when QC was out of range, TP #1

	explained the laboratory used the instrument printout to manually enter each patient's CBC results in the EMR. After the physician's review of the results, the printout was then shredded; TP #1 confirmed the laboratory had not retained the CBC printouts for a two-year period as required by CLIA, and there was no other mechanism to determine the mode in which the patient CBC was performed. .
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 reviews of the Medonic M Series Hematology analyzer procedures, Hematology quality control (QC) records, patient results, Quality Assurance (QA) records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure at least two levels of Hematology QC were within acceptable limits in both performance modes prior to analyzing patient specimens and reporting the results on four days in 2017-2018. The findings include: 1. A review of the Medonic M Series Hematology analyzer procedures revealed patients CBC's (Complete Blood Counts) may be tested in the MC (Microtainer) mode or the OT/CP (Open Tube/Cap Piercing) mode. The procedures required performance of quality controls in both modes with at least two levels within acceptable ranges in each mode before testing patients. 2. A review of the Hematology cumulative QC report revealed the following days when the laboratory had no documentation of at least two levels of QC within acceptable ranges in one mode of testing: A) 02/02/2017: MC Mode-Two levels of QC out of acceptable ranges [Corrective action for this problem documented "MC side not used"; however the laboratory had failed to retain instrument printouts to document patient CBC's were only run in the OT/CP mode.] B) 02/13/2017: OT/CP Mode-Low QC run in the Normal QC file and outside acceptable limits; no Normal QC run [No corrective action documented.] C) 05/26/2018: MC Mode-Two levels of QC out of acceptable ranges [No corrective action documented.] D) 11/10/2018: OT /CP Mode-No QC performed [No corrective action documented.] 3. A review of the cumulative patient log revealed patient testing was performed on the above four days, however the log did not specify whether the testing was performed in the MC or OT /CP mode; only the instrument printout documented this information, and the laboratory had failed to retain the patient CBC printouts. (Refer to D3041.) 4. During an interview on 12/19/2018 at 3:15 PM, TP #1 reviewed and confirmed the above noted findings. .
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	Based on reviews of the Medonic M Series Hematology analyzer procedures, Hematology quality control (QC) records, patient results, Quality Assurance (QA) records, employee files for testing personnel, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to implement corrective actions to prevent repeat occurrences when two to three levels of Hematology QC were outside acceptable limits in one or both performance modes. This was noted on seven days of patient testing in 2017-2018. The findings include: 1. A review of the employee files for testing personnel performing and resulting CBC's (Complete Blood Counts) on patient specimens revealed no documentation of training for moderate-complexity testing performed on the Medonic M Series Hematology analyzer for three out of nine testing personnel. The records revealed corrective actions for patients affected when quality controls (QC) performed by TP #8 exceeded acceptable limits on 7/1/2018 and 7/14/2018. Additional corrective action had to be taken again for patients affected when QC performed by TP #9 exceeded acceptable limits on 11/24/2018. (Refer to D6029.) 2. A review of the Medonic M Series Hematology analyzer procedures revealed patient's CBC's (Complete Blood Counts) may be tested in the MC (Microtainer) mode or the OT/CP (Open Tube/Cap Piercing) mode. The procedures required performance of quality controls in both modes with at least two levels within acceptable ranges in each mode before patient testing began, however QC was either not performed or was outside acceptable ranges in one mode of testing on 2/2/2017, 2 /13/2017, 5/26/2018, and 11/10/2018. (Refer to D5481.) 3. During the exit summation conference on 12/19/2018 at 3:30 PM, the above noted concerns with the effectiveness of the quality assurance protocols, and the need to implement additional corrective actions to prevent repeat occurrences of QC outages in one or both performance modes were reviewed and confirmed with Testing Personnel #1. .
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory test menu, the post-analytical laboratory procedures, a patient report printed from the Medisys Electronic Medical Record (EMR) system, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to implement a mechanism to ensure patient reports included all required parameters, and were retained for at least two years. The findings include: 1. On 12/19/2018 at approximately 8:45 AM, during the entrance tour of the laboratory, the surveyor reviewed the moderate-complexity testing procedures. TP #1 included on the test menu CBC's performed on the Medonic M Series Hematology analyzer, and stated the instrument was not interfaced with the Medisys EMR system. 2. On 12/19/2018 at 2:53 PM, the surveyor reviewed the laboratory's post-analytical process with TP #1 who provided a copy of a CBC report printed from the Medisys EMR. TP #1 stated staff manually entered the White and Red Blood Cell counts (WBC and RBC), Hemoglobin, Hematocrit, Platelet count and

	the Granulocytic and Lymphocytic % (percent) in the EMR system. A review of the report revealed units of measurement for the WBC, RBC, Hemoglobin, Hematocrit and Platelet count parameters were not specified. The surveyor also noted the results for the RBC Indices and the Mid % portion of the automated differential were not entered. 3. As the interviewed continued on 12/19/2018, TP #1 explained the laboratory also printed the Medonic cumulative patient log which included the data from all CBC's run each month; the surveyor then asked if the instrument printout was retained as a CBC report for each individual patient. TP #1 answered, "No"; after the physician's review of the results, the printout was then shredded. The laboratory did not have a mechanism of retaining a complete CBC report for the individual patients for a two-year period as required by CLIA. Thus the above noted findings were confirmed. .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on reviews of the Medonic M Series Hematology analyzer procedures, Hematology quality control (QC) records, patient results, Quality Assurance (QA) records, and an interview with Testing Personnel #1, the surveyor determined the Laboratory Director failed to implement additional mechanisms to ensure testing personnel followed procedures requiring at least two levels of Hematology QC were within acceptable limits in both performance modes prior to analyzing patient specimens, and reporting the results in 2017-2018. (Refer to D5481 and D5793.) .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on reviews of the Medonic M Series Hematology analyzer procedures, Hematology quality control (QC) records, patient results, Quality Assurance (QA) records, employee files for testing personnel, and an interview with Testing Personnel #1, the surveyor determined the Laboratory Director failed to ensure corrective actions were implemeted to prevent repeat occurrences when two to three levels of Hematology QC were outside acceptable limits in one or both performance modes. This was noted on seven days of patient testing in 2017-2018. (Refer to D5793.) The Laboratory Director further failed to document his review/approval of corrective

	actions taken on 11/24/2018 when 78 patient CBC'S (Complete Blood Count) were performed without at least two levels of QC within acceptable ranges. The findings include: 1. A review of information in the Personnel binder for TP #9 revealed documentation of corrective actions for 78 patients affected on 11/24/2018 when all three levels of quality controls (QC) were outside acceptable limits in the MC (Microtainer) mode, and no QC was run in the OT/CP (Open Tube/Cap Piercing) mode. There was no documentation the Laboratory Director had reviewed or approved the corrective actions (as indicated by a signature and date). 2. During a review of the records on 12/19/2018 at 10:45 AM, TP #1 confirmed the above noted findings. The effectiveness of the quality assurance protocols, and the need to implement additional corrective actions to prevent repeat occurrences of QC outages in one or both performance modes were also reviewed and confirmed with Testing Personnel #1 during the survey exit summation on 12/19/2018 at 3:30 PM. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a lack of training documentation in the personnel files for Testing Personnel (TP) #7, #8 and #9, a review of corrective actions for three incidents when TP #8 and #9 failed to ensure quality controls were within acceptable ranges, and an interview with TP #1, the surveyor determined the Laboratory Director failed to ensure an adequate training protocol for three of nine testing personnel was implemented, performed and documented before patient testing began. The finding include: 1. A review of the employee files for testing personnel performing and resulting CBC's (Complete Blood Counts) on patient specimens revealed no documentation of training for moderate-complexity testing performed on the Medonic M Series Hematology analyzer for the following personnel: A) TP #7-Hired in late 2016, however there was no review of this employee's credentials during the previous 1/11/2017 survey since she was not included on the CMS Form-209 (Laboratory Personnel Report). Annual competency evaluations were dated 7/1/2017 and 12/28/2018. B) TP #8-Hired July 2018, and C) TP #9-Hired September 2018 2. A further review of information in the Personnel binder revealed documentation of corrective actions for patients affected when quality controls (QC) performed by TP #8 exceeded acceptable limits on 7/1 /2018 and 7/14/2018. Additional corrective action had to be taken again for patients affected when QC performed by TP #9 exceeded acceptable limits on 11/24/2018. 3. During an interview on 12/19/2018 at 10:48 AM, the surveyor asked TP #1 about the training on the Medonic Hematology analyzer for the above noted testing personnel, since the three noted incidents requiring corrective actions may have indicated a systemic issue in the training protocol. TP #1 stated she documented the employee training by including printouts of the QC the TP ran while she observed. When asked if any other "training" was documented, TP #1 reviewed the employee files with the surveyor, and confirmed she did not have any other Medonic training documented. 4.

	As the interview continued on 12/19/2018, the surveyor then asked if Medonic had provided a training checklist or guidelines in their manuals. TP #1 checked their records, and returned with the "Hematology Training Medonic M Series" manual. The manual included guidelines in training the testing personnel in routine operation of the Medonic and troubleshooting when problems were encountered. The surveyor explained the Laboratory Director was responsible for ensuring a training protocol was implemented and documented for all testing personnel who performed moderate-complexity patient testing. The Laboratory Director should then assess the training of the Testing Personnel to ensure they could perform all testing operations reliably for accuracy of the patient test results. No documentation of training (except the QC printouts) was provided during the survey, thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor