Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1106632	11/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Nj Uc Paramus Dba Afc Urgent Care	67c E Ridgewood Avenue, Paramus, NJ	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT), interview with Testing Personnel (TP), the laboratory failed to ensure that all TP who perform Hematology testing participated in the American Proficiency Institute (API) PT in the calendar year 2022 and the 1st and 2nd events of 2023. The findings include: 1. A review of PT attestation records showed that 1 out of 10 TP performed PT in the aforementioned time frame. 2. TP #1 as listed on the CMS-209 form confirmed on 11/1/23 at 11:30 am that PT events were not rotated between all TP.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	This STANDARD is not met as evidenced by: Based on the surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all attestation statements provided by the American Proficiency Institute (API) for Hematology testing in calendar year 2023 were signed by the Laboratory Director (LD). The findings include: 1. The attestation statement was not signed by the LD for API Hematology testing 2nd Event in 2023. 2. TP #1 as listed on the CMS-209 form confirmed on 11/1/23 at 11:00 am that the attestation statement for the aforementioned event was not signed.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to retain all CV records for the Medonic M Series analyzer from 11/1/21 to 10/9/23. The finding includes: 1. The laboratory failed to retain all the Manufacturers Package Inserts (MPI) used for Calibration Verification for the Medonic M Series analyzer for 2 years. 2. The TP # 1 listed on the CMS-209 form confirmed on 11/1/23 at 11:45 am that the all CV records were not retained.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of patient Test Records (TR), Procedure Manual (PM), the Medonic M Series User Manual and interview with the Testing Personnel (TP), the laboratory failed to perform corrective action when the Medonic M Series had flagged codes from 10/27/23 to the date of survey. The findings include: 1. The procedure for " System Information Messages/ Indicators" in the PM states "The following pages will list indicators/flags and what those indicators/ flags mean. There will be a description of each indicator/flag and what needs to be done to troubleshoot." 2. Specimen Identification number 3322 had "BD" flagged analyte results for LYM, MID, LYM% and MID%. 3. The Medonic M Series User Manual for the "BD" flag states "Blood sample too old or pathological sample. Follow laboratory's protocol for

	verification of results." 4. There was no documented evidence corrective action was taken for the aforementioned flagged results. 5. The TP #1 as listed on the CMS-209 form confirmed on 11/1/23 at 12:15 pm that corrective action was not performed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 11/1/21 to the date of survey. The findings include: 1. The LD failed to delegate a qualified person to perform Competency Assessments. Cross refer D6004. 2. The LD failed to ensure that Performance Specifications procedures were adequate. Cross refer D6013. 3. The LD failed to ensure the Quality Control Program was maintained for laboratory services. Cross refer D6020. 4. The LD failed to ensure that policies and procedures are established to assure that they are competent. Cross refer D6030. 5. The LD failed to ensure TP followed the laboratory's procedures for test analyses reporting. Cross refer D6070. 6. The LD failed to ensure TP adhered to the laboratory's maintenance policy. Cross refer D6072.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Records (PR), Competency Assessment (CA) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to delegate competency evaluation to a qualified person for the performance of Hematology CA for calendar years 2022 and 2023. The finding includes: 1. CA was performed by TP #1 listed on the CMS-209 form who did not have a minimum of a bachelor's degree and therefore did not meet the qualifications found in CFR 493.1409, 493.1415, and 493.1421. 2. The TP #1 listed on the CMS-209 form confirmed on 11/1/23 at 10:30 am that the LD did not delegate the evaluation of competency to a qualified person.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of Complete Blood Cell (CBC) and automated differential Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that all PS records were adequate for all analytes run on the Medionic M Series Analyzer from 11/1/21 to the date of survey. The findings include: 1. There was no source cited for Normal CBC Patient Ranges. 2. There was no documented evidence a Normal CBC Reference Range verification study was performed. 3. TP #1 as listed on the CMS-209 form confirmed on 11/1/23 at 11:45 am that the laboratory failed to ensure that all PS records were adequate.
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 surveyor review of the Calibration Verification Records (CVR) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the Quality Control (QC) program was maintained for laboratory services provided from 11/1/21 to 10/9/23. The findings include: 1. There was no documented evidence the "Calibration" procedure for the Medonic M Series analyzer was followed by TP for the above mentioned time frame. 2. The TP #1 as listed on the CMS-209 form confirmed on 11/1/23 at 11:30 am the LD did not ensure the QC plan was maintained.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and

	proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Testing Personnel (TP) the Laboratory Director (LD) failed to have established written procedures for assessing the competency of TP from 11/1/21 to the date of survey. The findings include: 1. There was no written procedure or policy for how to assess the competency of new employees and the annual competency of TP. 2. TP #1 as listed on the CMS-209 form confirmed on 11/1 /23 at 10:30 am the LD failed to establish written policies and procedures for CA.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on surveyor observation the Medonic M Series analyzer Work records (WR), the Procedure Manual (PM) and interview with the Testing Personnel (TP), the TP failed to follow the laboratory's procedure for reporting patient test results. The Normal Patient Range (NPR) in the analyzer did not match the NPR in the PM from 11/1/21 to date of the survey. The findings include: 1. The NPR on the WR and PM differ as follows: a. The NPR on the WR had White Blood Cell (WBC) as 3.5 - 10.0 10^9 / l, but the PM had WBC NPR as 3.7 - 9.1 for Males and 4.7 - 8.4 for Females. b. The NPR on the WR had Red Blood Cell (RBC) as 3.50 - 5.50 10^12/ l, but the PM had RBC NPRwas 4.60 - 6.10 for Males and 4.15 - 4.96 for Females. c. The NPR on the WR had Hemoglobin (HGB) as 11.5 - 16.5 g/ dl, but the PM had HGB NPR as 12.9 - 16.2 for Males and 10.8 - 14.5 for Females. d. The NPR on the WR had Platelet (PLT) as 100 - 400 10^9/ l, but the PM had PLT NPR as 122K - 288K for Males and 154 - 363K for Females. 2. The TP #1 as listed on CMS-209 form confirmed on 11/1 /23 at 12:00 pm the laboratory failed to failed to follow the laboratory's procedure for reporting patient test results.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Logs (ML), Procedure Manual (PM) and interview with Testing Personnel (TP), the TP failed to adhere to the Maintenance policies for the Medonic M Series analyzer used for Complete Blood Count (CBC) testing from 11/1/21 to 10/9/23. The findings include: 1. There was no documented evidence the "Monthly Cleaning Procedure" as stated in the PM was performed. 2. There was no documented evidence the " Six Month Cleaning Procedure" as stated in

	the PM was performed. 3. The TP #1 as listed on the CMS-209 form confirmed on 11 /1/23 at 1:00 pm that TP failed to adhere to the maintenance policies.