Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2091276	11/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wells Walk In Urgent Care Pllc	3950 Spencer Hwy, Pasadena, TX	

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
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: Fed - D - 2016 - 493.803 Condition: Successful participation Fed - D - 6000 - 493.1403 - Moderate Complexity Laboratory Director Fed - D - 6063 - 493.1421 Testing Personnel Fed - D - 8100 - 493.1771 - Inspection Requirements The laboratory voluntarily ceased CBC (complete blood count) testing on the Medonic M Series hematology analyzer on 11/5/18 as evidenced by their letter dated 11/8/18.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Board of Bioanalyts (AAB) proficiency testing records, and confirmed in interview, the individual testing the proficiency testing samples and the lab director failed to attest to the routine integration of proficiency samples into the patient workload for 5 of 6 testing events in 2017 and 2018. The findings included: 1.Based on review of the AAB proficiency testing records from 2017 and 2018 revealed the individual testing person and lab director failed to sign the attestation for for the following 5 of 6 events in 2017 and 2018 2017 Hematology/Coagulation 1st, 2nd, 3rd event 2018 Hematology /Coagulation 1st, 2nd event 2. An interview with the technical consultant on 11/14/18 at 1000 hours in the nursing station confirmed the above findings.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)

	(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing records and interview of facility personnel, the laboratory failed to successfully participate in a proficiency testing program for the specialty of routine hematology. Refer to D2130
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of 2017 - 2018 American Board of Bionalysts (AAB) proficiency testing (PT) records and interview of facility personnel it was revealed that the laboratory failed to participate in the 1st and 2nd hematology testing event of 2017 and first testing event of 2018. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" on the 1st and 2nd hematology testing event of 2017 and first testing event of 2018 for this facility. 2. A review of AAB proficiency testing records revealed the laboratory received a 0% for the 2017 Q1 and Q2 Hematology PT and 2018 Q1 Hematology PT for "Failure to Participate." The PT summary was rated by the provider as unsatisfactory performance for all analytes for testing event 2017 Q1 and Q2 and 2018 Q1 for Hematology. 3. An interview of the managing director on 11/14/18 at 1000 hours in the nursing station confirmed the above findings. He confirmed the laboratory had failed to submit results to the proficiency testing company and that the laboratory had not performed any self-evaluation. key: CMS - Center for Medicare and Medicaid services

D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of American Board of Bioanalysts (AAB) proficiency testing (PT) records from 2017 and 2018, and confirmed in interview, the laboratory failed to attain a satisfactory performance (score of at least 80 %) for 2 of 3 events in 2017. Findings were: 1. Review of the 2017 AAB proficiency testing records revealed 2 of 3 consecutive events when the laboratory failed to attain at least an 80% score for 6 of 6 of the following analytes. 2017 Q1 event Hematology (0%) RBC (0%) WBC (0%) Cell ID (0%) Hgb (0%) Hct (0%) Platelets(0%) 2017 Q2 event Hematology (0%) RBC (0%) WBC (0%) Cell ID (0%) Hgb (0%) Hct (0%) Platelets(0%) 2. An interview with the technical consultant on 11/7/18 at 1030 hours in the laboratory confirmed the above findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of American Board of Bioanalysts (AAB) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to retain the proficiency testing records for 2 of 3 PT events in 2018. Findings were: 1. The CMS report 155 showed PT event scores for 2018 Q1 and 2018 Q2 events . 2. A review of proficiency testing (PT) records revealed there was no documentation of attestation statements and the instrument printouts for the PT testing performed for 2018 Q1 and Q2 events from AAB. 3. An interview with the technical consultant on 11/14/18 at 1040 hours confirmed the above findings. KEY: CMS- Center for Medicare and Medicaid Services
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on attempted review of quality control records from May to October 2018 and

	confirmed in interview, the laboratory failed to have a quality control plan that would detect errors over time for CBC (complete blood count) testing on the Medonic M Series hematology analyzer. The findings were: 1. Review of the May to October 2018 quality control data revealed no documentation the laboratory monitored quality control data over time. The laboratory failed to document the review of Levy Jennings or statistical calculations (mean, standard deviations, and coefficient of variation), which present an overall evaluation of quality control performance, and is a tool used to evaluate the accuracy and precision of controls over time. 2. An interview with the technical consultant on 11/14/18 at 1040 hours in the nursing station confirmed the above findings.
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 review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. Refer to D6018, D6020
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of American Board of Bioanalyts (AAB) proficiency testing records and confirmed in interview, the laboratory director failed to ensure that all proficiency testing reports received were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action. Findings were: 1. Based on review of the laboratory's Policy and Procedure Manual (effective 9/1/15) revealed "the survey will then be presented to the laboratory director or designee for evaluation and signature." 2. Based on review of the API proficiency testing records from 2017 and 2018 revealed no documentation of review for the following 5 of 6 events in 2017 and 2018 2017 Hematology/Coagulation 1st, 2nd, 3rd event 2018 Hematology /Coagulation 1st, 2nd event 3. An interview with the technical consultant on 11/14/18 at 1000 hours in the nursing station confirmed the above findings.
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 review of the laboratory quality control records and confirmed in interview, the laboratory director failed to ensure the laboratory had a quality control plan that would detect errors over time for CBC (complete blood count) testing on the Medonic M Series hematology analyzer. Refer to D5441
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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and interview with facility personnel, the laboratory director failed to ensure that 6 of 6 testing personnel had the appropriate documentation of education and appropriate training required to qualify to perform moderate complexity testing. (Refer to D6065 and D6066).
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education and training for 6 of 6 testing personnel. Refer to D6065, D6066
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a

	chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education to qualify 6 of 6 testing personnel for moderately complex testing for CBC (complete blood count) on the Medonic M Series hematology analyzer. Findings were: 1. A review of personnel records available revealed no documentation of education for 6 of 6 testing personnel. 2. An interview with the technical consultant on 11/14/18 at 0950 hours confirmed the above findings. CMS - Centers of Medicare and Medicaid Services
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of training for 6 of 6 testing personnel for moderately complex testing for CBC (complete blood count) on the Medonic M Series hematology analyzer. Findings were: 1. A review of personnel records available revealed no documentation of training for 6 of 6 testing personnel for moderately complex testing for CBC (complete blood count) on the Medonic M Series hematology analyzer. 2. An interview with the technical consultant on 11/14/18 at 1110 hours confirmed the above findings. CMS - Centers of Medicare and Medicaid Services
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to meet the requirements in 493.1773. Refer to D8103
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d)

	(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview, it was revealed the laboratory was not an active laboratory ready to perform non-waived hematology testing. No instrument, supplies or training of testing personnel were available for review on the date of survey 11/14/18. Findings were: 1. State agency received an initial application CMS116 on 11/21/16 which revealed the laboratory would perform 800 Hematology testing annually. A certificate of registration was processed with an effective date from 2/3/17 to 2/2/19. 2. Random review of laboratory records available revealed the laboratory performed patient testing from 02/3/17 until 11/5/18. Refer to patient alias list. 3. A tour of the facility on 11/14/18 at 1040 hours revealed an unplugged Medonic M Series hematology analyzer stored in the facility director's office. 4. A tour of the laboratory on 11/14/18 at 1030 hours revealed no reagents and quality control to perform CBC testing on the Medonic M Series hematology analyzer. 5. Review of the laboratory records available revealed no training records for 6 of 6 testing personnel. Cross refer to D6066 6. An interview with the facility director on 11/14/18 at 1140 hours in the breakroom confirmed the above findings.