Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2108161	07/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care - Lakewood	12105 W Alameda Pkwy, Ste 100, Lakewood, CO	

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
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 a record review and an interview with the laboratory manager, the laboratory director and testing personnel failed to sign the attestation statements from the American Proficiency Institute (API) for all events in 2021, 2022, and event 1 in 2023. Findings include: 1. A review of the laboratory records from API, revealed the attestation statements for complete blood count samples from API were not signed by the laboratory director and testing personnel. 2. An interview on 7/18/2023, with the laboratory manager at approximately 10:00 AM, confirmed the laboratory director and testing personnel failed to sign the attestation statements for complete blood counts tests from API.
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 a routine proficiency test desk review of the CASPER CMS-155 report for proficiency testing performance and an interview with the laboratory manager, the laboratory failed to achieve satisfactory performance scores for Hematology overall, Red Blood Cells (RBC), Hematocrit (HCT), and Platelets (PLT) for two out of three events, event 2 in 2022, event 1 in 2023 (See D2130, D2131). The laboratory performed approximatley 400 hematology tests per year.
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 a review of proficiency testing scores from the American Proficiency Institute (API), CASPER CMS-155 report and an interview with the laboratory manager, the laboratory failed to achieve a satisfactory score of at least 80 percent for Red Blood Cells (RBC), Hematocrit (HCT), and Platelets (PLT) for two out of three events, event 2 in 2022, event 1 in 2023 for testing performed on Medonics M hematology analyzer resulting in unsuccessful performance. The laboratory performed approximatley 400 hematology tests per year. Findings include: 1. A review of the proficiency testing scores from API and the CASPER CMS-155 Individual Laboratory Profile, revealed the laboratory failed to achieve satisfactory performance for RBC, HCT, PLT. Analyte Score Event, Year RBC 0 2, 2022 RBC 20 1, 2023 HCT 0 2, 2022 HCT 40 1, 2023 PLT 0 2, 2022 PLT 60 1, 2023 2. An interview with the laboratory manager on 7/18/2023 at approximately 11:45 AM, confirmed two out of three unsuccessful proficiency test scores for RBC, HCT, PLT.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: Based on a review of proficiency testing scores from the American Proficiency Institute (API), CASPER CMS-155 report and an interview with the laboratory manager, the laboratory failed to achieve a satisfactory score for Hematology overall for two out of three events, event 2 in 2022, event 1 in 2023 for testing performed on Medonics M hematology analyzer resulting in an overall unsuccessful performance. The laboratory performed approximatley 400 hematology tests per year. Findings include: 1. A review of the proficiency testing scores from API and the CASPER CMS-155 Individual Laboratory Profile, revealed the laboratory failed to achieve satisfactory performance for Hematology overall for event 2, 2022 was zero percent (0%), event 1, 2023 was sixty six percent (66%). 2. An interview with the laboratory manager on 7/18/2023 at approximately 11:45 AM, confirmed two out of three unsuccessful proficiency test scores for Hematology overall.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory director failed to ensure that a procedure manual was made available and followed by testing personnel who performed complete blood count tests on the Medonic M hematology analzyer since the last survey on 10/30/2020. Findings include: 1. A review of the laboratory procedure manual revealed the laboratory failed to ensure procedures were established for the Medonic M hematology analzyer and followed by 6 out of 6 testing personnel. 2. A review of the laboratory procedure manual revealed the laboratory manual contained a procedure for complete blood counts from another facility dated 2014. The original effective date of the laboratory was in 2016. 3. An interview on 7/18/2023, with the laboratory manager at approximately 2:15 PM, confirmed the laboratory director failed to ensure that a procedure manual is available for testing personnel who performed tests on the Medonic M.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a record review, an observation, and an interview with the laboratory manager, the laboratory testing personnel #1 (TP1) failed to follow the manufacturer's instructions for performing testing on the Medonic M hematology analyzer. Findings include: 1. A review of the laboratory documents revealed the laboratory failed to

	have the Medonic manufacturer's manual and failed to have a procedure for the test performance for complete blood counts (CBCs). 2. An observation on 7/18/2023, at approximately 12:10 PM, revealed that TP1 failed to perform the background checks and external quality control as instructed by the manufacturer. 3. The laboratory performed approximately 44 patient samples from October 2022 through July 2023. 4. An interview on 7/18/2023, with the laboratory manager at approximately 2:15 PM, confirmed the laboratory TP1 failed to follow instructions on how to perform background checks and external quality controls. 5. An interview on 7/18/2023, with TP1, at approximately 12:15 PM, revealed the TP1 was shown how to perform tests on the Medonic by another employee.
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 a record review and an interview with the laboratory manager, the laboratory failed to ensure that corrective actions were taken and documented for the Medonic M hematology analyzer when the system failed to meet the quality control requirements and troubleshooting to fix maintenance issues on the analyzer were not resolved since the last survey on 10/30/2020. Findings include: 1. A review of the laboratory records revealed the laboratory failed to document maintenance problems and quality control issues on the Medonic M hematology analyzer. 2. An interview on 7/18/2023, with the laboratory manager at approximately 2:15 PM, confirmed the laboratory failed to ensure that problems with the hematology were resolved and documented.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based a record review and an interview with the laboratory manager, the laboratory failed to ensure the complete blood count results received from a reference laboratory

	were electronically verified to ensure all the data is accurate from the records reviewed between April and November 2022. Findings include: 1. A review of 2 out of 3 patient reports revealed the complete blood counts received from a reference laboratory failed to state the normal value ranges for the percentages for neutrophils, lymphocytes, monocytes, eosinophils, and basophils in November 2022. 2. An interview on 7/18/2023, with the laboratory manager at approximately 2:20 PM, confirmed the laboratory failed to ensure that all reference value information was sent from the reference laboratory.
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 record review and an interview with the laboratory manager, the laboratory failed to ensure that patient test reports indicated the name of the laboratory that performed the test, and the date the test was performed from results received from a reference laboratory from the records reviewed in 2022. Findings include: 1. A review of 2 out of 3 patient reports revealed the complete blood counts (CBCs) and comprehensive metabolic panels (CMP) received from a reference laboratory failed to state the name of the laboratory that performed the tests and the date the tests were performed from the records reviewed between April and November 2022. 2. An interview on 7/18/2023, with the laboratory manager at approximately 2:20 PM, confirmed the laboratory failed to ensure that patient test reports for CBCs and CMPs stated the name of the laboratory and the date the test was performed.
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 record review and an interview with the laboratory manager, the laboratory director failed to ensure that 6 out of 6 testing personnel were properly trained on the Medonic M series hematology analyzer since the last survey on 10/30/2020. Findings include: 1. A record review of the laboratory personnel records revealed the

	laboratory failed to have available training records for the Medonic M hematology analyzer for 6 out of 6 testing personnel since the last survey on 10/30/2020. 2. An interview on 7/18/2023, with the laboratory manager at approximately 9:20 AM, confirmed the laboratory director failed to ensure that testing personnel were trained prior to patient testing.