Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0892730	02/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care At Lake Lucille	185 East Parks Highway, Wasilla, AK	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a lack of documentation and interview with Testing Person 1, the laboratory failed to establish policies and procedures to assess each testing person's competency for three of three testing persons who were performing nonwaived testing. Findings include: 1. No written policies or procedures were found during the survey to assess competency for three of three testing personnel who were performing nonwaived testing. 2. Testing Person 1 confirmed these findings 2/2/2022 at 3:30 pm.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the Medonic M series CBC analyzer procedure implemented on 6 /20/18, and interview with Testing Person 1, the laboratory failed to include reportable ranges for the CBC analytes Red Blood Cell (RBC), White Blood Cell (WBC), Platelet (PLT), and Hemoglobin (HGB). Findings include: 1. In the laboratory's procedure entitled 'Medonic M series CBC analyzer' there was no documentation of reportable ranges for RBCs, WBCs, PLTs, and HGB. 2. The laboratory performed approximately 18 CBCs each month during 2021. 3. Testing Person 1 confirmed these findings on 2/2/22 at 3:30 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on pipette calibration review and interview with Testing Person 1, the laboratory failed to ensure the 100 uL fixed volume pipette used in the Qualigen FastPack Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Free Thyroxine (FT4) tests followed the manufacturer's calibration requirements. Findings include: 1. The Microman 100 uL fixed volume pipette, serial number 05484, showed an expiration date of 10/30/2020. 2. The laboratory performs approximately 10 PSAs, 10 TSHs, and 10 FT4s annually. 3. Testing Person 1 confirmed these findings on 2/2/22 at 3:30 pm.
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 review of the Qualigen FastPack 2021 quality control records and interview with Testing Person 1, the laboratory did not evaluate the quality control results for

	Prostrate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Free Thyroxine (FT4) for accuracy and precision over time. Findings include: 1. The quality control records for the Qualigen FastPack had no documentation showing the evaluation of the accuracy and precision of test performance over time for PSA, TSA, and FT4. 2. The laboratory performs approximately 10 PSAs, 10 TSHs, and 10 FT4s annually. 3. Testing Person 1 confirmed these findings on 2/2/22 at 3:30 pm.
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 review of Medonic CBC Analyzer quality control records for October through December of 2021, and interview with Testing Person 1, the laboratory failed to document corrective actions on seven of seven days when quality control results were not within the manufacturer's acceptable range. Findings include: 1. The low hematology quality control for the Medonic CBC analyzer was outside the manufacturer's acceptable range on 10/28/21, 11/18/21, 11/24/21, 12/23/21, 12/24/21, and 12/30/21 with no documented corrective action. 2. The normal hematology quality control for the Medonic CBC analyzer was outside the manufacturer's acceptable range on 10/13/21 with no documented corrective action. 3. The laboratory performed approximately 18 CBCs each month during 2021. 4. Testing Person 1 confirmed these findings on 2/2/22 at 3:30 pm.
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 review of test reports for complete blood count (CBC) and interview with Testing Person 1, the laboratory failed to include the CBC units of measure on patient test reports. Findings include: 1. The CBC test reports did not include units of

	measure for the sixteen of the sixteen analytes reported on the test report for patient ID 29864. 2. The laboratory performed approximately 18 CBCs each month during 2021. 3. Testing Person 1 confirmed these findings on 2/2/22 at 3:30 pm.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of test reports for complete blood count (CBC) and interview with Testing Person 1, the laboratory did not include the CBC reference intervals or normal values on patient test reports. Findings include: 1. The CBC test reports did not include units of measure for the sixteen of the sixteen analytes reported on the test report for patient ID 29864. 2. The laboratory performed approximately 18 CBCs each month during 2021. 3. Testing Person 1 confirmed these findings on 2/2/22 at 3:30 pm.
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 quality control records, laboratory policies and procedures, and interivew with Testing Person 1, the Laboratory Director failed to ensure the documentation of remedial actions (refer to D6024); failed to ensure test reports included units of measure and normal ranges (refer to D6026); and failed to ensure testing personnel had documented training (refer to D6029) and competency assessments (refer to D6030).
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of Medonic CBC Analyzer quality control records for October through December of 2021, and interview with Testing Person 1, the laboratory director failed to ensure documentation ogf corrective action when quality control

	results were not within the manufacturer's acceptable range on seven of seven days. Refer to D5781
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of test report (patient ID 29864) for complete blood count (CBC) and interview with Testing Person 1, the laboratory director failed to ensure the patient test reports include units of measure and reference or normal values for sixteen of sixteen analytes on the test report. Refer to D 5805 and D5807.
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 lack of documentation and interview with Testing Person 1, the laboratory director failed to document training to provide the knowledge and skills necessary to be competent in the performance of nonwaived tests for three of three testing persons. Findings include: 1. No documentation was found that training was provided for three of three employees performing nonwaived testing. 2. Testing Person 1 confirmed these findings 2/2/2022 at 3:30 pm.
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 a lack of documentation and interview with Testing Person 1, the laboratory director failed to ensure written policies and procedures to monitor and assess each testing person's competency were established and failed to ensure competency assessments were documented for three of three testing persons performing nonwaived testing. Refer to D5209