Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2075862	05/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Davam Urgent Care	6022 Fm 1488, Magnolia, 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	An announced validation survey was performed on 05/31/2023. The laboratory was found to be in compliance with the CLIA regulations found at 42 CFR 493.1 through 493.1780. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference.
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 laboratory's policy, quality control reports from 2022 and 2023 and confirmed in interview, the laboratory failed to establish corrective action procedures for the quality control (QC) failures for one of two moderate tests: CBC

	(complete blood count) on the Medonic hematology analyzer. Findings included: 1. A review of the laboratory's policy Medonic under Quality Control revealed no corrective actions taken when control results are outside of acceptable limits. 2. A review of the laboratory's quality control report from August 2022 to January 2023 revealed three of twenty quality control failures for the following dates. 08/29/2022 low control 2220501 RBC - 2.08 10^12/L (acceptable range 2.12 - 2.36 10^12/L) HGB - 5.1 g/dL (acceptable range 5.2 - 5.8 g/dL) WBC - 2.8 10^9/L (acceptable range 3.2 - 3.8 10^9/L) 10/04/2022 low control 2220631 RBC - 2.04 10^12/L (acceptable range 2.13 - 2.37 10^12/L) HGB - 5.0 g/dL(acceptable range 5.1 - 5.7 g/dL) WBC - 2.2 10^9/L (acceptable range 3.2 - 3.8 10^9/L) 12/26/2022 low control 2220801 RBC - 2.15 10^12/L (acceptable range 2.13 - 2.3710^12/L) WBC - 2.6 10^9/L(acceptable range 3.2 - 3.8 10^9/L) 3. Review of the CMS 116 revealed the laboratory performed 5000 hematology tests annually. 4. An interview with the clinical supervisor on 05/31 /2023 at 1100 hours in her office confirmed the above findings. She acknowledged that the multiple repeats may include a new control material or new reagent but that it is not in a policy as to what steps their testing personnel should do when QC is out.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient test records from 2021 to 2022, and confirmed in interview, the laboratory failed to document four of four calibration verifications for CKMB (creatine kinase-myocardial band), Troponin, and DDimer on the Biosite Triage. Findings included: 1. Review of the Quidel Triage Cardiac Panel Quick Reference (QR9700000EN01 (02/18)) found online under QC (Quality Control) Cal Ver Controls stated "run every 6 months." 2. Review of the laboratory policy Alere Triage (revised 05/01/2018) stated "five levels of calibration verification shall be run every six months on moderate analytes." 3. No documentation was available for review of the four required calibration verification from 2021 to 2022 for the three analytes CKMB, Troponin, and DDimer on the Biosite Triage. 4. Review of the CMS116 revealed the laboratory performed 2000

	chemistry tests annually. 5. An interview with the clinical supervisor on 05/31/2023 at 1110 hours in her office confirmed the above findings.
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 laboratory and patient test records from 2021 to 2022, and confirmed in interview, the laboratory failed to monitor over time the accuracy and precision for three of three tests on the Biosite Triage: CKMB (creatine kinase-myocardial band), Troponin, and DDimer. Findings included: 1. Review of the quality control records for the Biosite Triage from 2021 to 2022 revealed no documentation of the laboratory monitoring over time the accuracy and precision for CKMB, Troponin, and DDimer. 2. Review of the CMS116 revealed the laboratory performed 2000 chemistry tests annually. 3. An interview with the clinical supervisor on 05/31 /2023 at 1110 hours in her office confirmed the above findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the quality control reports from 2022 and 2023 and confirmed in interview, the laboratory failed to document three of twenty corrective actions taken when hematology quality control was outside of established acceptable control limits. Findings included: 1. A review of the laboratory's quality control report from August 2022 to January 2023 revealed three of twenty quality control failures for the following dates without documentation of all corrective actions taken. 08/29/2022 low control 2220501 RBC - 2.08 10^12/L (acceptable range 2.12 - 2.36 10^12/L) HGB - 5.1 g/dL (acceptable range 5.2 - 5.8 g/dL) WBC - 2.8 10^9/L (acceptable range 3.2 - 3.8 10^9/L) 10/04/2022 low control 2220631 RBC - 2.04 10^12/L (acceptable range 2.13 - 2.37 10^12/L) HGB - 5.0 g/dL(acceptable range 5.1 - 5.7 g/dL) WBC - 2.2 10^9/L (acceptable range 3.2 - 3.8 10^9/L) 12/26/2022 low control 2220801 RBC -

	2.15 10^12/L (acceptable range 2.13 - 2.3710^12/L) WBC - 2.6 10^9/L(acceptable range 3.2 - 3.8 10^9/L) 2. The laboratory was asked for documentation of the corrective actions performed for the above dates. No documentation was provided. 3. Review of the CMS 116 revealed the laboratory performed 5000 hematology tests annually. 4. An interview with the clinical supervisor on 05/31/2023 at 1100 hours in her office confirmed the above findings. key: RBC - red blood cells HGB - Hemoglobin WBC - white blood cells