Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2206832	04/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Family Care Walk In Clinic, Inc	15001 S First St, Milan, TN	

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
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 observation of the laboratory, review of the Abbott CELL-DYN Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) manufacturer's operator's manual, review of patient CBC w/Diff instrument printouts, lack of procedure, and staff interview, the laboratory failed to have a procedure to follow when the CELL-DYN instrument flagged CBC w/Diff results. The findings include: 1. Observation of the laboratory on 04/16/24 at 8:00 a.m. revealed the Abbott CELL-DYN Emerald (serial #030820-008386) on the counter used for performing patient testing for CBC w/Diff. 2. A review of the manufacturer's operator's manual

	revealed the following: "The CELL-DYN Emerald displays a measurand flagging message when a sample exhibits any reportable abnormalities as detected by the analyzer. The messages are created when one of the following sample abnormalities is present: " Dispersional Data alerts (H, h, L, l, ++++, D, ----) " Suspect Measurand Flags (s) " Count Invalidation Flags (*)" Table 3.4 on page 3-14 of the operator's manual listed the following information related to flagged White Blood Cell and Differential results: WBC and Differential, result flag= *, text in flags box=L1. Causes listed included platelet aggregates, NRBCs, giant platelets, cryoglobulins, incomplete lysis of RBCs, small lymphocytes, fibrin clots, and a shift in WBC cell distribution due to EDTA anticoagulant equilibration. Differential, Result Flag = s, Text in Flags Box = L2. The causes listed included the presence of myelocytes, lymphoblasts, or basophils. Differential-Result Flag = s, Text in Flags Box = L3, The causes listed included the presence of eosinophils or myelocytes." Differential-Result Flag = *, Text in Flags Box = L5. The cause listed included large-size cells present. The manufacturer's listed actions, depending on the flag, included checking the specimen for clots or agglutination, following laboratory protocol for reviewing a stained smear, and redrawing and retesting the specimen as required. The table on page 3-16 of the operator's manual listed the following information related to flagged platelet and mean platelet volume flags: PLT, MPV, Result Flag=*, Text in Flags Box = P1-The causes listed included the presence of an abnormal quantity of debris, contaminated reagent, electron noise, microbubbles or small cells. PLT, MPV-Result Flag = *, Text in Flags Box = P2. The cause listed was the possible presence of schistocytes. PLT, MPV-Result Flag = *, Text in Flags Box - P3. The causes listed were the presence of microcytic RBCs, shistocytes, giant platelets, sickle cells, and platelet clumps. The manufacturer's listed actions, depending on the flag, included checking a background count, repeating the same specimen, reviewing a stained smear, and verifying the platelet count by a different method. 3. A review of patient instrument printouts revealed the following patients with white blood differential results that were flagged with "s" and a Text Box Flag of L3: patient number two, performed on 04/01/23; patient number four, performed on 03/04/24; and patient number five, performed on 04/12/24. No actions were documented in response to the flagged results. 4. The laboratory procedure manual did not include specific actions to take when results from the CBC instrument were flagged. 5. The technical consultant confirmed during an interview on 04/16/24 at 11 a.m. that the laboratory did not have a procedure to follow when the instrument flagged results for CBC w/Diff. WORD KEY: EDTA=Ethylenediaminetetraacetic acid MPV=Mean Platelet Volume NRBC=Nucleated Red Blood Cell RBC=Red Blood Cell WBC=White Blood Cell PLT=Platelet
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 observation of the laboratory, review of the manufacturer's operator's manual, instrument maintenance log, lack of documentation, and staff interview, the laboratory failed to perform weekly bleach clean for the Abbott CELL-DYN CBC w /Diff instrument for one of four months reviewed from 2022, 2023 and 2024. The findings include: 1. Observation of the laboratory on 04/16/24 at 8:00 a.m. revealed

	the Abbott CELL-DYN Emerald (serial #030820-008386) on the counter used for performing patient testing for CBC w/Diff. 2. A review of the manufacturer's operator's manual revealed, "Bleach Cleaning the system with a bleach solution is performed weekly." 3. The laboratory's instrument maintenance log listed bleach cleaning as a monthly task. 4. Weekly bleach cleaning was not documented in December 2022 (one of four months reviewed). 5. During an interview on 04/16/24 at 11 a.m., the technical consultant confirmed that the laboratory failed to document weekly bleach cleaning for the Abbott CELL-DYN CBC w/Diff instrument in December 2022.
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 review of patient test reports and an interview with the technical consultant, the CBC results that were manually entered into the patient electronic medical record (EMR) failed to include the units of measure (UOM) for four of four patients reviewed from 2022, 2023 and 2024. The findings include: 1. Review of patient CBC results that were manually entered into the patient EMR revealed the results did not include the UOM for four of four patients reviewed from 2022, 2023, and 2024 (patient number one reported on 12/01/22, patient number two reported on 04/01/23, patient number three reported on 09/05/23, and patient number four reported on 03/04/24). Results reported in the EMR included the WBC, RBC, Hemoglobin, Hematocrit, and Platelet count. 2. The technical consultant confirmed during interview on 04/16/24 at 11 a.m. that the CBC results manually entered into the patient's EMR failed to include units of measure.