Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2101056	03/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pflugerville Emergency Center, Llc	21315 N Texas 130, Building 4, Pflugerville, 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	Based on an announced validation inspection, the laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
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 manufacturer's instructions, the laboratory's policy and procedure, laboratory's checklist, calibration records, and interview, the laboratory failed to follow their own procedure for performing and documenting the calibration

every six months for the Medonic M-Series Complete Blood Count (CBC) for two of five calibrations reviewed in 2022 and 2023. Findings follow. A. Review of the Medonic M-Series User's Manual, February 2016 Article # 1504472, under 7.2 Calibration stated, "Step 10 If all parameters have acceptable CVs proceed to the next step, if not rerun calibration following steps above. Step 11 The new calibration factor can be entered in three ways. The recommended method is to select the [USE CAL] button which will automatically calculated the new calibration factor using target range from assay values... Step 12 In the first and second methods the calibration factor is automatically calculated once either the [USE CAL] button is pressed or target value is entered. Step 13 Once calibration factor has been entered using one of the methods above, operator will be prompted to enter a 4-digit Operator ID... and an Authorization Code (REQUIRED) before the new value can be changed or updated. Step 14 Authorized operator can update or change calibration factor by inputting the Authorization Code [2576]. Step 15 Perform steps 9-12 for RBC, MCV, PLT, HGB, WBC, and MPV parameters. To move to the next parameter press [NEXT]. Step 16 It is recommended to not change preset calibration factors for RDW%... Step 17 Once parameters are calibrated, press [EXIT] and a screen will be displayed asking operator if a calibration report is wanted, [SEND], [PRINT], or [EXIT] can be selected. It is recommended that calibration reports be printed and archived in case it may be needed for future reference...." The laboratory failed to perform steps 14-17. B. Review of the laboratory's policy and procedure titled Medonic M-Series Hematology, revised 09/18/2020, at Calibration stated, "Instrument calibration will be performed: When there is a reformulation of a vendor's reagent or when switching to a different reagent vendor When indicated by quality control data Following major maintenance or service At least every six months." C. Review of the laboratory's Medonic calibration checklist titled Medonic M-Series Calibration stated, "9. Scan and run the calibrator 5 times in a row in open mode, mix well between runs. 10. Once the 5 runs are complete, go to the main menu. Press Advanced>Calibration>Whole Blood... 11. The first screen is RBC. Check that the CV is below cutoff. If not, contact the lab manager. If it is, USE CAL. Please do not miss this part of steps 11 through 16. You will be prompted to enter a password 2576... Press NEXT. 12. The next screen is MCV. Check that the CV is below cutoff. If not, contact the lab manager. If it is, press USE CAL. Please do not miss this part of steps 11 through 16... Press NEXT. 13. The next screen is PLT. Check that the CV is below cutoff. If not, contact the lab manager. If it is, press USE CAL. Please do not miss this part of steps 11 through 16... Press NEXT. 14. The next screen is MPV. Check that the CV is below cutoff. If not, contact the lab manager. If it is, press USE CAL. Please do not miss this part of steps 11 through 16... Press NEXT. 15. The next screen is HGB. Check that the CV is below cutoff. If not, contact the lab manager. If it is, press USE CAL. Please do not miss this part of steps 11 through 16... Press NEXT. 16. The next screen is WBC. Check that the CV is below cutoff. If not, contact the lab manager. If it is, press USE CAL. Please do not miss this part of steps 11 through 16... Press NEXT. *You will see a separate screen for RDW at the end. Just press Next to skip. This will bring you back to the beginning. 17. Once calibrations have been set for each parameter, press exit twice. you'll be prompted to print the calibration log. Do so, and label it "Post-Cal"..." The laboratory failed to perform steps 11-17. D. A Review of the calibration records from 2022 and 2023, as listed by date performed, revealed: 1. 05/06/2022 No post-calibration report. (The post calibration report listed the target values used in the calibration and also served as confirmation the calibration was accepted.) The pre-calibration records showed the last successful completed calibration was on 11/16/2021. 2. 07/30/2022 No post-calibration report. The pre-calibration records showed the last successful completed calibration was on 11/16/2021. 3. 11/25/2022 Calibration records complete. 4. 05/02

	/2023 Calibration records complete, and showed the 11/25/2022 calibration in the pre-cal report was the next successful calibration performed since 11/16/2021 (an elapsed time of one year). C. Phone interview with the Director of Laboratory Services on March 6, 2024 at 1055 hours confirmed the findings. KEY: RBC = Red Blood Cell Count MCV = Mean Corpuscular Volume PLT = Platelet HGB = Hemoglobin WBC = White blood cell count MPV = Mean Platelet Volume RDW = Red cell Distribution Width
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: I. Based on review of calibration verifications and interview, the laboratory failed to perform calibration verifications every six months for D-Dimer, Myoglobin, Creatine Kinase- Myocardial Band (CKMB), and Troponin I performed on the Quidel Triage for three of four events reviewed. Findings follow. A. Review of calibration verifications from January 2022 - January 2024 (four events) showed one performed 01/13/2024. Additional calibration verifications were requested on March 6, 2024 at 1155 hours but not provided. B. Phone interview with the Director of Laboratory Services on March 5, 2024 at 0925 hours acknowledged they just started doing calibration verifications on the Triage. II. Based on review of calibration verifications and interview, the laboratory failed to perform calibration verifications every six months for Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Glucose, Blood Urea Nitrogen (BUN), Creatinine, Hemoglobin, Hematocrit, pH, Carbon Dioxide partial pressure, (pCO2), Oxygen partial pressure (pO2), and Lactate performed on the Abbott i-STAT for three of four events reviewed. Findings follow. A. Review of calibration verifications from January 2022 - January 2024 (four events) showed one performed 01/13/2024. Additional calibration verifications were requested on March 6, 2024 at 1155 hours but not provided. B. Phone interview with the Director of Laboratory Services on March 5, 2024 at 0925 hours acknowledged they just started doing calibration verifications on the i-STAT.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of a comparison of test results, and interview, the laboratory failed to compare test results for Hemoglobin and Hematocrit obtained from the Medonic M-Series analyzer and the Abbott i-STAT twice a year in 2022 and 2023 for four of four events reviewed. Findings follow. A. Comparison of test results for 2022 and 2023 for Hemoglobin and Hematocrit performed on the Medonic M-Series and the Abbott i-STAT was requested on March 6, 2024 at 1200 hours but not provided. B. Interview with Technical Consultant #2 (as listed on the CMS form 209) on March 6, 2024 at 1200 hours confirmed they just started doing comparisons for Hemoglobin and Hematocrit in January 2024.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory's policy and procedure, laboratory's checklist, calibration records, and interview, the laboratory failed to follow thier own procedure for performing and documenting the calibration every six months for the Medonic M-Series Complete Blood Count (CBC) for two of five calibrations reviewed in 2022 and 2023 (see D5403).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and procedure, data logs, instrument print-outs, patient test reports, calibration verifications, comparison of test results, and interview, the technical consultant failed to perform technical and scientific oversight as evidenced by: 1. The laboratory failed to perform calibration verifications every six months for D-Dimer, Myoglobin, Creatine Kinase-Myocardial Band (CKMB), and Troponin I performed on the Quidel Triage for three

	of four events reviewed (see D5439 I). 2. The laboratory failed to perform calibration verifications every six months for Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Glucose, Blood Urea Nitrogen (BUN), Creatinine, Hemoglobin, Hematocrit, pH, Carbon dioxide partial pressure (pCO2), Oxygen partial pressure (pO2), and Lactate performed on the Abbott i-STAT for three of four events reviewed (see D5439 II). 3. The laboratory failed to compare test results for Hemoglobin and Hematocrit obtained from the Medonic M-Series analyzer and the Abbott i-STAT twice a year in 2022 and 2023 for four of four events reviewed (see D5775).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, educational credentials, and interview, the technical consultant failed to perform the competency evaluations for 17 out of 17 randomly selected competency evaluations reviewed from 2022 and 2023. Findings follow. A. Review of the laboratory's policy and procedure titled Lab Testing Personnel Competency Assessment, revised 09/13 /2022, under Description stated, "Competency shall be assessment [assessed and] completed by the Facility Manager, Lab Director, Lab Champion, or Director of Lab Services each six months for the first year of employment and annually thereafter." The policy did not require a technical consultant to perform competencies. B. Review of competency evaluations showed the following competency evaluations were performed by testing personnel: 1. Semi-annual competency evaluations for testing personnel #2 (as listed on the CMS form 209) performed by former testing personnel #3 (as listed on the pre-survey paperwork titled Laboratory Personnel) on 09/27/2022 and 03/31/2023; 2. Semi-annual competency evaluations for testing personnel #3 performed by former testing personnel (not listed on the Laboratory Personnel form) on 05/08/2023 and testing personnel #2 on 10/21/2023; 3. Semi-annual competency evaluations for testing personnel #4 performed by testing personnel #2 on 09/12/2023 and testing personnel #13 on 02/24/2024; 4. Annual competency evaluations for testing personnel #5 performed by former testing personnel #3 on 10/08/2022 and testing personnel #2 on 10/05/2024; 5. Semi-annual competency evaluations for testing personnel #6 performed by former testing personnel #3 on 03/23/2023 and testing personnel #2 on 09/10/2023; 6. Semi-annual competency evaluations for testing personnel #7 performed by former testing personnel #3 on 02/22/2023 and testing personnel #2 on 08/18/2023; 7. Annual competency evaluations for testing personnel #8 performed by former testing personnel #3 on 12/10/2022 and testing personnel #2 on 12/03/2023; 8. One semi-annual competency evaluation for testing personnel #9 performed by testing personnel #2 on 09/12/2023 9. Annual competency evaluations for testing personnel #10 performed by former testing personnel #3 on 08 /25/2022 and testing personnel #2 on 08/15/2023. C. Review of educational credentials revealed: 1. Former testing personnel #3 and former testing personnel (not listed) had a high school diploma; 2. Testing personnel #13 had an Associate of Applied Science in Emergency Medical Technology; 3. Testing personnel #2 had a Bachelor of Science in Nursing, with one year laboratory experience. D. Interview with testing personnel #2 on March 6, 2024 at 1620 hours confirmed competencies were performed by testing personnel who did not qualify as technical consultants.

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 pre-survey paperwork, educational credentials and interview, the laboratory failed to have documentation of education qualifying 4 out of 13 testing personnel to perform non-waived testing. See D6065.
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 pre-survey paperwork, educational credentials and interview, the laboratory failed to ensure that 4 out of 13 testing personnel reviewed for the moderately complex test systems had documentation of qualifying education prior to performing patient testing. Findings follow. A. Review of the pre-survey paperwork titled Laboratory Personnel showed: 1. testing personnel #3 (as listed on the CMS Form 209) was hired 11/14/2022; 2. testing personnel #8 was hired 12/29/2021; 3. testing personnel #13 was hired 04/28/2023; 4. testing personnel #15 was hired 07/11 /2023. B. Review of the educational credentials showed: 1. testing personnel #3 had an Associate's Degree of Applied Science in Diagnostic Medical Imaging - Radiology, with no high school diploma on file; 2. testing personnel #8 had an Associate's Degree of Applied Science in Radiography, with no high school diploma on file; 3. testing personnel #13 had an Associate's Degree of Applied Science in Emergency Medical Technology, with no high school diploma on file; 4. testing personnel #15 had an Associate's Degree of Applied Science in Radiologic Technology, with no high school diploma on file; C. Interview with the Facility Manager/Technical Consultant #2 (as listed on the CMS form 209) on March 5, 2024 at 1120 hours confirmed the findings.