Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2115116	08/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Frontline Er	7331 Gaston Avenue Suite 180, Dallas, 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	Noted deficiency and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. Based on the onsite survey conducted 08/30/2018, this facility was found to be in substantial compliance for the specialties/subspecialties in which it was surveyed. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the laboratory's policies, random review of patient test records, and staff interview, it was revealed that the laboratory failed to follow their own Complete Blood Count (CBC) policy to ensure that patient results outside of the laboratory's established ranges are repeated. Findings included: 1. The laboratory's policy titled "Policy for Repeating CBC Tests" (Signed by the Laboratory Director on 11/01/2014) stated "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when patient results are outside of the following range:" "RBC Less than 4.00 or greater than 6.00 million WBC Less than

	4.00 or greater than 20.00 thousand HCT Less than 30% or greater than 50% HGB Less than 10 or greater than 18 mg/% PLT Less than 150 or greater than 450 thousand" 2. Review of patient test records from August 2018 revealed the following 5 of 38 patients in which results within the defined repeat range were NOT repeated: a. 08/05/2018 Patient A6616 PLT=143 b. 08/11/2018 Patient A6663 PLT=139 c. 08 /12/2018 Patient A6665 WBC=3.6 d. 08/13/2018 Patient A6670 RBC=3.84 e. 08/28 /2018 Patient A6836 RBC=6.07 3. During an interview on 08/30/2018 at 01:23 PM in the laboratory, the Technical Consultant confirmed that results within the defined repeat range were NOT being repeated.
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 (No revision information available; information from manufacturer Zip Drive) for the Medonic M Series (Serial Number 27922), laboratory's policies, random review of patient test records, and staff interview, it was revealed that the laboratory's Complete Blood Count (CBC) policy failed to ensure that results with alerts or flags were verified prior to reporting these results to the provider. Findings included: 1. The Medonic M series manufacturer's instructions in the section titled "Troubleshooting and System Messages" revealed the following flag indicators, messages, descriptions, and actions: a. Indicator=BD Message=WBC DIFF: High interference between populations Description=The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action=Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. b. Indicator=OM Message=WBC DIFF: Only one WBC population found; slide review advised. Description=There was only one mode in the WBC distribution between LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. 2. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" (approved and signed by the laboratory director on 10/08 /2016) revealed: "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials

	according the procedures in the unit operator's manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure in correctly followed. Sometimes the flags will disappear when the sample is allowed to equilibrate at room temperature for 15 to 20 minutes or by re-drawing the patient. If the flags disappear, then report that result. If the flags persist, then report and have the clinician review the patient's results in totality and review the patient clinically. The lab will then perform whatever follow-up action the clinician requests." This policy does not ensure that the results with alerts or flags are verified prior to reporting the results to the provider. 3. A random review of patient medical records from August 2018 revealed the following patient results with alerts and flags were reported to the provider without verification of the result. a. 08/13/2018 Patient A6678 Flag--OM: Only one WBC population found; slide review advised. No documentation of a slide review. b. 08/13/2018 Patient A6678 Flag--BD: High interference between populations. No documentation of a slide review. 4. During an interview on 08/30/2018 at 01:23 PM in the laboratory, the Technical Consultant confirmed that results were reported without flagged result verification.
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 review of manufacturer's instructions (No revision information available; information from manufacturer Zip Drive) for the Medonic M-Series hematology analyzer (Serial Number 27922), review of patient records and staff interview revealed the laboratory failed to follow manufacturer's instructions to verify results with alerts or flags. Findings included: 1. The manufacturer's instructions for the Medonic M-Series hematology analyzer under the section titled "Troubleshooting and System Messages" stated: a. Indicator=BD Message=WBC DIFF: High interference between populations Description=The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action=Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. b. Indicator=OM Message=WBC DIFF: Only one WBC population found; slide review advised. Description=There was only one mode in the WBC distribution between LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. 2. A random review of patient medical records from August 2018 identified the following patient results with alerts and flags on both the initial and repeated runs. a. 08/13/2018 Patient A6678 Flag-OM WBC DIFF: Only one WBC population found; slide review advised. No documentation of a slide review. b. 08/13/2018 Patient A6678 Flag-BD WBC DIFF: High interference between populations. No documentation of a slide review. 3. The laboratory was asked to provide documentation of a slide review for result verification. No documentation was provided. 4. During an interview on 08/30/2018 at 01:23 PM in the laboratory, the Technical Consultant confirmed that results were reported without verification with a slide review. Word Key: DIFF=Differential WBC= White Blood Count RBC=Red Blood Count HCT=Hematocrit HGB=Hemoglobin PLT=Platelet LYM=Lymphocyte GRAN=Granulocyte

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on review of the laboratory verification studies (performed 08/15/2016) for the Medonic M Series complete blood count (CBC) analyzer, laboratory records and staff interview, it was revealed that the laboratory failed to provide normal patient ranges for different ages and genders. Findings included: 1. Review of a random sampling of 11 patient records from February 2018 through August 2018 revealed ALL reports with the following normal ranges for CBC results: WBC=3.5-10.0 LYM%= 15.0-50.0 MID%= 2.0-15.0 GRA%=35.0-80.0 LYM=0.5-5.0 MID=0.1-1.5 GRAN=1.2-8.0 RBC=3.50-5.50 HGB=11.5-16.5 HCT=35.0-55.0 MCV=75.0-100.0 MCH=25.0-35.0 MCHC=31.0-38.0 RDW%=11.0-16.0 PLT=100-400 MPV=8.0-11.0 2. Review of a random sampling of 11 patient records from February 2018 through August 2018 revealed the following gender and ages for the patients: Patient A5028 Female/Age =54 Patient 5128 Male/Age=10 Patient A5378 Male/Age=56 Patient A5412 Female/Age=16 Patient A5905 Male/Age=16 Patient A6066 Male/Age=19 Patient A6224 Male/Age=7 Patient A6332 Female/Age=15 Patient A6564 Female /Age=62 Patient A6665 Male/Age=50 Patient A6814 Female/Age=16 3. The laboratory was asked to provide documentation of verification of CBC normal ranges based on patient gender and age. No documentation was provided. 4. During an interview on 08/30/2018 at 11:11 AM in the laboratory, the Technical Consultant confirmed that the laboratory used the same CBC normal ranges for all patients. B. Based on review of the laboratory verification studies (performed 08/15/2016) for the Medonic M Series complete blood count (CBC) analyzer, laboratory records and staff interview, it was revealed that the laboratory failed to utilize the reportable range established in the verification studies. Findings included: 1. Review of the verification study record titled "CDS Reportable Range Verification Medonic M Series SN 27922" revealed the validated reportable range and the reportable range utilized by the laboratory for the following analytes: a. WBC Verified reportable range was 0.8-87.0 Reportable range in use was 0.5-80.0 b. PLT Verified reportable range was 11-921 Reportable range in use was 30-1000 2. Review of the laboratory record titled "Medonic M Series Method Validation Evaluation" stated, "The Lab Director should review the results of the Reportable Range/Linearity study. No patient results may be reported outside the linear range unless procedures/protocols are developed to use when results are outside of the validated linear (reportable) range. 3. The Reportable Range/Linearity study performed does NOT support the WBC low reportable value of 0.5 in use by the laboratory. The Reportable Range/Linearity study performed does NOT support the PLT high reportable value of 1000 in use by the laboratory. 4. During an interview on 08/30/2018 at 10:37AM in the laboratory, the Technical Consultant confirmed the above findings.
D5813	TEST REPORT CFR(s): 493.1291(g)

	The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and confirmed in staff interview, it was revealed the laboratory failed to have documentation to define critical values for Brain Natriuretic Peptide (BNP), Myoglobin, CKMB, and Troponin analytes. Findings included: 1. Review of the laboratory procedure manual revealed a procedure titled "Critical Values." The laboratory failed to have documentation for BNP, Myoglobin, CK-MB, and Troponin critical values. 2. The laboratory was asked to provide documentation of critical values for BNP, Myoglobin, CKMB and Troponin. No documentation was provided. 3. During an interview on 08/30/2018 at 01:45 PM in the laboratory, the Technical Consultant confirmed the above findings.