Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2104317	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
First Call Medical Center	10981 Johns Hopkins Rd, Laurel, MD	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the procedure manual and eyewash logs and interview with the technical consultant (TC), the laboratory failed to test the function of the faucet mounted eyewash stations with the frequency designated in the procedure manual. Findings: 1. The "Quality Assessment" procedure stated that "Faucet mounted eyewash station should be tested weekly and allowed to flush for 30-60 seconds. This testing will also be documented." 2. The eyewash log stated "Check box once verified eye station working correctly" and contained a grid with rows for 12 months and columns to check off three separate locations and enter initials of the staff who performed the eyewash station check. The log indicated that the faucet mounted eyewash stations were checked monthly instead of weekly. 3. During the survey on 09/16/2022 at 3:45 PM, the TC confirmed that staff were flushing the eyewash stations monthly and not weekly as stated in the procedure manual.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical

	consultant (TC), the laboratory failed to verify the accuracy of analytes tested using the Triage MeterPro chemistry analyzer at least twice annually. Findings: 1. The laboratory validated the Triage MeterPro on 07/07/2021 and began patient testing in 08/2021 to test for D-dimer and the Cardiac panel which included the analytes creatine kinase MB, myoglobin, and troponin I. 2. Analytes D-dimer, myoglobin, and troponin I were not included in subpart I and required verification of accuracy at least twice annually. 3. The laboratory enrolled in an approved PT program for the 2022 2nd event that included myoglobin and troponin I. The PT samples were tested on 05 /23/2022. 4. There were no records indicating that the laboratory verified accuracy for myoglobin and troponin I between 07/07/2021 and 05/23/2022. 5. There were no records indicating that the laboratory verified accuracy for D-dimer since 07/07/2021. 6. During the survey on 09/16/2022 at 3:45 PM, the TC confirmed that the laboratory did not verify the accuracy of myoglobin and troponin I between 07/07/2021 and 05/23 /2022 and did not verify accuracy for D-dimer since 07/07/2021.
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: I. Based on laboratory procedure manual and quality control (QC) record review and interview with the testing personnel (TP) and technical consultant (TC), the laboratory did not ensure that written procedures for performing parallel testing of new hematology controls accurately reflected the current practice in the laboratory. Findings: 1. The procedure "Analytic Monitoring", "Quality Control Protocol" states "Parallel testing of new lot numbers of QC shall be performed for preferably 5 days to confirm validity of new controls before being put into use." The "CBC Control Log" states "When opening a new control lot number, run previous controls for 5 days along with the new lot number to check for discrepancy." 2. During an interview at 11: 25 AM the TP stated that they perform parallel testing of new and old lot numbers of hematology controls 1 time before starting the new lot number. 3. A review of QC records from March through May 2022 showed that the "new" lot number of hematology controls (lot # 22203) was tested in parallel with the "old" lot number of controls (lot # 22201) 1 time on 05/22/2022. The previous "new" lot number of controls (lot # 22201) was parallel tested with the previous "old" lot number of controls (lot # 22110) 1 time on 03/14/2022. 4. During an interview on 09/16/2022 at 3:30 PM the TC confirmed that the laboratory's procedures for performing parallel testing of hematology controls do not reflect the current practice in the laboratory. II. Based on laboratory procedure manual and record review and interview with the technical consultant (TC), the laboratory did not ensure that written procedures for performing quality assurance (QA) accurately reflected the current practice in the laboratory. Findings: 1. The procedure "Post-analytic Monitoring", "Result Reporting" states, "Patient Test Management will be conducted at least biannually to insure complete and accurate transmission of information from ordering and collection of sample to results being reported. Five randomly selected samples will be evaluated to include LIS transmission if applicable." 2. QA record review showed that there was

	no documentation that biannual "Patient Test Management" reviews had been performed. 3. During an interview on 09/16/2022 at 2:00 PM the TC confirmed that the laboratory was not performing the "Patient Test Management" reviews.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical consultant (TC), the laboratory failed to ensure that procedures and changes in procedures were approved, signed, and dated by the laboratory director (LD) before use. Findings: 1. The laboratory performed testing using the Quidel Triage MeterPro for the cardiac panel and D-dimer test kits and was using the test kit product inserts as the testing procedure. 2. Neither the cardiac panel or D-dimer test kit product inserts nor the Triage MeterPro user manual were approved, signed, and dated by the LD prior to patient testing. 3. Within the procedure manual were two versions of the proficiency testing (PT) procedure. The TC confirmed at 2:00 PM that the revised version of the PT procedure had not been approved, signed, and dated by the LD. 4. During the survey on 09/16/2022 at 3:45 PM, the TC confirmed that not all procedures and changes in procedures had been approved, signed, and dated by the LD prior to use.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant (TC), the laboratory did not ensure that hematology controls were labeled with the date that they were put in to use. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that the opened and in use "CDS Boule Con Diff Tri-Level" hematology controls in the laboratory refrigerator were not labeled with the date that they were put in to use. 2. During an interview on 09/16/2022 at 3:30 PM, the TC confirmed that the hematology controls in use were not labeled with the date that they were opened.
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 review of maintenance records and interview with the technical consultant (TC), the laboratory failed to document the lot number of cleaning reagents used for instrument maintenance on the hematology analyzer. Findings: 1. The laboratory used a monthly maintenance log for the Medonic M-series hematology analyzer that included sections to record daily, monthly, and six month maintenance activities as well as calibration. 2. The monthly maintenance used the "Boule Cleaning Kit Reagents" named "Monthly Cleaning (Hypochlorite)" and "Clot Prevention (Enzymatic)." The monthly log contained spaces to document the lot number of each cleaning reagent, the date maintenance was performed, and initials of the personnel who performed the maintenance. 3. Monthly maintenance logs were reviewed from 01 /2021 - 06/2022 for a total of 18 months. 4. The lot numbers for the "Monthly Cleaning (Hypochlorite)" reagent were not recorded for 16 of 18 months and for the "Clot Prevention (Enzymatic)" reagent were not recorded for 17 of 18 months. 5. During the survey on 09/16/2022 at 3:45 PM, the TC confirmed that the lot numbers of the cleaning reagents used for monthly instrument maintenance were not recorded on the maintenance logs.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of instrument records and monthly quality assessment (QA) reviews and interview with the technical consultant (TC), the laboratory failed to ensure that testing using the Triage MeterPro was monitored for performance and results reliability. Findings: 1. The laboratory began using the Triage MeterPro in 08/2021 to test for D-dimer and the cardiac panel which included creatine kinase MB, myoglobin, and troponin I. 2. External controls were tested with each new lot or shipment of test materials or every 30 days and recorded on a log. 3. Performance of the MeterPro instrument quality control (QC) was assessed each day of patient testing with a "QC Device" and was recorded on a log. 4. The logs for performance of the external controls and the MeterPro instrument QC had sections at the bottom for a signature and date of review. None of the logs were signed and dated. 5. Every month the TC completed a QA review worksheet that included the QC and maintenance for each analyzer used by the laboratory. 6. The Triage MeterPro instrument was not added to the monthly QA review until 08/2022. 7. During the survey on 09/16/2022 at 3:45 PM, the TC confirmed that QC and maintenance for the Triage MeterPro was not reviewed as part of the monthly QA from 08/2021, when patient testing began, through 07/2022.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved

	proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director failed to ensure that the laboratory was enrolled in an approved PT program for analytes tested using the Triage MeterPro chemistry analyzer. Findings: 1. The laboratory began using the Triage MeterPro for patient testing in 08/2021 to test for D-dimer and the cardiac panel which included creatine kinase MB, myoglobin, and troponin I. 2. Creatine kinase MB was a regulated analyte (included in subpart I) and D-dimer, myoglobin, and troponin I were unregulated. 3. Laboratory PT records were reviewed for the 2020 3rd event through the 2022 3rd event. 4. The laboratory was not enrolled in a chemistry PT program until the 2022 2nd PT event in which PT samples were tested on 05/23/2022. 5. Analytes included in the PT chemistry core event were creatine kinase MB, myoglobin, and troponin I. 6. The laboratory was not enrolled in a PT program for the regulated analyte creatine kinase MB prior to testing patient specimens. 7. The laboratory did not verify the accuracy of the unregulated analytes prior to enrollment in the chemistry core PT event. Cross-refer to tag D5217 for more details. 8. During the survey on 09/16/2022 at 3:45 PM, the TC confirmed that the laboratory was not enrolled in an approved PT program for creatine kinase MB prior to patient testing.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that performance of the Triage MeterPro testing was monitored as part of the laboratory's monthly quality assessment activities from 08/2021, when patient testing began, through 07/2022. Cross-refer to tag D5791 for more details.
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 record review and interview with the testing personnel (TP) and the technical consultant (TC), the lab director (LD) failed to ensure that prior to testing patients' specimens, all testing personnel (TP) 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. Findings: 1. The laboratory currently has 9 TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209) who are actively performing hematology and chemistry testing. 2. A review of training records from 2020 to 2022 showed that 9 of 9 TP did not have documentation that they had received their initial training before performing hematology testing; and 3. Eight of 9 TP did not have documentation that they had received their initial training before performing chemistry testing. 4. During an interview at 1:45 PM on the day of the survey, TP #12 stated that they had performed initial training on the other TP but that it was not documented. 5. During an interview on 09/16/2022 at 3:30 PM the TC confirmed that the LD failed to ensure that TP received appropriate training before performing chemistry and hematology testing.
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 competency assessment record review and interview with the technical consultant (TC), the laboratory director (LD) did not ensure that policies and procedures were established and followed to monitor the competency of all personnel who conduct preanalytic, analytic, and postanalytic phases of testing. Findings: 1. The laboratory currently has 9 TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209) who are actively performing hematology and chemistry testing. Two TP were hired less than 6 months before the date of the survey. 2. A review of competency assessment records from 2020 to 2022 showed that 7 of 7 TP who had been employed longer than 6 months did not have documentation that competency assessments had been performed after 6 months of performing laboratory testing; and 3. Six of 6 TP who had been employed longer than 1 year did not have documentation that competency assessments had been performed annually. 4. During an interview at 1:00 PM on the day of the survey, TP #12 stated that they had performed competency assessments on the other TP. A review of this TP's credentials showed that they were not qualified as a TC (Bachelor of Science with two years' experience). 5. During an interview on 09/16/2022 at 3:30 PM the TC confirmed that there was no documentation of competency assessments performed by the unqualified TP on 9 of 9 TP.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3)

	(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the laboratory was enrolled in an approved proficiency testing program for regulated analytes tested using the Triage MeterPro chemistry analyzer and failed to ensure that accuracy for the unregulated analytes tested using the Triage MeterPro was verified at least twice annually. Cross-refer to tags D6015 and D5217 for more details.
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: The technical consultant failed to perform and document the competency reviews on all TP to ensure that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Cross-refer to D6030 for details.