Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2114168	07/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
First Call Medical Center	15646 Old Columbia Pike, Burtonsville, 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
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 written procedures, the laboratory procedures did not include step-by-step instructions for collecting nasal specimens from patients for SARS-CoV-2 testing. Findings: 1. Page 2 of the laboratory written procedure refers to manuals with guidelines to collect patient specimens, but the written procedure did not include instructions and diagrams showing collection of specimens; and 2. The written procedures did not include instructions to identify and reject unsuitable patient specimens submitted for testing.

D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on record review, the laboratory did not perform corrective actions when the refrigerator temperature readings failed to meet the laboratory's criteria for acceptability. Findings: 1. On April 1, 2022 the refrigerator temperature (acceptable range 2-8 degree Centigrade) was 1.2 degree Centigrade, on March 21, 2022 the temperature was 1.7 degree Centigrade and on February 24, 2022 the temperature was 1.8 degree Centigrade. The laboratory did not perform corrective actions for these three days, did not check reagents for deterioration and did not adjust the temperature and recheck it later to see that the adjustment corrected the temperature.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director did not ensure quality control programs were maintained to document quality control corrective actions for the SARS-CoV-2 testing performed. Findings: 1. The laboratory procedures include a quality control corrective action log to document quality control problems, but the laboratory uses the CAPA log that is not specifically designed to capture quality control problems and provide a mechanism to document corrective actions; and 2. This was confirmed with the technical supervisor the morning of the day of survey.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record review and interview, the technical supervisor did not ensure that the revised FDA instructions for use (IFU) for the Lyra Direct SARS Cov-2 direct assay were implemented or investigated to determine if the revised instructions were still applicable. Findings: 1. On May 25, 2021 the FDA issued revised instructions for use for the Lyra Direct SARS-Cov-2 RNA test performed on the Quant Studio-7 and instructed laboratories to perform a 1:10 and 1:100 dilution of patient specimens that had a cycle count of less than 5, if the review of the data showed that dilutions were needed to avoid false negative results; 2. The laboratory written procedure did not

	have instructions to staff explaining how to perform a review of results with a count less than 5 to determine if dilutions were necessary; 2. The technical supervisor did not ensure that the revised IFU was followed or was no longer required; and 3. Noon on the day of survey, the surveyor interviewed the testing person and asked if the patient counts were reviewed and if they were investigated further when counts fell below five and the testing person replied that the counts were not reviewed.