Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0699866	03/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Laboratory Inc	Island Med Ctr Suite 6, Sunny Isle, St Croix, VI	

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	A Centers for Medicare & Medicaid Services (CMS) New York CLIA Branch Location federal surveyor conducted an announced CLIA recertification survey at Clinical Laboratory Inc. on March 21, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiencies was found during the announced routine CLIA recertification survey performed on March 21, 2023.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review with the laboratory procedures and interview with testing personnel (TP) #1 and #5, the laboratory failed to establish a competency assessment procedure that assess the competency of testing personnel for each test procedure performed and that assesses the competency of consultants/supervisors for their supervisor responsibilities from March 2021 to March 2023. Findings Include: 1. On March 21, 2023 around 12:45 pm, review of laboratory procedures revealed, the laboratory's competency assessment procedure did not state to assesses the competency of testing personnel for each test procedure performed and to assess the of consultants /supervisors for their regulatory responsibilities. 2. TP Competencies performed from 2021 and 2022 did not assess TP for each test system they performed. 3. The Technical consultant/technical supervisor and general supervisor were not assessed for their supervisory responsibilities performed in 2021 and 2022. 4. TP#1 confirmed the above findings on March 21, 2023 around 4:00 pm
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 Hematology department policies and procedures and interview with testing personnel (TP) #1, the laboratory failed to include the test by step performance, performance of quality control and the laboratory's system for entering results in the patient record and reporting patient test results in the manual differential (diff) procedure in use from March 2021 to March 2023. Findings Include: 1. On March 21, 2023, review of the manual diff procedure revealed, the procedure did not include: - Test by step performance. - Performance of quality control. - The laboratory's system for entering results in the patient record and reporting patient test results. 2. TP#1 confirmed the findings above on March 21, 2023, at 1:45 pm.
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: Based on review of the Mindray BC5390 Analyzer calibration records and interview with testing personnel (TP) #1, the laboratory failed to calibrate the Mindray BC5390 complete blood count (CBC) analyzer at least once every six months from March 2021 to March 16, 2023. Findings Include: 1. On the day of survey, March 21, 2023, review of the Mindray BC5390 calibrations records revealed the laboratory did not perform calibrations on the Mindray BC5390 CBC analyzer at least every 6 months from March 2021 to March 16, 2023. 2. Calibration for the Mindray was performed from: - August 11, 2020 to July 20, 2021 (11 months). - July 20, 2021 to March 16, 2023 (15 months). 3. Appropriately 11,801 CBC tests were performed in 2022. 3. TP#1 confirmed the Mindray was not calibrated every 6 months from March 2021 to March 16, 2023 on March 21, 2023 around 1:30 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with testing personnel (TP) #1, the laboratory failed to document positive and negative QC at least once each day of patent testing for tests performed in the departments of Microbiology, Immunology, Hematology and Urinalysis from March 2021 to March 2023. Findings Include: 1. On the day of survey, March 21, 2023, review of laboratory QC records revealed, positive and negative QC was not documented each day of patient testing for the following tests: - Microscopic Manual Differentials. - Microscopic Urinalysis. - Microscopic Parasitology. - The Alere HCG combo kit. - ASI Mono Test Kit. - ASI RPR Test Kit. - ASI Sickle Cell test Kit. - ASI Rubella Test Kit. - Stanbio Rheumatoid Factor test Kit. - Mini Cube Analyzer. - Cepheid GeneXpert - CoV2/Flu/RSV. - Cepheid GeneXpert - CT/NG. 2. In the departments of Microbiology, Immunology, Hematology and Urinalysis approximately 28,239 tests were performed in 2022. 3. TP #1 confirmed the findings above on March 21, 2023 around 3:00 pm.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of microbiology department records and interview with testing personnel (TP) #1, the laboratory failed to document each batch of media for sterility, its ability to support growth and its ability to select or inhibit specific organisms from March 2021 to March 2023. Findings Include: 1. On the day of survey, March 21, 2021, review of the microbiology records revealed, the laboratory did not document each batch of media for sterility, its ability to support growth and its ability to select or inhibit specific organisms March 2021 to March 2023. 2. Approximately 3,219 Bacteriology tests were performed in 2022. 3. TP #1 confirmed the above findings on March 21, 2022 around 2:15 pm.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 review of the laboratory quality assessment records and interview with testing personnel (TP) #1 and #5, the laboratory director failed to establish a quality assessment program that assess the laboratory's pre - analytical , analytical and post analytical systems to assure the quality of the laboratory from March 2021 to March 2023. Finding Include: 1. On the day of survey, March 21, 2023 review of laboratory policies and procedures revealed, the laboratory did not establish a QA procedure the reviews the laboratory's pre - analytical , analytical and post analytical systems from March 2021 to March 2023. 2. Approximately 80,269 tests were performed in 2022. 3. TP #1 and #5 confirmed there is no QA procedure in place on March 21, 2023 around 4:00 pm.