Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0922328	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Community Medical Laboratory Inc	9149 Estate Thomas Ste 102, Charlotte Amalie, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to sign the attestation statement for ten out of ten proficiency testing events reviewed in 2021. 1. Record review of ten proficiency testing events (FH9-A, FH9-B, C-B, C-A, J1-A, J1-B, COVS-A, CGL-A, CGL-B, and CGL-C) in 2021 revealed the laboratory director did not sign the attestation statement. 2. On September 23, 2021 at approximately 2:00 PM, Testing Personnel #1 confirmed that the laboratory director did not sign the attestation.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to test hematology proficiency samples the same number of times as patients in two of five hematology proficiency testing events reviewed. Findings: 1. Review of the procedure "Proficiency Testing" stated "(3) Run survey and evaluate same a a patient." 2. Review of hematology testing proficiency event FH9-A 2021 revealed all samples (FH9-1, FH9-2, FH9-3, FH9-4, FH9-5) were tested in duplicate. Review of event FH9-

	B 2020 revealed samples FH9-07 and FH9-08 were tested in duplicate. 3. Review of procedure "Reporting Critical Results Procedure" stated "Any result that is flagged as a critical in the LIS (indicated by bold red print), or per the chart below must be repeated and noted in the LIS as "repeated and verified"". 4. Review of the hematology testing proficiency event FH9-A 2021 revealed samples FH9-1, FH9-2, and FH9-4 did not have any critical results as defined by the "Reporting Critical Results Procedure". Review of the hematology testing proficiency event FH9-B 2020 revealed sample FH9-7 did not have any critical results as defined by the "Reporting Critical Results Procedure". 5. On September 23, 2021 at approximately 2:00 PM, Testing Personnel #1 and Testing Personnel #2 confirmed the above proficiency testing was performed in duplicate.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of documentation and interview, the laboratory failed to retain the documentation of the normal patient Prothrombin mean study for the International Normalized Ratio (INR) calculation for one of one lot of thromboplastin reagent reviewed. Findings: 1. During review of the INR calculation for the current lot of thromboplastin, the surveyor requested documentation of the normal patient Prothrombin mean study. 2. At approximately 2:00 PM on September 22, 2021, Testing Personnel #1 stated that the laboratory did not retain the documentation.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to review one of two analytes with unacceptable results for chemistry proficiency testing event C-A 2021. Findings: 1. Review of C-A 2021 revealed two analytes (Glucose and Carbon dioxide (CO2)) with unacceptable results. 2. Documentation of review was available for CO2. No documentation of review was found for the unacceptable glucose results. 3. On September 23, 2021 at approximately 2:00 PM, Testing Personnel #1 confirmed there was no documentation of the review for the unacceptable glucose results available.
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 record review, lack of documentation, and interview, the laboratory failed to verify twice annual accuracy for one of 12 new tests added to the test menu in the last two years. Findings: 1. Proficiency testing records from 2020 and 2021 were reviewed for the new tests added to the laboratory's testing menu. 2. No twice annual verification of accuracy documentation was found for C-Reactive Protein (CRP). 3. On September 23, 2021 at approximately 2:35 PM, Testing Personnel #1 confirmed that there was no proficiency testing for CRP and the test was added to the laboratory's test menu in late 2020.
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 record review and interview, the laboratory director failed to sign and date one of three procedure manuals reviewed. Findings: 1. Review of the Chemistry procedure manual "Revision and Review Signature Page" revealed two signatures. 2. On September 23, 2021 at approximately 12:45 PM, the owner confirmed that neither signature was the laboratory director.
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 record review and interview, the laboratory failed to follow the manufacturer's instructions for reporting for one of one SARS-CoV-2 tests reviewed. Findings: 1. Review of the package insert for the Dimension EXL SARS-CoV-2 Total antibody assay (CV2T) under "Conditions of Authorization for the Laboratory" stated "Authorized laboratories using the Dimension EXL CV2T assay will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 2. Review of one of one patient report for CV2T revealed that the authorized Fact sheet was not included with the test result report. 3. On September 23, 2021 at approximately 12:09 PM, the owner confirmed that the authorized Fact sheet was not included with the test result report.
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: Based on record review, lack of documentation, and interview, the laboratory failed to verify the manufacturer's reference intervals for 11 out of 14 verification of performance specifications reviewed. Findings: 1. Review of verification of performance specifications for C-Reactive Protein, Magnesium, Total Iron Binding Capacity, Iron, Vitamin B12, Folate, Ferritin, Urine Protein, Urine Sodium, Urine Potassium, and Urine Chloride revealed no documentation of verification of the manufacturer's reference intervals. 2. On September 23, 2021 at approximately 09:52 AM, testing personnel #1 confirmed the manufacturer's reference intervals were not verified.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document corrective actions when temperatures fell outside the acceptable limits or were not recorded for 17 out of 20 months of temperature logs reviewed. Findings: 1. Review of procedure "Refrigerator/Freezer/Room Environment Preventative Maintenance" stated under Section "Daily" to "(2) Record the temperatures on the temperature log along with your initials. (3) Report all out of range results and problems to the supervisor. Document any corrective action taken at the bottom of the page." 2. Review of 20 months of temperature logs revealed the following: a. August 2021 - No corrective action for temperatures out of range on August 5th, 9th, and 13th. b. July 2021 - No corrective action for temperatures out of range on July 1st, 15th, and 23rd. c. June 2021 - Temperatures missing on June 17th. d. April 2021 - Temperatures missing on April 16th, 19th, 20th, and 23rd. e. March 2021 - No corrective action for temperatures out of range on March 3rd, 9th, and 10th. Temperature missing on March 11th. f. February 2021 - No corrective action for temperatures out of range on February 3rd, 4th, 5th, and 8th. g. January 2021 - No corrective action for temperatures out of range on January 7th, 19th, 20th, 21st, 27th, 28th, and 29th. h. December 2020 - No corrective action for temperatures out of range on December 1st, 2nd, and 3rd. Temperatures missing on December 11th. i. November 2020 - No corrective action for temperatures out of range on November 3rd, 4th, 10th, and 18th. Temperatures missing on November 6th and 12th. j. October 2020 - Temperatures missing October 1st, 2nd, 5th, 6th, 7th, 8th, 9th, 13th, 14th, 15th, 16th, 19th, 20th, 21st, 22nd, 23rd, and 26th. No corrective action for temperatures out of range on October 22nd and 23rd. k. August 2020 - No corrective action for temperature out of range on August 5th. l. July 2020 - No corrective action for temperatures out of range on July 7th, 10th, 13th, and 17th. m. June 2020 - No corrective action for temperature out of range on June 9th. n. May 2020 - No corrective action for temperatures out of range May 11th, 19th, and 29th. o. March 2020 - Temperature missing on March 24th. p. February 2020 - No corrective action for temperature out of range on February 14th. Temperature missing on February 11th. q. January 2020 - Temperature missing

	on January 11th. 3. During interview on September 22, 2021 at approximately 2:45 PM, Testing Personnel #1 confirmed multiple temperatures did not have corrective action documented.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have the accurate reference interval available for two of six tests reviewed. Findings: 1. Review of the verification of performance specifications for Prothrombin time (PT) revealed the proposed reference interval was 9.3 -11.4 seconds. The calculated 2 Standard deviation range was 9.3 -10.7 seconds. 2. Review of one of one patient reports revealed the reference interval on the report for PT was 9.6-10.8 seconds. 3. Review of the verification of performance specifications for Activated Partial Thromboplastin Time (PTT) revealed the proposed reference interval was 24.5 - 32.8 seconds. The statistical analysis range was 24.9 -31.4 seconds. 4. Review of one of one patient reports revealed the reference interval on the report for PTT was 24.0 - 34.0 seconds. 5. During interview on September 22, 2021 at approximately 3:34 PM, Testing Personnel #1 confirmed that the reference interval on the patient test report did not match the verification study.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director did not possess a license to practice medicine in the Virgin Islands and did not meet the qualification requirements. (See D6078)
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a

	doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director did not possess a license to practice medicine in the Virgin Islands and did not meet the qualification requirements. Findings: 1. The laboratory provided a North Carolina physician license for the laboratory director. 2. In interview on September 22, 2021 at approximately 09: 30 AM, the owner confirmed the license was not from the Virgin Islands. 3. No additional documentation was provided prior to the end of the survey.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the clinical consultant did not possess a license to practice medicine in the Virgin Islands and did not meet the qualification requirements. (See D6135)
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the

	laboratory is located. This STANDARD is not met as evidenced by: Based on record review and interview, the clinical consultant did not possess a license to practice medicine in the Virgin Islands and did not meet the qualification requirements. Findings: 1. The laboratory provided a North Carolina physician license for the clinical consultant. 2. In interview on September 22, 2021 at approximately 09: 30 AM, the owner confirmed the license was not from the Virgin Islands. 3. No additional documentation was provided prior to the end of the survey.