Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0922328	06/30/2026
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
D0000	A recertification survey was completed on June 30, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policies and procedures and confirmed in interview with the owner of the laboratory, the laboratory failed to have a mechanism in place to conduct investigation of complaints for 2 of 2 years (2024 and 2025). 1) In direct observation on 6/29/2026 at 1:45 PM in the laboratory manager's office, a verbal complaint was heard. The owner of the laboratory arrived stating there had just been a patient that complained to providers upstairs regarding services rendered at the laboratory that day, and that the laboratory may receive a call about it. 2) Review of the laboratory's policies and procedures did not reveal a component to address and investigate complaints from patients and providers. 3) The laboratory was unable to provide documentation of any complaints or grievances received by the laboratory in 2024 and 2025. 4) In an interview on 6/29/2026 at 1:45 PM, the owner of the laboratory confirmed that the laboratory received calls on occasion from patients or providers for miscellaneous complaints and handled these events expeditiously, but did not formally document or have policies/procedures specific to these events.
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 of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, lack of supervisory competency assessment records, review of laboratory policies and interview with the General Supervisor (GS) #1, the laboratory failed to establish written policies and procedures to assess supervisor competency for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory's Form CMS 209 revealed 2 GSs listed. 2) The laboratory was unable to provide competency assessment records for the supervisors listed on the Form CMS 209. 3) Review of the laboratory's policies and procedures titled 'Community Medical Laboratory General Supervisor Responsibilities' revealed instructions on competencies for Testing Personnel (TP), but no components for consultant and/or supervisor competencies. 4) In an interview on 6/29/2026 at 10:00 AM, GS#1 confirmed the laboratory did not perform competencies for supervisors.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of test records, and interview with General Supervisor (GS) #1, according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to establish and follow written policies and procedures for conditions of specimen transportation for 133 of 133 patients in 2025. Findings Included: 1) Upon request, the laboratory could not provide policies and procedures for conditions of specimen transportation for patient specimens received from outside facilities for testing. 2) Review of the laboratory's test records titled 'Community Medial Laboratory' Order Choice Utilization Report-Totals' revealed a total of 133 patient specimens received from the laboratory's draw facility in Red Hook, via courier or staff, to the laboratory for testing in 2025. 3) In an interview on 6 /30/2026 at 11:51 AM, GS#1 confirmed the laboratory did not have policies and procedures outlining conditioning for specimen transportation.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 direct observation, review of manufacturer's instructions, laboratory policy and procedures, test records, verification studies and established reference ranges, and interview with the General Supervisor (GS#1) according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to follow the policy in establishing a new patient normal mean for 1 of 2 new lots used of Dade Innovin reagents for the Sysmex CA-600 analyzer in 2024 and 2025 (random review). 1. Based on direct observation on July 1, 2026 at 11:50 AM, one Sysmex CA-600 (Serial Number 41533) analyzer was in use 2. Review of the manufacturer's instructions 'Siemens Healthineers Dade Innovin 11528733_en Rev. 13' stated the following instructions on page 4 of 9: "The mean normal Prothrombin Time (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot using the method used to analyze the patient samples and, where appropriate, using the coagulation analyzer used for the analysis. Follow appropriate laboratory guidelines for establishing an MNPT, if applicable. Use of CLSI guideline is recommended." 3. Review of the laboratory's policy titled 'Community Medical Laboratory Establishing MNPT Range Procedure' stated the following: "The laboratory collects specimens from a minimum of 10 normal individuals (check the manufacturer's guidelines for the specific criteria and exclusions for the "normal" pool of individuals) and performs a PT using the new low of thromboplastic reagent. Procedure: Establishing MNPT 1. Phlebotomists are informed to collect an extra citrate tube on 10 patients that are NOT on anti-coagulant medications ("normal" patient population). 2. Once collected, the 10 sample are ran using the new lot of Innovin. 3. Calculate the mean of the 10 sample, this is the mean normal PT range (MNPT). 4. Document all results on the New Lot of Innovin Worksheet ..." The written procedure did not state the laboratory's verified established normal reference ranges ("normal" patient population range) for staff to follow as part of each new Innovin lot study. 3. Review of the laboratory's Validation on the Sysmex CA-600 and review of patient test reports revealed the laboratory's established PT reference interval for normal patients as 9.3 to 10.7. 4. Review of the laboratory's New Lot Studies in 2024 and 2025 (random review) revealed the following: a. Innovin Lot Number 564654, New Lot Study conducted 12/10/24 revealed the usage of patients with PT values greater than 10.7 for four out of ten patients used for MNPT calculations. The values greater than the laboratory's established normal reference range were 11.10, 11.20, 11.40, 11.50. b. Innovin Lot Number 564672, New Lot Study conducted 05/09/25 revealed the usage of all ten patients within the laboratory's established normal reference range of 9.3 to 10.7. 5. In an interview on June 30, 2026, at 10:40 AM, the GS#1 confirmed the normal pool of patients used for the new lot Innovin study on 12/10/24 were higher than the laboratory's established reference range, and did not have the established normal reference range in the MNPT range procedure for staff to follow.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

	This STANDARD is not met as evidenced by: Based on direct observation, review of quality control (QC) records, laboratory test records, policies and procedures, and confirmed in interview with the General Supervisor (GS) #1 according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to take corrective action by evaluating patient test results obtained since the last acceptable test run after QC failures required recalibration on the Siemens Dimension EXL analyzer for 3 of 250 testing days in 2025 (Random review). Findings Included: 1) During a laboratory tour on 6/29/2026 at 3:00 PM, one Siemens Dimension EXL (Serial Number DE271189) was observed in use. 2) Review of QC records for 2025 revealed control failures and subsequent recalibrations performed for the following analytes on 3 of 250 testing days: a. Folate, 2/19/2025 b. Iron, 12/10/2025 c. Alkaline Phosphatase (ALP), 12/5/2025 3) Review of laboratory test records revealed the following patient tests run on the day prior to recalibrations performed, due to QC failure, with no patient evaluation: a. Folate, 2/18/2025, Patient tests run - 4 (Sample IDs: 637625, 655525, 635225, 655925) b. Iron, 12/09/2025, Patient tests run - 5 (Sample IDs: 4502325, 4503225, 4496125, 4487925 ...) c. ALP, 12/4/2025, Patient tests run - 35 (Sample IDs: 4420725, 4422525, 4422025, 4437025 ...) 4) Review of the laboratory's policy titled 'Community Medical Laboratory Chemistry Department's Quality Control Policy', did not contain instructions to conduct patient evaluations after recalibrating due to QC failures. 5) In an interview on 6/29/2026 at 3:05 PM, GS#1 confirmed the laboratory did not perform corrective actions by evaluating patient test results obtained since the last acceptable test run after QC failures requiring recalibration.
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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, Quality Assurance (QA) reviews and interview with the General Supervisor (GS) #1 according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to conduct QA reviews in accordance with written policies and procedures for 2 of 2 years (2024 an 2025). Findings Included: 1) Review of the laboratory's written policy titled 'Community Medical Laboratory Chemistry Department's Quality Control Policy' stated the following: "The Supervisor will review QC data at least weekly and review monthly QC summaries" 2) Review of the laboratory's weekly and monthly QC reviews in 2024 and 2025, as part of QA, revealed only monthly QC reviews being performed and signed by the GSs. 3) In an interview on 6/29/2026 at 2:18 PM, GS#1 confirmed as part of the laboratory's QA, the SOP stated supervisor's were to review QC weekly, but the task was being performed monthly only.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently,

	and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, lack of position delegation records, review of laboratory policies, and interview with the General Supervisor (GS) #1, the laboratory director failed to delegate, in writing, the duties and responsibilities for individuals appointed General Supervisor (GS) roles for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory's Form CMS 209 revealed 2 GSs listed. 2) The laboratory was unable to provide role delegations signed by the Laboratory Director (LD) for the supervisors listed. 3) Review of the laboratory's policies and procedures titled 'Community Medical Laboratory General Supervisor Responsibilities' revealed the following: a. "(b) The director or technical supervisor may delegate to the general supervisor the responsibility for - (1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specificiations. (2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning. (3) Providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel." 4) Review of laboratory documentation of corrective actions, remedial actions (i.e. PT failures), orientation /training of all four Testing Personnel (TPs) and semi-annual/annual TP competencies (2024 and 2025) revealed GS#1 or 2 as the individuals performing these supervisory tasks. 5) In an interview on 6/29/2026 at 10:00 AM, GS#1 confirmed both GSs were responsible for the responsibilities above, but did not have signed record of a formal role designation for these responsibilities by the LD.