

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 48D0922328	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Community Medical Laboratory Inc	Street Address, City, State 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	The Centers for Medicare & Medicaid Services (CMS) New York CLIA Branch Location federal surveyors conducted an announced CLIA recertification survey at the Community Medical Laboratory on March 23, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements the specific deficiencies are as follows:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of hematology critical values, lack of documentation, and staff interview the laboratory failed to conduct hematology manual differential for testing personnel. Findings include: 1. On March 23, 2023 at approximately 11:35 AM during a review of the critical value reference sheet, the document revealed that the laboratory performs manual hematology differentials for instrument flags for blasts, atypical lymphocytes and abnormal white/red blood cells. 2. The surveyor requested hematology competency records for manual differential performed by the testing personnel. TS#1 stated " I didn't know we had to perform those competencies". 3. During the exit interview at approximately 4:20 PM, the laboratory director (LD) confirmed the laboratory does not perform the hematology manual differential competency.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical</p>

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:

Refer to D5209 Based on a review of policy and procedures for the hematology section of the laboratory , lack of documentation, and staff interview the laboratory director failed to establish a policy for the hematology manual differential competency for testing personnel. Findings include: 1. On March 23, 2023, at approximately 4:20 PM during the exit interview, the surveyor requested hematology manual differential competency for testing personnel and the policy and procedure to determine the criteria for the differential . 2. The laboratory director confirmed their is no established policy or procedure for hematology manual differentials for the laboratory testing personnel.