Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0902976	03/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Community Medical Clinic	712 Settoon Street, Oak Grove, LA	

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 Certification Survey was performed on March 6, 2019 at Community Medical Clinic, CLIA ID # 19D0902976. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 record review and interview with personnel, the laboratory failed to establish complete written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on March 6, 2019 at 10:37 am, Personnel 6 stated that she updated the competency assessment forms but did not update the policy manual to reflect the changes. Personnel 6 confirmed the laboratory's current competency policy did not include the identified six (6) procedures.

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 with personnel, the laboratory failed to perform an assessment for an unacceptable proficiency test (PT) results for 2017 and 2018. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "All unacceptable results must be investigated by reviewing the data submitted for clerical errors, rerunning the samples, and checking for any quality control or maintenance issues on the instrument for the time testing was performed. Document any issues found on an investigation report for each unacceptable result." 2. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) PT results revealed the laboratory received the following unacceptable results: a) 2017 Hematology /Coagulation -3rd Event: Sample HEM-11 for Red Cell Count b) 2018 Hematology /Coagulation - 3rd Event: Sample HEM-12 for Lymphocytes % c) 2018 Hematology /Coagulation - 3rd Event: Sample HEM-11 for Red Cell Count 3. In interview on March 6, 2019 at 11:07 am, Personnel 6 stated that since the event was not a failure then the individual unacceptable results was not investigated. Personnel 6 confirmed the laboratory did not perform an assessment for unacceptable PT results.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to label blood specimens per laboratory policy. Findings: 1. Review of the laboratory's policy for "Specimen Collections" revealed "All specimens collected must be labeled with at least two identifiers, preferably full name and date of birth. The date and time of collection must also be noted. Please note: Any specimen that is not properly labeled must be discarded!" 2. Direct observation by surveyor on March 6, 2019 during the laboratory tour revealed the following three patients labeled with a first and last name only: a) Patients 1 - 3 3. In interview on March 6, 2019 at 10:40 am, Personnel 6 stated that she was unaware that testing personnel were not labeling specimens correctly. Personnel 6 confirmed the blood specimens were not labeled according to laboratory policy.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and

	when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to label control materials for the Horiba Medical ABX Micros 60 Hematology analyzer with expiration dates for proper use. Findings: 1. Observation by surveyor during the laboratory tour on March 6, 2019 revealed the laboratory utilizes the Horiba Medical ABX Micros 60 analyzer with Horiba Minotrol 16 controls for Complete Blood Count (CBC) testing. 2. Review of the Horiba Medical Minotrol 16 package insert for quality control (QC) under "Stability and Storage" revealed "Opened tubes are stable for the 16 days provided they are handled properly." 3. Further observation by surveyor during the laboratory tour revealed the laboratory did write a date on the vials but the date did not specify whether for put in use or expiration on open vial stability for the following control lot: a) Horiba Minotrol 16 - Lot MX416, Exp 5/5/19 4. In interview on March 6, 2019 at 10:29 am, Personnel 2 stated the date written on the QC material was a put into use date. Personnel 6 confirmed the laboratory did not label control material as needed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform and document instrument maintenance as defined by the manufacturer for the Horiba Medical ABX Micros 60 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on March 6, 2019 revealed the laboratory utilized the Horiba Medical ABX Micros 60 analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's Micros 60 Maintenance Log revealed the laboratory performs the following maintenance: a) Weekly Friday or Monday Backflush x3 Concentrated Clean b) Monthly Change Reagents Print Graphs /Statistics 3. Further review of the laboratory's maintenance logs for January 2018 through February 2019 revealed the following dates without the required weekly and monthly maintenance performed: a) November 12 - 16, 2019: no documentation of weekly maintenance b) November 2018: no documentation of monthly maintenance c) December 24 - 28, 2018: no documentation of weekly maintenance d) January 7 - 11, 2019: no documentaion of weekly maintenance e) January 14 - 18, 2019: no documentation of weekly maintenance 4. In interview on March 6, 2019 at 11:11 am, Personnel 6 stated she was unable to find documentation of maintenance being performed. Personnel 6 confirmed the weekly and monthly maintenance was not performed as required.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to label blood specimens per laboratory policy. Refer to D5311. 2. The laboratory failed to label control materials for the Horiba Medical ABX Micros 60 Hematology analyzer with expiration dates for proper use. Refer to D5415.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D5211.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical 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: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to label blood specimens per laboratory policy. Refer to D5311. 2. The laboratory failed to label control materials for the Horiba Medical ABX Micros 60 Hematology analyzer with expiration dates for proper use. Refer to D5415. 3. The laboratory failed to perform and document instrument maintenance as defined by the manufacturer for the Horiba Medical ABX Micros 60 analyzer. Refer to D5429.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure the procedures to assess personnel competency were complete. Refer to D5209.