Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0902976	10/21/2021
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	An onsite PT Desk Review was performed on October 21, 2021 at Community Medical Clinic - (CLIA #19D0902976). Community Medical Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.807 CONDITION: Reinstatement of laboratories performing nonwaived testing 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing results from CASPER 0155D and the

	laboratory's American Proficiency Institute (API) proficiency testing reports, the laboratory failed to successfully participate in proficiency testing as evidenced by: 1. The laboratory failed to achieve a score of at least 80% for Cell I.D. or WBC Diff for four (4) of five (5) consecutive testing events in 2020 and 2021 in the specialty of Hematology resulting in non-inital unsuccessful performance. Refer to D2130.
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on review of proficiency testing results from CASPER 0155D and the laboratory's American Proficiency Institute (API) reports, the laboratory failed to achieve a score of at least 80% for Cell I.D. or WBC Diff for four (4) of five (5) consecutive testing events in 2020 and 2021 in the specialty of Hematology resulting in non-initial unsuccessful performance. Findings: 1. Review of the CASPER 0155D report for Proficiency Testing and the laboratory's API proficiency testing results revealed the laboratory received the following scores in 2020 and 2021 resulting in a non-inital unsuccessful performance: a) 2020 2nd event Cell I.D. or WBC Diff score received 0% b) 2020 3rd event Cell I.D. or WBC Diff score received 53% c) 2021 1st event Cell I.D. or WBC Diff score received 60% d) 2021 2nd event Cell I.D. or WBC Diff score received 0% 5. In interview on October 21, 2021 at 2:18 pm, Technical Consultant 2 stated the laboratory did perform the proficiency testing but did not submit the results for the 2020 2nd event. Technical Consultant 2 further stated the raw data was not available to review the 2020 3rd event for errors and the 2021 1st event failures was due to possible bad samples being received by the laboratory. 6. In further interview on October 21, 2021 at 2:18 pm, Technical Consultant 2 stated the laboratory did not participate in the 2021 2nd event proficiency testing and subsequently scored 0%.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on observation of laboratory instrumentation, review of the laboratory's

	Proficiency Testing policy, American Proficiency Institute (API) proficiency testing records and CASPER 0155D report as well as interview with personnel, the laboratory failed to achieve a score of at least 80% for Cell I.D. or WBC Diff for four (4) of five (5) consecutive testing events in 2020 and 2021 in the specialty of Hematology resulting in non-inital unsuccessful performance. Findings: 1. Observation during the laboratory tour on October 21, 2021 at 3:51 pm revealed the laboratory utilizes a Sysmex CLIA waived XW-100 Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's Proficiency Testing policy revealed "Please note: For the Hematology section of proficiency testing, if one result is unacceptable for a particular specimen, that whole specimen is graded as a failure for that event. Failures in any one section for two consecutive events will result in suspended patient testing. In order to resume patient testing, acceptable performance must be verified by split sample testing, personnel retraining, or acceptable scores on subsequent proficiency testing". 3. In an interview on October 21, 2021 at 2:18 pm, Technical Consultant 2 stated that the laboratory utilized the Horiba ABX Micros 60 Hematology analyzer for Complete Blood Count (CBC) testing until the installation of the Sysmex CLIA waived XW-100 Hematology analyzer which was put into use for patient testing on September 13, 2021. 4. Review of the CASPER 0155D report for Proficiency Testing results revealed the laboratory received the following scores in 2020 and 2021 resulting in a non-inital unsuccessful performance: a) 2020 2nd event Cell I.D. or WBC Diff score received 0% b) 2020 3rd event Cell I.D. or WBC Diff score received 53% c) 2021 1st event Cell I.D. or WBC Diff score received 60% d) 2021 2nd event Cell I.D. or WBC Diff score received 0% 5. In interview on October 21, 2021 at 2:18 pm, Technical Consultant 2 stated the laboratory did perform the proficiency testing but did not submit the results for the 2020 2nd event. Technical Consultant 2 further stated the raw data was not available to review the 2020 3rd event for errors and the 2021 1st event failures was due to possible bad samples being received by the laboratory. 6. In further interview on October 21, 2021 at 2:18 pm, Technical Consultant 2 stated the laboratory did not participate in the 2021 2nd event proficiency testing and subsequently scored 0%. 7. Review of the Task 1&3 form provided by the laboratory revealed 507 WBC DIFF tests performed annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyor during the laboratory tour and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on October 21, 2021 revealed the following expired supplies: a) Located on blue phlebotomy tray: * Red SST vacuette tubes, Lot B200135P, Expiration 07/07/21, Quantity eleven (11) tubes * Red SST vacuette tubes, Lot B190838S, Expiration 02/08/21, Quantity one (1) tube b) Located in 2nd cabinet drawer beside whirlpool refrigerator: * E Swab Collection & Preservation of aerobic, anaerobic and fastidious bacteria, Lot 201533605, Expiration 09/30/21, Quantity eight (8) swabs c) Located in 2nd cabinet

	drawer beside whirlpool refrigerator: * Fisher finest Transport Swab, Lot OC12A, Expiration 09/12/21, Quantity four (4) swabs 2. In interview on October 21, 2021 at 4: 03 pm, Technical Consultant 2 confirmed the above identified supplies were expired.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, quality control records and the manufacturer's package inserts as well as interview with personnel, the laboratory failed to document the confirmation of mean and ranges for Quality Control (QC) for Hematology testing as required by the manufacturer. Findings: 1. Review of the Horiba Medical ABX Minotrol 16 quality control (QC) package insert under "Performance and characteristics" section revealed "Assay values on a new lot of control should be confirmed before it is put into routine use. The laboratory recovered mean should be within the assay range". 2. Review of the laboratory's "Lot to Lot Verification" revealed "Procedure: Before the current lot of Hematology QC expires, begin running the new lot concurrently with the old. After running the current QC and verifying it is in range, run all 3 levels of the new lot. In order to not affect the monthly statistics, remove the current smart card and insert the new one. Be sure to switch out the smart cards after running the new lot. This should be done for 3 days. After this is done, send the completed form to the technical consultant to be signed. Once it has been approved, the new lot of QC can be put into use. Do not use the new lot until it has been signed off by the technical consultant". 3. Review of the laboratory's Quality Control (QC) records for April 2021 through September 2021 revealed the laboratory utilized the manufacturer's ranges for the following lot numbers: a) ABX Minotrol 16 QC: Lot MX428 L, MX428 N, MX428 H; Expiration 06/05/2021 b) ABX Minotrol 16 QC: Lot MX429 L, MX429 N, MX429 H; Expiration 08/05/2021 c) ABX Minotrol 16 QC: Lot MX430 L, MX430 N, MX430 H; Expiration 10/05/2021 4. In interview on October 21, 2021 at 4:42 pm, Technical Consultant 2 stated that testing personnel should manually verify QC ranges against manufacturer's package insert ranges but she could not find documentation for the verification. Technical Consultant 2 further stated that the laboratory had switched to an automated internet upload system with Horiba Medical for the QC material.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.

	1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that proficiency testing samples are satisfactory as required. Refer to D6016.
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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of proficiency testing results from CASPER 0155D and the laboratory's proficiency testing records, the Laboratory Director failed to ensure that proficiency testing samples are satisfactory as required. Findings: 1. The laboratory failed to achieve a score of at least 80% for Cell I.D. or WBC Diff for four (4) of five (5) consecutive testing events in 2020 and 2021 in the specialty of Hematology resulting in non-inital unsuccessful performance. Refer to D2130.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to document the confirmation of mean and ranges for Quality Control (QC) for Hematology testing as required by the manufacturer. Refer to D5469.
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 for assessing personnel competency were maintained. Findings: 1. The Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of three (3) testing personnel reviewed. Refer to D6053.
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 by surveyor, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the

	specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to document the confirmation of mean and ranges for Quality Control (QC) for Hematology testing as required by the manufacturer. Refer to D5469.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview with personnel, the Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of three (3) testing personnel reviewed. Findings: 1. In interview on October 21, 2021 at 2:30 pm, Technical Consultant 2 stated that Testing Personnel 3 was hired for prn work in January 2021. 2. Review of the laboratory's personnel records for Testing Personnel 3 revealed the laboratory did not have documentation of a semi-annual competency assessment due July 2021. 3. In interview on October 21, 2021 at 2:30 pm, Technical Consultant 2 confirmed the laboratory did not have the semi-annual competency assessment for Testing Personnel 3.