

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0902976	<b>(X3) Date Survey Completed</b>  10/21/2021
<b>Name of Provider or Supplier</b>  Community Medical Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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
<b>D2016</b>	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-initial unsuccessful performance. Refer to D2130.
<b>D2017</b>	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-initial 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%.
<b>D2130</b>	<p>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-initial 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-initial 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&amp;3 form provided by the laboratory revealed 507 WBC DIFF tests performed annually.</p>
<b>D5417</b>	<p>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 &amp; 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.</p>
<b>D5469</b>	<p>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</p>

	<p>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.</p>
<b>D6000</b>	<p>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.</p>
<b>D6014</b>	<p>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.</p>
<b>D6016</b>	<p>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-initial unsuccessful performance. Refer to D2130.</p>
<b>D6020</b>	<p>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.</p>
<b>D6030</b>	<p>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.</p>

<b>D6036</b>	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.
<b>D6042</b>	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.
<b>D6053</b>	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.