Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0693739	05/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Westcare Medical Center Apmc	1220 Barataria Blvd, Marrero, 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 Special focus survey was performed at Westcare Medical Center, APMC-CLIA ID 19D0693739 on May 13, 2022. Westcare Medical Center, APMC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1100 CONDITION: Facility Administration
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Review of the laboratory's test menu revealed the laboratory utilizes the Quidel Quickvue for SARS COV-2 testing. 2. Review of the manufacturer's instructions revealed "Authorized laboratories * using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. Review of the laboratory's records revealed the laboratory did not have a Fact Sheet for the Quidel Quickvue SARS COV-2. 4. In interview on May 13, 2022 at 9:40 am the Technical Consultant 1 confirmed the laboratory does not provide "fact sheets" to patients for the Quidel Quickvue SARS COV-2 tests. 5. Review of the laboratory's test menu revealed the laboratory performs 1,429 Quidel Quickvue SARS COV-2 tests annually.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100

	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of test logs, and interview with personnel, the laboratory failed to report 2,104 SARS COV-2 results to the state as required. Findings: 1. In interview on May 13, 2022 at 9:11 am, Technical Consultant 1 stated the laboratory utilized the BD Veritor system for SARS COV-2 testing January 27, 2021 through August 12, 2021. Technical Consultant 1 further stated the laboratory stopped utilizing the BD Veritor system and switched to Quidel Quickvue test kits for SARS COV-2 testing on September 17, 2021. 2. Observation by surveyor during the laboratory tour on May 13, 2022 at 10:33 am revealed the laboratory utilized Quidel Quickvue antigen SARS COV-2 test kits. 3. In interview on May 13, 2022 at 9:49 am, Technical Consultant 1 stated the laboratory tried to set up reporting in 2021, but the laboratory's system did not have the ability to automatically submit results. Technical Consultant 1 further stated the laboratory did not report any SARS COV-2 results to the state. 4. Review of the laboratory's SARS COV-2 test logs revealed the laboratory tested 836 patients January 18, 2021 through August 26, 2021 utilizing the BD Veritor system and 1,268 patients September 17, 2021 through May 12, 2022 utilizing the Quickvue test kits.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to establish written policies for reporting SARS COV-2 results. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures for reporting SARS COV-2 results, to include, but not limited to who is responsible, and frequency of reporting. 2. In interview on May 13, 2022 at 9:49 am, Technical Consultant 1 confirmed the laboratory did not have a written policy for reporting positive and negative SARS COV-2 results to the state.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's instructions, patient final test reports, test menu, and interview with personnel, the laboratory failed to include the Food and Drug Administration (FDA) Emergency Use Authorization statement on SARS COV-2 patient final reports. Findings: 1. Observation by surveyor during the laboratory tour on May 13, 2022 10:33 am revealed the laboratory utilizes the Quidel Quickvue SARS COV-2. 2. Review of the manufacturer's instructions revealed "This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories." 3. Review of the following random selection of patient final reports for SARS COV-2 revealed the laboratory did not include the identified Emergency Use Authorization statement on patient final reports: Patient 392457 Patient 392430 Patient 403163 4. In interview on May 13, 2022 at 12:12 pm, Technical Consultant 1 confirmed the laboratory's patient final reports for SARS COV-2 did not include the identified statement. 5. Review of the laboratory's test menu revealed the laboratory performs 1,429 SARS COV-2 tests annually.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. 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 patient final reports included required pertinent information. Refer to D5805.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.