Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0693739	03/12/2020
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 Certification Survey was performed on March 12, 2020 at Westcare Medical Center, CLIA ID # 19D0693739. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 observation, record review, and interview with personnel, the laboratory failed to follow the manufacturer's requirements for the Ictotest. Findings: 1. Observation by surveyor during laboratory tour on March 12, 2020 revealed the laboratory utilizes Siemens Ictotest Reagent tablets for bilirubin testing. Surveyor observed Ictotest Reagent tablets, lot # 284076A, in drawer located in the laboratory. 2. Review of the manufacturer's package insert under "Quality Control" section revealed "For best results performance should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened." 3. In interview on March 12, 2020 at 11:30 am, the Technical Consultant stated no quality control is done. The Technical Consultant further stated when a new lot of tablets are received it is put into use without testing with quality controls. 4. In further interview on March 12, 2020 the Technical Consultant stated she was unable to determine at the time of the survey how many patients had the Ictotest performed .
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: *** Repeat deficiency from previous survey conducted on March 21, 2018. *** Based on record review and interview with personnel, the laboratory failed to follow their written policies and procedures to address competency for the Technical Consultant. Findings: 1. Review of the laboratory's "Competency Assessment" policy revealed "Testing personnel and technical consultant assessment must be performed annually with six required procedures in their competency assessment, pre-analytic, analytic, post analytic which includes proficiency testing and quality control program. 2. Review of personnel records for the Technical Consultant revealed no documentation of competency assessments for her Technical Consultant duties for 2018 and 2019. 3. In interview on March 12, 2020 at 10:52 am, the Technical Consultant stated the Laboratory Director did not perform an annual competency assessment for her duties as Technical Consultant.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to monitor the temperature where supplies are stored. Findings: 1. Observation by surveyor during laboratory tour on March 12, 2020 revealed the following items stored in a storage room without monitoring the temperature: a) BD Vacutainer K2EDTA blood collection tubes, Lot 9280900, Quantity: two (2) boxes b) BD Vacutainer K2EDTA blood collection tubes, Lot 9260556, Quantity: three (3) boxes c) Vacuette blood collection tubes, Lot B191139U, Quantity: one (1) box 2. Review of the manufacturer's storage requirements revealed the following: a) BD Vacutainer blood collection tubes, storage requirement 4-25 degrees Celsius b) Vacuette blood collection tubes, storage requirement 4-25 degrees Celsius 3. In interview on March 12, 2020 at 9:20 am, the Technical Consultant stated the laboratory does not monitor the temperature of the storage room where the identified items are stored.
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 and interview with personnel, the laboratory failed to label stain in a secondary container with identity, expiration date, and storage requirements. Findings: 1. Observation by surveyor during laboratory tour on March 12, 2020 revealed a stain in a secondary container without identity, storage requirement, and expiration date included. 2. In interview on March 12, 2020, the Technical Consultant stated the filtered Wright stain (Wrights One Step Stain, Lot # 8681-00) was in the identified container. The Technical Consultant confirmed the container was unlabeled.
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 and interview with personnel, the laboratory failed to ensure laboratory supplies had not exceeded their expiration date. Findings: 1. Observation by surveyors during the laboratory tour on March 12, 2020 revealed the following expired blood collection tubes: a) BD Vacutainer SST, Lot # 9058692, Expiration date: 2020-02-29, Quantity: eleven (11) tubes b) BD Vacutainer SST, Lot # 9030868, Expiration date: 2020-01-31, Quantity: four (4) tubes 2. In interview on March 12, 2020, Testing Personnel 3 confirmed the identified items were expired.
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 the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to monitor the temperature where supplies are stored. Refer to D5413. 2. The laboratory failed to label stain in a secondary container with identity, expiration date, and storage requirements. Refer to D5415. 3. The laboratory failed to ensure laboratory supplies had not exceeded their expiration date. Refer to D5417.
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: *** Repeat deficiency from previous survey conducted on March 21, 2018. *** Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D5209.