

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0464394	(X3) Date Survey Completed 10/26/2022
Name of Provider or Supplier West Carroll Memorial Hospital	Street Address, City, State 706 Ross 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 Recertification survey was performed October 24, 2022 through October 26, 2022 at West Carroll Parish Hospital, CLIA ID # 19D0464394. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of policies, review of performance specification studies and interview with personnel, the laboratory failed to ensure complete verification of performance studies for Chemistry testing. Findings: 1. Observation by surveyors during the laboratory tour on October 24, 2022 at 11:16 am revealed the laboratory utilizes the Siemens Dimension EXL with LM analyzer for Chemistry testing for the following tests: Acetaminophen, Albumin, Alcohol, Alkaline Phosphatase, Alanine Transaminase, Amylase, Aspartate Transferase, B-type Natriuretic Peptide, Blood Urea Nitrogen, Calcium, Troponin, Creatine Kinase-MB, Lactate Dehydrogenase, Creatine Phosphokinase, Cholesterol, Triglycerides, High Density Lipoprotein, Carbon Dioxide, Creatinine, C Reactive Protein, Digoxin, Dilantin, Direct Bilirubin, Iron, Ferritin, Folate, Free Thyroxine, Glucose, Lipase, Magnesium, Phosphorus, Potassium, Prostate Specific Antigen, Salicylate, Sodium, Total Iron Binding Capacity, Total Bilirubin, Total Protein, Thyroid Stimulating</p>

Hormone, Uric Acid, Vancomycin, Vitamin B12, Vitamin D 25OH, Chloride, Microalbumin, Hemoglobin A1C

2. Review of the laboratory's policy for Instrument /Assay Validation/Install revealed "Each laboratory must perform the following performance verification studies prior to reporting patient results: 1. ACCURACY: The laboratory is responsible for verifying that the method produces correct results. Verification of accuracy can be accomplished by: * Testing reference materials of known concentrations * Comparing results of tests performed by the laboratory against the results of a reference method; or * Comparing split samples results with results obtained from a method which is shown to provide clinically valid results. For qualitative methods, the laboratory must verify that the method will identify the presence/absence of the analyte. 2. PRECISION: The laboratory is responsible for verifying the precision of each test system by assessing day to day, run to run (between run) precision, and within run variation, as well as operator variance. This may be accomplished by: * Repeat testing of known patient samples over time; * Testing QC material in duplicate and over time; * Repeat testing of calibration material over time. Exception: For fully automated systems that are not user dependent, operator variance does not need to be evaluated. Within-Run Precision: A measure of reproducibility from the same sample or same sample type when analyzed at a minimum of 10 times. It is the measure of agreement between replicate measurements of the same sample. The SD and CV are compared to the manufacturer's procedural claim and/or peer group data to determine acceptability. Between-Run Precision: Total precision is determined by SD and CV of daily quality control data calculated from multiple runs. The SD and CV are compared to the manufacturer's procedural claim and/or peer group data to determine acceptability. Multiple operators must participate in between-run precision to get a measure of operator variance. 3. REPORTABLE RANGE: The laboratory is responsible for verifying the reportable range of patient test results for each test system. Verification of reportable range may be accomplished by: * Assaying low and high calibration materials or control materials. The reportable range includes all results that may be reliably reported and is also called the analytical measurement range (AMR). The AMR is the range of analyte values that a method can directly measure in the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. 4. REFERENCE RANGE (NORMAL VALUES): The laboratory must verify that the manufacturer's reference intervals (reference range or normal values) are appropriate for the laboratory's patient population. This may be accomplished by testing an appropriate number of "normal" donor specimens to verify the manufacturer's claims for normal values; however, a minimum of 20 donors is required. The "Reference Study Questionnaire" must be completed and signed prior to collecting donor specimens. Certain conditions and/or medications will disqualify donors from participation in the study. Reference intervals should be validated over several days, at different times of the day, including such variables as age of reagent, different vials of reagent, different operators, etc... NOTE: If a formal reference interval study is not possible or practical, as decided by the medical director, the laboratory should evaluate the use of published data for its own reference intervals, and retain documentation of this evaluation. The laboratory may use the manufacturer's reference range provided it is appropriate for the laboratory's patient population. If the manufacturer has not provided reference ranges appropriate for the laboratory's patient population, the laboratory may use published reference ranges. The laboratory must evaluate an appropriate number of specimens to verify the manufacturer's claims for normal values or, as applicable, the published reference ranges." 3. Review of the laboratory's performance specification (validation) studies revealed the following information was not included: a) Verification of reference ranges b) Review of raw data/summary of review by the Laboratory Director for

	<p>acceptability c) Acceptability criteria for studies 4. In interview on October 25, 2022, the General Supervisor stated the laboratory adopted the previous reference range due to the same population and platform. The General Supervisor confirmed the laboratory did not have a summary for studies or an acceptability criteria in place.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy, performance studies, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Findings: 1. The laboratory failed to ensure complete verification of performance studies for Chemistry testing. Refer to D5421.</p>
<p>D6040</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and performance studies as well as interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.</p>