

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0464394	(X3) Date Survey Completed 04/15/2021
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 Certification Survey was performed April 12, 2021 through April 15, 2021 at West Carroll Memorial Hospital, CLIA ID # 19D0464394. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document remedial action for unacceptable Chemistry proficiency testing scores. Findings: 1. Review of the laboratory's policy for Proficiency Testing under "Result Review" revealed "Any misses, either graded or ungraded should be reviewed and investigated. Documentation of all reruns, calibrations, service repairs, QC monthly graphs showing shifts or trends, etc... should be included with the investigation form". 2. Review of the laboratory's 2021 American Proficiency Institute (API) Proficiency Testing (PT) records revealed the laboratory received the following unacceptable results: a) 2021 Chemistry - Core -1st event: CM-05, NT pro-BNP, unacceptable 3. Further reievew of the 2021 API Proficiency Testing records revealed the laboratory did not have documentation of corrective action, investigation, or remedial action for the unacceptable score. 4. In interview on April 12, 2021 at 2:03 pm, the General Supervisor stated that the unacceptable score was missed upon review of proficiency</p>

testing results. The General Supervisor confirmed remedial action was not taken for the above Chemistry score.

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:

I. Based on observation, record review and interview with personnel, the laboratory failed to establish its own expected range of responses for ZeptoMetrix quality control (QC) material. Findings: 1. Observation by surveyor during laboratory tour on April 12, 2021 at 9:15 am revealed the laboratory utilizes the Cepheid GeneXpert analyzer with ZeptoMetrix NaTrol External Run Control for the following tests: a) Chlamydia & Gonorrhea (CT/NG) b) Clostridium Difficile (C. Difficile) c) Flu/RSV/SARS-CoV-2 2. Review of the ZeptoMetrix Corporation NATrol External Run Controls package insert under "Expected Results" revealed "Each laboratory must evaluate the product and establish their own acceptance criteria". 3. Review of the laboratory's quality control (QC) records revealed the laboratory did not establish its own acceptance criteria for the ZeptoMetrix external control material. 4. In interview on April 15, 2021 at 2:15 pm, Personnel 4 stated he was unaware that QC should be established. Personnel 4 confirmed the laboratory uses the responses provided by the manufacturer and does not establish their own. II. Based on observation, record review, and interview with personnel, the laboratory failed to validate its own expected responses for the Maine Molecular Quality Control material. Findings: 1. Observation by surveyor during the laboratory tour on April 12, 2021 at 9:15 am revealed the laboratory utilizes the Maine Molecular Quality Control (MMQCI) material for the Biofire Respiratory panel 2.1. 2. Review of the MMQCI external control package insert revealed "Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs". 3. Review of the laboratory's QC records revealed the laboratory did not validate lot to lot control materials for the MMQCI external control. 4. In interview on April 15, 2021 at 2:15 pm, Personnel 4 confirmed the laboratory uses the manufacturer's expected responses and does not validate new lots of control materials.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D2094

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, 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 establish its own expected range of responses for ZeptoMetrix quality control (QC) material. Refer to D5469 I. 2. The laboratory failed to validate its own expected responses for the Maine Molecular Quality Control material. Refer to D5469 II.

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 observation, 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. Refer to D5469 I & II.