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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 19D0464390 | (X3) Date Survey Completed 01/15/2021 |
| Name of Provider or Supplier West Carroll Medical Clinic | Street Address, City, State 502 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 |
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| D0000 | A Certification Survey was performed on January 15, 2021 at West Carroll Medical Clinic, CLIA ID # 19D0464390. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS form, personnel records, and interview with personnel, the laboratory failed to ensure the Laboratory Director assessed competency for two (2) of two (2) Technical Consultants reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the following personnel serves as Technical Consultants: a) Personnel 4 b) Personnel 5 2. Review of the laboratory's "Personnel Requirements" policy under "Job Description: Medical Director/Laboratory Director" revealed the following responsibility: a) Monitoring the continuing education/competency of the Compliance Specialist and Technical Consultant initially and annually thereafter. 3. Review of the personnel records revealed the laboratory did not have a documented 2019 and 2020 annual competency assessment for their duties as Technical Consultant for the following two (2) of two (2) personnel: a) Personnel 4 b) Personnel 5 4. In interview on January 15, 2021 at 10:40 am, Personnel 5 stated the Technical Consultant competency evaluation policy should be to perform assessment once upon hire until the change of personnel but the policy has not been updated to state the frequency. Personnel 5 confirmed the Laboratory Director did not perform an annual competency for the Technical Consultants.</p> |

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| <p>D5407</p> | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on policy and procedure manual review and interview with personnel, the laboratory failed to have current policies and procedures approved and signed by the current Laboratory Director. Findings: 1. Review of the laboratory's policy and procedure manual on January 15, 2021 at 10:35 am revealed the following policies which is not an inclusive list were not approved and signed by the current Laboratory Director: a) Personnel Requirements b) Personnel Assessment c) BinaxNow COVID-19 Ag Card 2. In interview on January 15, 2021 at 11:00 am, Personnel 5 stated that the previous Laboratory Director retired in 2019 and the current director has approved and signed some but not all of the policies and procedures in use.</p> |
| <p>D6030</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(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;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to ensure the Laboratory Director assessed competency for two (2) of two (2) Technical Consultants reviewed. Refer to D5209. 2. The Technical Consultant failed to perform a competency assessment at least semi-annually during the first year for one (1) testing personnel. Refer to D6053.</p> |
| <p>D6031</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> |

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5407.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Consultant failed to perform a competency assessment at least semi-annually during the first year for one (1) testing personnel. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the laboratory has three (3) testing personnel. 2. Review of personnel records revealed the laboratory performed an initial evaluation on Personnel 6 on September 20, 2019. 3. Further review of personnel records revealed the laboratory did not have documentation of a semi-annual competency assessment for Personnel 6 which was due in March 2020. 4. In interview on January 15, 2021 at 10:17 am, Personnel 5 who serves as the Technical Consultant stated she forgot to perform the six (6) month evaluation for the newly hired personnel.