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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>19D0465030   | <b>(X3) Date Survey Completed</b><br><br>06/17/2021 |
| <b>Name of Provider or Supplier</b><br><br>Gregory D Lord, Md  | <b>Street Address, City, State</b><br><br>301 W Fertitta Blvd, Leesville, LA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D0000</b>              | A Recertification survey was performed on June 17, 2021 Gregory D Lord, MD, CLIA ID # 19D0465030. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.  |
| <b>D3031</b>              | <p><b>RETENTION REQUIREMENTS</b><br/>CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policy, quality control records and manufacturer inserts as well as interview with personnel, the laboratory failed to retain data for quality control mean and range establishment for at least two (2) years for Chemistry testing. Findings: 1. Review of the laboratory's quality control (QC) records and instrument ranges for Chemistry testing revealed the laboratory established their own means and ranges for QC acceptability prior to putting in use March 16, 2021. 2. The laboratory was unable to provider surveyor with QC data to support the laboratory's means and ranges of acceptability in use for the following QC lots: Bio-Rad Liquichek Multiqua Level 1, Lot # 45871 Bio-Rad Liquichek Multiqua Level 2, Lot # 45872 Bio-Rad Liquichek Multiqua Level 3, Lot # 45873 Technopath Level 1, Lot #32208181 Technopath Level 2, Lot #32208182 Technopath Level 3, Lot #32208183 3. In interview on June 17, 2021 at 11:21 am, Testing Personnel stated the laboratory established their own QC means and ranges for the chemistry controls. The Testing Personnel further stated she was unable to find the raw data for QC range establishment.</p> |
| <b>D6022</b>              | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D3031.