| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 04D0991904 | 11/08/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Southern Medical Group | 211 East Stadium, Magnolia, AR | |

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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| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Through an interview with laboratory staff, a review of BioRad Lyphochek quality control assay sheets and instructions for use for the current lot of controls, a review of monthly "Quality Control Individual Reports", a review of package inserts for BioRad quality control, it was determined the laboratory failed to establish statistical parameters for acceptable quality control ranges of tests performed on the ECi analyzer. Survey findings follow: A. During an interview at 12:08 a.m. on 10/31 /2019, laboratory employee #3 (as listed on the form CMS-209) stated for evaluation of acceptability of quality control the laboratory is, "going by the package insert". B. BioRad Lyphochek quality control material instructions for use state, "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." C. A review of assay values, from package inserts, for five analytes tested on the Lyphocheck Controls revealed the following package insert ranges: Ferritin Level 1 28.2 to 56.1; Ferritin Level 2 79.6 to 136; Ferritin Level 3 216 |

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| | to 354 Vitamin B12 Level 1 222 to 470; Vitamin B12 Level 2 476 to 751; Vitamin B12 Level 3 733 to >1000; Free T4 Level 1 1.21 to 2.15; Free T4 Level 2 4.86 to 5.80; PSA Level 1 .659 to .955; PSA Level 2 1.99 to 2.78; PSA Level 3 10.6 to 14.8; Testosterone Level 1 95.1 to 205; Testosterone Level 2 573 to 1029; and Testosterone Level 3 1156 to 2014. D. A review of acceptable ranges listed on the September 2019 "Quality Control Individual Reports", printed from the chemistry analyzer, shows the following ranges programmed into the analyzer which do not match the package insert assay values: Ferritin Level 1 32.2 to 52.2; Ferritin Level 2 95.34 to 120.66; Ferritin Level 3 252.14 to 317.86; Vitamin B12 Level 1 328.32 to 363.68; Vitamin B12 Level 2 529.08 to 622.92; Vitamin B12 Level 3 835.99 to 962.01; Free T4 Level 1 1.538 to 1.822; Free T4 Level 2 5.12 to 5.54; PSA Level 1 .745 to .869; PSA Level 2 2.208 to 2.632; PSA Level 3 11.694 to 13.706; Testosterone Level 1 137.8 to 162.2; Testosterone Level 2 754.68 to 857.32; and Testosterone Level 3 1498.1 to 1681.9. In further review of the September 2019 "Quality Control Individual Reports" there were several days with quality control results outside of the listed ranges without corrective actions or repeated quality control results due to the use of package insert ranges as acceptable ranges. E. During the interview at 12:08 a.m. on 10/31/19, laboratory employee #3 stated that she doesn't know where the acceptable ranges programmed into the instrument originated and she further confirmed the package insert ranges are the ranges used to determine if quality control is acceptable. |