| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 04D1071460 | 01/20/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Nea Baptist Clinic Paragould | 4700 West Kingshighway, Paragould, 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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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of the new instrument validation documentation for the moderate complexity chemistry tests performed on the Abbott I-Stat, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to validate the precision of the new test system. Survey findings include: A. During a review of the validation documentation for the Abbott I-Stat, it was determined the standards used for validation of accuracy and reportable range were only analyzed once each. Multiple runs of the same standard are required to calculate CV% which is a measure of precision. B. The surveyor requested documentation of validation of the precision but none was available for review. C. In an interview at 9:52 a.m. on 1/20/2021 laboratory employee #3 (as listed on the form CMS-209) confirmed the lack of documented validation of the precision for the Abbott I-Stat. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified |

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| | in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of the Individualized Quality Control Plan (IQCP) for moderate complexity chemistry tests performed using the Abbott I-Stat analyzer and through interviews with laboratory staff, it was determined the IQCP failed to include all three required components. Survey findings include: A. During a review of the IQCP for the Abbott I-Stat chemistry analyzer, the surveyor determined the IQCP consisted of a risk assessment and quality control plan, but did not include the required quality assessment component of the IQCP. B. In an interview at 10:20 on 1/20/2021, laboratory employee #3 (as listed on the form CMS-209) confirmed the lack of quality assessment component in the IQCP for the Abbott I-Stat. |