

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0663100	(X3) Date Survey Completed 08/21/2018
Name of Provider or Supplier Vidalia Medical Associates	Street Address, City, State 200 Maple Drive, Vidalia, GA	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, review of the Laboratory Personnel Report form (CMS 209) and staff interview, the laboratory failed to rotate testing of PT samples among all testing personnel who test patient samples. Findings include: 1. Review of the CMS 209 revealed 2 employees listed as testing personnel. 2. Review of PT attestation statements for 2017 and 2018 revealed testing personnel # 1 signed all PT attestations in 2017 and 2018. 3. Interview with testing personnel # 1 and the laboratory manager (see CMS 209) in the conference room on August 21, 2018 at 4 pm confirmed testing personnel # 2 test patient samples but has not participated in testing PT samples.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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</p>

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:

Based on review of the laboratory's 2017 and 2018 quality control (QC) records for testing performed on the TOSOH A1A 900 endocrinology analyzer and the Dimension Expand chemistry analyzer, review of corrective action logs and staff interview, the laboratory failed to establish criteria for acceptability of the controls. NOTE: This is a repeat deficiency and was cited at the 7/26/2016 survey. Findings include: 1. Review of 2017 and 2018 Levey Jennings (LJ) charts for testing performed on the TOSOH A1A 900 analyzer and the Dimension Expand chemistry analyzer revealed control values for most analytes fall within plus or minus 1 standard deviation from the mean. Review of statistics calculated from control values obtained from March 2018 through August 2018 revealed the laboratory did not use the standard deviation calculated from testing performed by their laboratory to determine the acceptable range for control values. Review of control values obtained by the laboratory also revealed the standard deviation calculated on testing performed in their laboratory is much lower for most analytes than the standard deviation used to determine acceptability of controls. This caused acceptable ranges of plus or minus 2 standard deviations from the mean to be too broad. 2. Review of corrective action logs for 2017 and 2018 revealed repeated out of range controls for 8 analytes. Most values for out of range controls are barely outside the acceptable range. Review of LJ charts show no control values plotted outside 2 standard deviations and the out of range controls are not included in calculation of spastics. This resulted in control ranges being too narrow. 3. Interview with the laboratory manager and testing personnel # 1, (see CMS 209) on August 21, 2018 at 4:30 pm in the conference room confirmed the laboratory does not use the standard deviation calculated from testing performed in their laboratory to determine acceptable ranges of controls and the LJ charts are not a true representation of values obtained by their laboratory.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's testing personnel competency assessment checklist as well as staff interview, the technical consultant failed to ensure the competency assessment policy and procedure for testing personnel met the 6 required criteria. Findings include: 1. Review of the laboratory competency assessment checklist revealed it does not include: A. Direct observation of patient test performance, including patient preparation, specimen handling, processing and testing B. Monitoring recording and reporting of test results. C. Assessment of test performance using previously analyzed samples. D. Assessment of problem solving skills. 2. Interview with the laboratory manager and testing personnel #1 (see CMS 209) on August 21, 2018 in the conference room at 4:30 pm confirmed competency assessment does not include the four required criteria listed above.