

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2117616	(X3) Date Survey Completed 02/20/2020
Name of Provider or Supplier Shelbyville Medical Center	Street Address, City, State 415 N Cedar St, Shelbyville, IL	
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 laboratory records and interview with the laboratory technical consultant (TC); the laboratory failed to ensure participation of all testing personnel (TP) in the proficiency testing (PT) program for 6 of 6 PT events in 2018 through 2019. Findings Include: 1. College of American Pathologist (CAP) PT records from 2018 through 2019 were reviewed. 2. Review of the CAP PT attestation statements for 6 of 6 PT events in 2018 through 2019 found that TP#3, as identified on the CMS-209 (laboratory personnel report) had performed all the events and TP#1 and TP#2, also listed on the CMS-209, had not participated in any PT events. 3. On survey date 2-20-2020, at 12:25 pm the above survey findings were confirmed by the TC.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified 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.</p>

This STANDARD is not met as evidenced by:
 Based on review of laboratory records and interview with testing personnel (TP) #3 and the technical consultant (TC); the laboratory failed to follow the laboratory's Individual Quality Control Plan (IQCP) for external control procedures for 20 of 20 months reviewed. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "POC-EPOC Blood Analysis System", which stated on page 3, under the heading of "Quality Control": "Aqueous Blood Gas, Electrolyte, Metabolite and Hematocrit liquid controls are run on each new lot or shipment of Test Cards or every thirty days, whichever is more frequent. GAS-ISE1 & 3, HCT-A & B are the levels used. This plan, coupled with the attached risk assessment complete the IQCP for EPOC blood analysis system." 2. Review of quality control records for 2 of 6 patient testing dates found that external liquid GAS-ISE1 and 3 failed to be performed with a new lot of BGEM test cards when they were put into use for patient testing. Test Date BGEM Test Card Lot External Control Testing Date 06-24-2019 00-19071-10 07-10-2019 02-11-2020 00-19248-10 02-12-2020 3. Review of quality control testing found no external quality controls were performed when new lots of BGEM cartridges were put into use from July 2018 through February of 2020. 4. Interview with TP#3, on 02-20-2020, at 11:15 am, confirmed external quality controls were not ran when new lots of BGEM test cartridges were put into use. 5. On survey date 2-27-2019, at 1:00 pm, the TC confirmed the laboratory failed to follow the laboratory's IQCP procedure and perform external quality controls on each new lot of BGEM cartridges put into use for patient testing.

D5805

TEST REPORT
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
 Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to include all the required components of a laboratory test report for 6 of 6 patient test reports reviewed. Findings Include: 1. Review of 6 of 6 patient test reports for creatinine testing found the laboratory failed to indicate the name and/or address of the laboratory where testing was performed. Patient Identification Test Date Missing Information P1 11-21-2018 No Address P2 12-13-2018 No Address P3 03-05-2019 No Address P4 06-24-2019 No Name or Address P5 08-14-2019 No Name or Address P6 02-11-2020 No Name or Address 2. On survey date 02-20-2020, at 12:25 pm, the TC confirmed the above findings.

D6054

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

annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the technical consultant (TC); the laboratory's technical consultant failed to ensure annual competency assessments were completed for 2 of 2 testing personnel by a qualified TC. Findings Include: 1. Review of the laboratory's policy and procedure manual policy, "Technical Consultant Responsibilities and Competency", stated on page 2 of 4 that the technical consultant is responsible for the following: "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." 2. Review of annual competency assessment records for testing personnel (TP) #1 and TP#3 found the competency assessments completed in 2019 or 2020 were not performed by a qualified TC. 3. During survey date 02-20-2020, at 12:25 pm, the TC confirmed the 2019 and 2020 competency assessments of TP#1 and TP#3 failed to be completed by a qualified technical consultant.