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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D2117616 | (X3) Date Survey Completed 06/07/2018 |
| 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 |
|---------------------------|---|
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC) #2; the laboratory failed to monitor epoc BGEM test card storage temperatures to ensure accurate and reliable storage of chemistry reagents. Findings Include: 1. Review of the laboratory procedure, "POC - EPOC BLOOD ANALYSIS SYSTEM", states "Always store Test Cards at room temperature (15C-30C). 2. Review of the laboratory's temperature logs found no documentation for storage temperature monitoring of epoc BGEM test cards. 3. On survey date 06-07-2018, at 2:00 pm, TC#2 confirmed the laboratory failed to document storage temperatures for epoc BGEM test cards.</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</p> |

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with technical consultant (TC) #2; the laboratory failed to perform control procedures using the number and frequency specified by the laboratory's individual quality control plan (IQCP) for Creatinine testing 3 of 6 patient test reports reviewed. Findings include: 1. Review of the IQCP for creatinine testing on the epoc blood analysis system state that "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." 2. Review of patient tests results found that for 3 of 6 patient results reviewed found no quality control testing was performed for epoc BGEM Test Card Lot# 18-046-20 prior to patient testing. Patient Identification Test Date P3 04-11-2018 P4 04-12-2018 P5 05-02-2018 3. Additionally, review of the epoc quality control log from March 5, 2018 through May 16, 2018 found the laboratory failed to run liquid controls every thirty days as described in the QCP from March 5, 2018 to April 9, 2018. 4. On survey date 06-07-2018, at 2:00 pm, TC #2 confirmed that external quality controls were not performed for BGEM Test Card Lot# 18-046-20 prior to patient testing for 3 of 4 patient test results reviewed and external liquid controls were not performed every 30 days as described in the QCP in March through April of 2018.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the technical consultant (TC) #2; the laboratory failed to establish a quality assessment plan and identify and correct problems with epoc testing for creatinine. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the individual quality control plan (IQCP) for creatinine testing on the epoc blood analysis system. The IQCP failed to include a Quality Assessment plan. 2. Review of epoc creatinine testing found the laboratory failed to follow the IQCP by not performing external quality controls as required. See D5445. 3. Further review of laboratory records also identified the laboratory failed to follow the IQCP by not ensuring creatinine test cartridges storage temperatures were monitored. See D5413. 4. On survey date 6-07-2018, at 2:00 pm, TC #2 confirmed the laboratory had failed to establish a Quality Assessment policy for epoc creatinine testing and identify and correct problems.

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 technical consultant (TC) #2; the laboratory test reports failed to include the name and address of where testing was performed for 5 of 5 creatinine test reports reviewed. Findings Include: 1. Review of 5 of 5 patient test reports (Patient IDs: P2, P3, P4, P5, P6) for creatinine testing failed to indicate the following: a. The name and address of the laboratory location where the test was performed. 2. During survey date 06-07-2018, at 2:00 pm, the above findings were confirmed by TC#2.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of laboratory records and interview with technical consultant (TC) #2; the laboratory failed to have a technical consultant (TC) who meets the qualification requirements of 493.1411. Findings Include: 1. The laboratory failed to have qualifying documents for 2 of 2 technical consultants, as identified on the CMS-209 (Laboratory Personnel Report). See D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is

responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory technical consultant (TC) #2; 2 of 2 laboratory personnel listed on the CMS-209, as technical consultants, failed to meet the qualification requirements for the position. Findings Include: 1. Review of the CMS-209 identified 2 individuals designated as technical consultants. Review of personnel records for 2 of 2 TC's found they failed to meet the educational/experience requirements. a. TC#1 - Doctor of Medicine. No experience documenting 1 year of experience in non-waived chemistry testing provided. b. TC#2 - No educational documentation provided showing proof of a bachelor's degree in a chemical, physical, biological or clinical lab science. 2. On survey date 06-07-2018, at 2:00 pm the above findings were confirmed by TC#2.