

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0313177	(X3) Date Survey Completed 02/18/2020
Name of Provider or Supplier Covenant Medical Group	Street Address, City, State 220 Fort Sanders West Blvd, Mob 11, Suite 301, Knoxville, TN	
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 observation of a Cardiac Cartridge for the Triage Meter stored at room temperature, manufacturer's storage requirements and interviews with the Technical Consultant and Laboratory Supervisor, it was determined the room temperature storage expiration date was not denoted on the cartridge for 2/18/2020. The findings include: 1. Observation during laboratory survey at approximately 12:00 p.m. February 18, 2020 of a Cardiac Cartridge stored at room temperature, Lot #: T10655R, Expiration date: 3/03/2020 with no documentation of room temperature storage expiration date. 2. Manufacturer's storage requirements for Triage Meter cartridges are 14 days at room temperature after being removed from refrigerator storage. 3. Interviews with Technical Consultant and Laboratory Supervisor at approximately 2:00 p.m. February 18, 2020 confirmed the Triage Meter Cardiac Cartridge was observed on 2/18/2020 stored at room temperature with no documentation of the 14 day room temperature expiration date. =====</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

===== Based on a review of the Laboratory's Calibration Verification records for the Triage Meter and upon interview with the Technical Consultant and Laboratory Supervisor, determined the laboratory failed to ensure that calibration verification was performed at six month intervals during 2019. The findings include: 1. A review of Calibration Verification records for the Triage Meter for D-Dimer, Troponin and CK-MB testing revealed no calibration verifications documented after 4/30/2019. 2. An interview with the Technical Consultant and Laboratory Supervisor at approximately 2:00 p.m. on February 18, 2020 confirmed the calibration verifications for the Triage Meter were not performed at six month intervals during 2019.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

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.

This STANDARD is not met as evidenced by:

===== Based on a review of the Laboratory's IQCP (Individualized Quality Control Plan) for the Triage Meter testing to include CK-MB, D-Dimer and Troponin, review of 30 day QC documentation, and upon interview with the Technical Consultant and Laboratory Supervisor, it was

determined the laboratory failed to perform and document external QC every 30 days as required for February 2020. The findings include: 1. A review of the IQCP Quality Control Plan states to perform external QC every 30 days for the Triage Meter testing. 2. A review of the monthly QC documentation for all respective tests listed revealed no external QC documentation since 1/6/2020. 3. An interview at approximately 2:00 p.m. on February 18, 2020 with the Technical Consultant and Laboratory Supervisor confirmed the external monthly QC failed to be performed every 30 days from 1/06 /2020. =====

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 five patient tracer reports from June 2018 to January 2020 and upon interviews with the Technical Consultant and Laboratory Supervisor, it was determined the test reports did not contain report dates. The findings include: 1. A review of five patient tracer reports for 6/26/2018, 12 /13/2018, 4/10/2019, 11/08/2019 and 1/27/2020 revealed no test report date found on the patient reports. 2. Interviews at approximately 2:00 p.m. on February 18, 2020 with the Technical Consultant and Laboratory Supervisor confirmed that patient tracer reports from June 2018 to January 2020 did not contain test report dates.
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