Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0958200	04/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Covenant Medical Group	1300 Old Weisgarber Rd, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: ========== Based on review of 20 testing personnel competency records, lack of documentation for 6 month competencies and annual competencies and upon interview with the Laboratory Manager, determined the laboratory failed to document 6 month competencies after hire and annual competencies for 2017 for testing personnel who perform Complete Blood Count's (CBC's). The findings include: 1. Review of 20 testing personnel competency records hired after 2016. 2. Lack of 6 month competencies for 4 of 20 testing personnel after hire dates. 3. Lack of 2017 annual competencies for 8 of 20 testing personnel. 4. Interview with the Laboratory Manager at approximately 1:00 p.m. April 8, 2019 confirmed the laboratory failed to document 6 month competencies after hire date for 4 testing personnel and annual competencies for 2017 for 8 testing personnel who perform CBC testing. ==========
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: ========== Based on review of Proficiency Testing for presence or absence of sperm since 2018, lack of procedure for post-vasectomy analysis and upon interview with the Medical Laboratory Technician (MLT), determined the providers were performing post-vasectomy analysis and review of procedure manual revealed there was no procedure in place for this test. The findings include: 1. Review of Proficiency Testing revealed analysis performed for presence or absence of sperm since 2018. 2. Lack of procedure for post-vasectomy analysis. 3. Interview with the MLT at approximately 1:00 p.m. April 8, 2019 confirmed the providers were performing post-vasectomy analysis and there was no procedure in place for collection, testing and reporting of post vasectomy specimens. ==========
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: ========== Based on a review of the laboratory's procedure manual which lacked normal patient values and critical alert values for Troponin and D-dimer tests performed on the Triage Meter and upon interview with the Laboratory Manager and Medical Laboratory Technician (MLT), the laboratory failed to define normal and critical alert values for Troponins and D-dimers since 2018. The findings include: 1. A review of the laboratory's procedure manual revealed lack of normal patient values and critical alert values for Troponins and D-dimers performed on the Triage Meter since 2018. 2. An interview at approximately 1:00 p.m. April 8, 2019 with the Laboratory Manager and MLT confirmed the procedure manual lacked normal patient values and critical alert values for Troponin and D-dimer testing. ==========
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: ========== Based on observation of Troponin and D-dimer Calibrators and Quality Control (QC) Materials for the Triage Meter, stored in laboratory freezer, review of freezer temperature charts for 2018 and 2019, manufacturer's storage requirements and interview with the Laboratory Manager and Medical Laboratory Technician (MLT) determined the storage requirements for Troponin and D-dimer Calibrators and QC Materials were not met for 2018 and 2019. The findings include: 1. Observation during laboratory survey at approximately 12:00 p.m. April 8, 2019 of Troponin and D-dimer Calibrators and QC Materials stored in laboratory freezer. 2. Review of freezer temperature charts for 2018 and 2019 revealed temperatures were recorded between (minus 14 degrees Celsius) and (minus 19 degrees Celsius). 3. Manufacturer's storage requirements for Troponin and D-dimer Calibrators and QC Materials states (minus 20 degrees Celsius or colder). 4. Interview with Laboratory Manager and MLT at approximately 1:00 p.m. April 8, 2019 confirmed the storage of Troponin and D-dimer Calibrators and QC Materials in laboratory freezer when storage requirements were not met for 2018 and 2019. ==========