Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0872713	(X3) Date Survey Completed 01/23/2018
Name of Provider or Supplier Trinity Medical Associates Of Knoxville	**Street Address, City, State** 280 Fort Sanders West Blvd Suite 101, 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
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 lack of panic or alert values for the Complete Blood Count (CBC) test upon review of the laboratory's procedure manual and interview with the Laboratory Supervisor, the laboratory failed to include panic or alert values for the CBC test for 2016 or 2017. The findings include: 1. A review of the laboratory's procedure manual for 2016 and 2017 revealed no panic or alert values included for the CBC test. 2. An interview at approximately 11:30 a.m. January 23, 2018, with the Laboratory Supervisor confirmed there were no panic or

	alert values included in the procedure manual for CBC testing for the two year period of review. _____
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: _____ Based on a review of the Laboratory's Microscopic Evaluation of Urine Sediment Procedure, review of the standardized text book procedure and an interview with the laboratory supervisor, determined the laboratory failed to establish and verify the specifications of the urine centrifuge rpm's for the evaluation of the Microscopic Evaluation of Urine Sediment for 2016 and 2017. The findings include: 1. A review of the laboratory's Microscopic Evaluation of Urine Sediment Procedure stated that urines will be spun for 2.5 minutes at 3400 rpm's. 2. A review of the standardized text book procedure (Reference: Schumann, G. Gerry, Urine Sediment Examination 1980) states to "Centrifuge urine in 12 ml centrifuge tubes for five minutes between 1500 to 2000 rpm's (copy attached). 3. An interview with the laboratory supervisor at approximately 1:00 p.m. January 23, 2018 confirmed the laboratory had not established and verified the performance specifications for the urine centrifuge rpm's for the evaluation of microscopic urine sediment for the two year period. reviewed. _____
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: _____ Based on review of four electronic medical record (EMR) Complete Blood Count (CBC) reports and interview with the Laboratory Supervisor, the laboratory failed to maintain a record system for identification of the testing personnel performing CBC's for 2017. The findings include: 1. A review of four EMR patient CBC reports in 2017 revealed no testing personnel identification. 2. An interview at 1:00 p.m. January 23, 2018 with the Laboratory Supervisor confirmed the EMR system failed to have a system in place for

	identification of testing personnel performing CBC's for 2017. _____
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 lack of all 6 competency assessment criteria upon review of 17 of 17 testing personnel competency evaluations and interview with the laboratory supervisor, the Technical Consultant failed to include all 6 required competency assessment criteria for 2016 and 2017. The findings include: 1. Upon review of competency evaluations for 17 of 17 testing personnel, it was revealed they lacked all 6 required competency criteria for 2016 and 2017. 2. An interview at approximately 11:00 a.m. January 23, 2018 with the laboratory supervisor, confirmed the Technical Consultant failed to contain all 6 criteria for assessing competency for 17 of 17 testing personnel for the two year period. _____