Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0702012	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Health Of New England Medical Group	1515 Allen St, Springfield, MA	

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
D0000	A CLIA recertification survey was conducted for the Trinity Health of New England Medical Group laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing review and interview, the laboratory failed to maintain a copy of all proficiency testing records as evidenced by the following: a) A review of proficiency testing records for calendar years 2019, 2020, and 2021 (6 testing events) revealed the fact that the attestation statements provided by the proficiency testing program were not available for four (4) of the six (6) testing events reviewed (American Proficiency Institute (API)) proficiency testing attestation statements for all three testing events of 2020; and, the first testing event of 2021). b) The technical consultant interviewed on 4/28/21 at 9:46 AM confirmed that the attestation statements for the above events were not printed out, signed by the analysts and laboratory director or designee and maintained in the proficiency testing record. .

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for newly introduced test systems as evidenced by the following: Alfa Wasserman Ace Axcel: Accuracy: a) In May of 2019 the laboratory put into place a new Chemistry analyzer for the performance of moderate complexity chemistry testing. A review of the validation studies for accuracy revealed that the laboratory failed to obtain performance specifications that met or exceeded the manufacturer's claims of accuracy for one (1) of twenty one (21) analytes. b) A review of the Calcium accuracy study revealed that the laboratory obtained a correlation coefficient of 0.630. The laboratory tested thirty (30) specimens covering the range of 8.3 to 10.4 milligrams/deciliter. c) The manufacturer's claims for accuracy in the package insert was stated as 0.9935. The manufacturer's accuracy study included one hundred and eleven (111) patient samples covering the range of 0.7 to 14.2 milligrams/deciliter. c) The current technical consultant interviewed on 4/28/21 at 10:30 AM confirmed that the accuracy data for calcium did not meet the manufacturer's claims for accuracy. The laboratory performs 1155 Calcium tests annually. Cepheid Genexpert: Accuracy: a) In September of 2019 the laboratory put into place a new analyzer for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae. A review of the validation studies for accuracy revealed that the laboratory failed to include any positive specimens when performing an accuracy study for Chlamydia trachomatis. All ten specimens included in the accuracy study were negative. b) The current technical consultant interviewed on 4/28/21 at 9:50 AM confirmed that positive specimens for Chlamydia trachomatis should have been included in the accuracy study. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on policy review and interview, the laboratory failed to establish a maintenance protocol for the laboratory microscope as evidenced by the following: a) Procedure

	review on 4/28/21 revealed no written policies regarding microscope maintenance. There was no documentation that maintenance of the microscope had been performed on a regular basis. b) Laboratory technologist number 1 confirmed in an interview on 4 /28/21 at 1:55 PM that a maintenance schedule had not been set up for the microscope.
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 policy review and interview, the laboratory failed to complete the requirements for a complete Individualized Quality Control Plan (IQCP) implemented for one test system as evidence by the following: Cepheid Genexpert: a) The laboratory implemented a test system for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae in September of 2019. A review of the laboratory's quality control revealed that a risk assessment or quality control plan for the system had not been completed prior to implementing quality control procedures. The laboratory had performed twenty samples of quality control in order to establish an IQCP. However no risk assessment or quality control plan, approved by the laboratory director, that specified the number, type, and frequency of controls to be performed.for the test system could be found during the time of the survey. b) Interview with the technical consultant on 4/28/21 at 10:00 AM confirmed that the IQCP risk assessment and a quality control plan had not been performed. .
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview, the laboratory failed to document the immediate reporting of critical values for two (2) out of twenty (20) patient records that contained critical values as defined by the laboratory. Findings include: a) Two (2) patient charts reviewed contained critical or panic values for Potassium. The laboratory's critical value policy stated that "all critical values must be brought to the attention of the attending provider immediately". There was no documentation in the patient's medical record for the two (2) patient records that contained critical Potassium values to document the date, time, and person to whom

	the test results were reported. b) The current technical consultant confirmed in an interview on 4/28/21 at 12:10 PM that critical value reporting was not being adequately documented by laboratory personnel. .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on procedural review and interview, the laboratory failed to maintain documentation to verify that the Quality Assessment (QA) policy and procedure was followed to monitor, assess, and, when indicated, correct problems identified in the postanalytic systems as evidenced by the following: a) A review of the laboratory procedure manual on 4/28/21 revealed that there was a QA procedure in place for quarterly audits which included the post analytical portion of QA but the laboratory failed to perform the postanalytic portion of the QA since July of 2020. b) The technical consultant confirmed in an interview on 4/28/21 at 1:20 PM that the QA was being performed but had not included the post analytical portion. .
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation, the laboratory director failed to provide a safe environment in which employees are protected from potential chemical and biological hazards as evidenced by the following: * On the day of the survey at 11:55 AM it was observed that a bottle of soda was stored in the refrigerator used for laboratory reagent and supply storage. Laboratory technologist number 2 stated that she had forgotten to remove the soda from the refrigerator.