Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482286	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Christus Trinity Clinic	2006 Moores Lane, Texarkana, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records and procedures from 2020 and 2021 and confirmed with interview, the laboratory failed to establish and follow policies to verify the accuracy of two of two nonregulated analytes twice annually either through enrollment in proficiency testing or method comparison studies. (FSH, LH) Findings were: 1. Review of the laboratory records from 2020 and 2021 revealed the laboratory performed twice annually method comparison studies of the following 2 nonregulated analytes: FSH and LH. 2. A review of the laboratory's policies and procedures revealed the laboratory did not have a procedure to verify the accuracy of the non-regulated analytes FSH and LH at least twice annually. 3. An interview with the primary testing person on 2/16/22 at 1145 hours in the break room confirmed the above findings. key: FSH - follicle-stimulating hormone LH - luteinizing hormone
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 review of quality control (QC) documents, instrument printouts, and confirmed in interview, the laboratory failed to have a written policy in place for the establishment of QC mean and standard deviation (SD) for six of six Bio-Rad Liquichek Immunoassay Plus Control lots used on the Beckman Coulter Access 2 immunoassay System in 2021. 1. Review of the laboratory procedure titled "Chemistry Controls" section "Expected Results" Paragraph 2 stated: "BIORAD controls. The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts were derived from the replicate analyses and are specific for the lot of the product. The individual lab should establish their own ranges and use the package insert as a guide." 2. Review of the laboratory QC documents for the Beckman Coulter Access 2 Immunoassay System has the following change from the previous lot number to the current lot number for the Bio-Rad Liquichek Immunoassay Plus Control in May 2021: - Previous Lot number 85260: With Levels 1, 2, and 3 as 85261, 85262, and 85263 respectively. - Current Lot number 85270: With Levels 1, 2, and 3 as 85271, 85272, and 85273 respectively. 3. Review of the instrument QC history had the following mean and ranges for the new and old lot of Bio-Rad Liquicheck Immunoassay that was put in use in May 2021: - Current lot in use: Level 1 Lot 85271 Exp 2/28/2023 Analyte - Mean - (Acceptable Range) - Unit FRT4 - 0.7330 - (0.583 - 0.883) - ng/dL TSH3 - 0.6800 - (0.569 - 0.791) - uIU/mL hFSH - 7.280 - (5.72 - 8.84) - mIU/mL hLH - 3.7800 - (3.03 - 4.53) - mIU/mL Level 2 Lot 85272 Exp 2/28/2023 Analyte - Mean - (Acceptable Range) - Unit FRT4 - 2.546 - (2.11- 5.086) - ng/dL TSH3 - 5.590 - (4.681 - 6.499) - uIU/mL hFSH - 18.150 - (14.64 - 21.66) - mIU/mL hLH - 21.140 - (17.45 - 34.83) - mIU/mL Level 3 Lot 85273 Exp 2/28/2023 - In Use May 2021 Analyte - Mean - (Acceptable Range) - Unit FRT4 - 3.6770 - (3.146 - 4.208) - ng/dL TSH3 - 31.32 - (26.019 - 36.621) - uIU/mL hFSH - 46.81 - (37.72 - 55.90) - mIU/mL hLH - 66.93 - (54.63 - 79.23) - mIU/mL - Previous lot in use: Level 1 Lot 85261 Exp 11/30/2022 Analyte - Mean - (Acceptable Range) - Unit FRT4 - 0.8240 - (0.698 - 0.950) - ng/dL THS3 - 0.6467 - (0.5723 - 0.7211) - uIU/mL hFSH - 6.7290 - (5.226 - 8.232) - mIU/mL hLH - 3.890 - (3.356 - 4.424) mIU/mL Level 2 Lot 85262 Exp 11/30/2022 Analyte - Mean - (Acceptable Range) - Unit FRT4 - 2.8850 - (2.504 - 3.266) - ng/dL THS3 - 5.2796 - (4.6607 - 5.8985) - uIU/mL hFSH - 19.1290 - (14.419 - 23.839) - mIU/mL hLH - 19.5570 - (17.004 - 22.11) - mIU/mL Level 3 Lot 85263 Exp 11/30/2022 Analyte - Mean - (Acceptable Range) - Unit FRT4 - 4.0110 - (3.405 - 4.617) - ng/dL THS3 - 30.4143 -

	(26.6517 - 34.1769) - uIU/mL hFSH - 42.860 - (35.42 - 50.30) - mIU/mL hLH - 64.22 - (55.925 - 72.515) - mIU/mL 4. In an interview with the primary testing person in the laboratory on 2/16/2022 at 11:45 hours, the surveyor queried for the documentation of the established means and acceptable range listed for the BioRad Liquicheck Immunoassay QC in use. The testing person stated that they established their own means and acceptable range for each new lot. Surveyor queried for the laboratory procedure and none was provided. 5. In and interview with the on 2/16/2022 at 11:50 hours in the laboratory, the primary testing person confirmed that the laboratory did not have written policy for the establishment of new lot BioRad Liquicheck Immunoassay QC for the Beckman Coulter Access 2 Immunoassay
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 surveyor direct observation, laboratory environmental records, review of the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to monitor the temperature for the storage of laboratory supplies for 2020 and 2021. The findings include: 1. During a tour of the facility on 2/16/2022 at 09:30 hours, the surveyor observed the following laboratory supplies in the hallway outside the laboratory with a storage requirement of 4-25 (degrees) Celsius: 4mL greiner bio-one K2E EDTA collection tubes - 5 boxes - Lot number C2110334, Expiration (EXP) 1/31/2023 4mL BD Vacutainer Lithium Heparin collection tubes - 1 box - Lot 1137407, EXP: 9/30/2022 4mL BD Vacutainer Lithium Heparin collection tubes - 1 box - Lot 1288712, EXP: 2/28/2023 4mL BD Vacutainer K2 EDTA collection tubes - 3 boxes - Lot 1288704, EXP: 2/258/2023 8.5 mL BD Vacutainer SST collection tubes - 1 box - Lot 1209112, EXP" 7/31/2022. 2. Surveyor queried on 2/16/22 at 11:10 hours for the temperature monitoring environmental logs for 2020 and 2021 for the hallway and none was provided. 3. Review of the CMS form 116 section VIII "Non-Waived Testing" lists a total estimated annual test volume as 17,280. 4. In an interview on 2/16/22 at 11:10 hours, testing person 1 confirmed that the laboratory had not monitored the temperature in hallway where laboratory supplies was stored for 2020 and 2021.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records from 2020 and 2021 and

	confirmed in interview, the technical consultant failed to document annual competency evaluations of one of two personnel performing nonwaived patient testing. Findings were: 1. A review of the facility's 2020 and 2021 personnel files, revealed that one of two testing personnel contained no documentation at the time of the survey, of annual competency evaluations for the year 2020 and 2021 relating to laboratory testing. 2. An interview with the primary testing person on 2/16/22 at 1000 hours in the break room confirmed the above findings.