Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0483768	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Christus Trinity Clinic Palestine Magnolia	3201 S Loop 256 Suite 800, Palestine, 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	An onsite survey conducted 04/13/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory proficiency testing records, and confirmed in an interview, the laboratory failed to test proficiency testing samples in the same manner as it tests patient specimens for four of nine events reviewed, for chemistry core and hematology/coagulation, in 2022 and 2023. The findings included: 1. Review of the laboratory policy titled "Proficiency Testing Performance and Review", section "Policy" had the following statement: "2. As closely as is practical, recognizing that some special handling may be required due to the nature of proficiency testing materials, proficiency survey analysis is performed in the same manner as regular patient samples." 2. Review of the laboratory policy titled "Critical Laboratory Values", section "Policy" had the following statement: "Any test performed in-house that demonstrates a critical value should be called to the immediate attention of the clinician after the result(s) have been verified by testing personnel by repeat testing." 3. Review the laboratory's established critical values and the proficiency testing records for Chemistry and Hematology / Coagulation 2022 and

	the Chemistry Core 1st event of 2023, which had the following critical values with no documentation of verification through repeat testing: 2022 Chemistry Core 2nd Event Sample - Analyte - Reported Result - Laboratory's Critical Criteria CH-07 - Glucose - 47 mg/dL - Less than 54 mg/dL CH-06 - Potassium - 6.6 mmol/L - Greater than 6.0 mmol/L CH-07 - Potassium - 2.8 mmol/L - Less than 3.0 mmol/L CH-10 - Potassium - 6.4 mmol/L - Greater than 6.0 mmol/L 2022 Hematology / Coagulation 2nd Event Sample - Analyte - Reported Result - Laboratory's Critical Criteria COU-08 - Hemoglobin - 6.8 g/dL - Less than 7 grams/dL 2022 Hematology / Coagulation 3rd Event Sample - Analyte - Reported Result - Laboratory's Critical Criteria COU-12 - Hemoglobin - 18.1 g/dL - Greater than 18 grams/dL COU-14 - Hemoglobin - 6.7 g/dL - Less than 7 grams/dL 2023 Chemistry Core 1st Event Sample - Analyte - Reported Result - Laboratory's Critical Criteria CH-01 - CO2 - 14 mmol/L - Less than 15 mmol /L CH-03 - Sodium - 173 mmol/L - Greater than 160 mmol/L 4. In an interview on 4 /13/2023 at 1035 hours, in the office, the technical consultant confirmed that verification of critical results had not been performed for the above proficiency testing records.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Review of laboratory policy, quality control (QC) records, patient test results, and confirmed in an interview, the laboratory failed to evaluate 60 of 60 patients to the last acceptable QC when QC results failed to meet the laboratory's established criteria for acceptability, on the Vitros 5600 Chemistry Analyzer, for records reviewed in May 2022 and January 2023. The findings included: 1. Review of the laboratory policy titled "Quality Control Program", section 17. "Ortho Clinical Vitros 5600 Analyzer" stated the following: "17.6 The mean, standard deviation index (SDI), and coefficient of variation index (CVI) are evaluated in Cerner. 17.8 Remedial cation taken to bring out-of-range controls within range or to repair malfunctioning analyzers are documented in the LIS and/or on the appropriate log." Surveyor queried as to the acceptable range used in Cerner for the acceptability criteria. The technical consultant stated they used a 2SD range. 2. Random review of laboratory QC records for the Vitros 5600 chemistry analyzer for May 2022 and January 2023, had the following three QC that failed to meet the laboratory's established criteria for acceptability with no documentation of the evaluation of patients to the last acceptable QC. May 2022: 5 /04/2022 Analyte: LH, Lot 85263 Acceptable Range: 50-21 - 59.41 Result: 59.59 Documented corrective action: "Calibrator getting old/ change to new lot # reagent" 1 patient with LH testing since the last acceptable QC on 5/3/2022: Accession number: 22-122-009716 5/27/2022 Analyte: Lipase, Lot 45861 Acceptable Range: 81.01 - 133.01 Result: 61.00 Documented corrective action: "Will repeat on new cartridge of slides" 2 patients with lipase testing since the last acceptable QC on 5/26/2023: Accession number: 22-146-006161 22-146-009980 January 2023: 1/25/2023 Analyte: Total Protein, Lot 45931 Acceptable Range: 3.378 - 4.134 Result: 4.200 Documented

	corrective action: "will recalibrate" 57 patients with total protein testing since the last acceptable QC on 1/24/2023, to include the following sampling of 10: Accession number: 23-024-005206 23-024-006156 23-024-005762 23-024-006429 23-024-007770 23-024-004106 23-024-011789 23-024-005354 23-024-010311 23-024-011499 3. In an interview on 4/13/2023 at 13:05 hours, in the office, the technical consultant confirmed that the laboratory did not evaluate patients to the last acceptable QC for QC failures that did not meet the laboratory's acceptability criteria on the Vitros 5600 chemistry analyzer. Key: LH - Luteinizing Hormone
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on a review of laboratory policy and confirmed in an interview, the laboratory failed to retain instrument printouts for CBC testing from the DxH600 hematology analyzer for four of four months from January to April 2022. The findings included: 1. Review of the laboratory policy titled "Record Retention Policy" had the following statement: "17. Instrument printout reports and/or tapes are maintained for the current year plus two (2) previous years." 2. Surveyor queried for the instrument printouts for the DxH600 hematology analyzer for January through April of 2022 and none was provided. 3. In an interview on 4/13/2023 at 14:45 hours, in the office, the technical consultant confirmed that the laboratory did not retain CBC instrument printouts from the DxH600 hematology analyzer for January to April 2022. Key: CBC - Complete blood count