

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0482286	(X3) Date Survey Completed 04/11/2023
Name of Provider or Supplier Christus Trinity Clinic	Street Address, City, State 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	An onsite survey conducted 4/11/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory quality control (QC) documents, patient final reports, and confirmed in interview, the laboratory failed to evaluate 39 of 39 patient test results to the last acceptable QC for QC issues reviewed in July and November of 2022, that were outside of the laboratory's established criteria for acceptability on the Horiba Micros 60 hematology analyzer. The findings included: 1. Review of the laboratory policy titled "Remedial Action Policy" had the following statement: "B. CONTROLS OUT OF ACCEPTABLE RANGE - Results of control and calibration materials fail to meet the laboratory's established criteria for acceptability. NOTE: All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if the patient results have been adversely affected. Appropriate remedial action must be taken to ensure the reporting of accurate and reliable patient test results. " 2. Review of the Horiba Micros 60 hematology analyzer quality control records and corrective action comments for July and November 2022 included the following five QC issues that failed to meet the laboratory's established criteria for acceptability and did not have documented patient</p>

remediation: July 2022: 7/11/2022: QC corrective action comments stated the following: "Issues with all 3 controls and with fresh bottles of QC. Did a needle clean and bleached apertures and did startup and repeat all QC and all ok but still need to watch." The following 7 patients were tested since the last acceptable QC on 7/7/2022: 101961555 100951460 100925086 100949342 100949842 100943586 100924846 7/21/2022: QC corrective action comments stated the following: "Repeat still out, do auto-clean, repeat" The following 13 patients were tested since the last acceptable QC on 7/20/2022: 101968246 100951404 100950629 100948122 100942905 100879333 100950547 100946564 100945813 100942495 100937332 100942280 102073804 November 2022: 11/1/2022: QC corrective action comment stated the following: "\$flag>do auto-clean and repeat" The following 4 patients were tested since the last acceptable QC on 10/31/2022: 100948911 100947329 100943839 101963033 11/16/2022: QC corrective action comment stated the following: "Replaced lyse and cleaner. Still got flag on repeat. Did auto-clean and repeat." The following 7 patients were tested since the last acceptable QC on 11/15/2022: 102125479 100949897 100946275 100953181 101173419 100951163 101829666 11/22/2022: QC corrective action comment stated the following: "Called service about the new lot of QC and the flag issues. I did a bleach of apertures and tried to run new lot QC. L1 and L2 was okay but after running hi QC x5, the \$flag never went away." The following 8 patients were tested since the last acceptable QC on 11/21/2022: 100943607 100942000 100950193 100943712 102125007 100951315 100938084 100946719 3. In an interview on 4/11/2023 at 14:30 hours, in the breakroom, testing person (TP) 2 confirmed that the evaluation of patients to the last acceptable QC had not been performed for the above quality control issues that failed to meet the laboratory's established criteria for acceptability on the Horiba Micros 60 hematology analyzer.