

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2159499	(X3) Date Survey Completed 07/07/2023
Name of Provider or Supplier Dmctx1, Pllc	Street Address, City, State 703 W Bluff, Woodville, 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 07/07/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory proficiency testing (PT) records, and confirmed in an interview, the laboratory failed to attest that proficiency testing samples were tested in the same manner as patient specimens for two of four hematology coagulation PT events reviewed from 2022 to 2023. The findings included: 1. Review of the laboratory policy titled "Proficiency Testing", section 4 "Testing" had the following statement: "d. Testing personnel will sign attestation and submit all documentation to the laboratory director to sign and review." 2. Review of the American Proficiency Institute (API) PT Attestation Statement page had the following instructions: "Signatures Required - For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." 3. Review of the API 2022 and 2023 testing event attestation pages had the following two events missing required signatures: 2022</p>

Hematology / Coagulation 3rd Event: No laboratory director or testing personnel signature 2023 Hematology / Coagulation 1st Event: No laboratory director signature
4. In an interview on 7/7/2023 at 12:00 hours, in the breakroom, testing personnel (TP) 1 confirmed that the PT attestation pages did not have all the signatures required.