Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2159499	**(X3) Date Survey Completed** 11/08/2021
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of instructions for use (IFU), patient testing log for random dates in June 2021 and August 2021, the annual test volume, and confirmed in interview, the laboratory failed to follow manufacturers' instruction for the temperature storage for four of four waived tests: SARs-CoV-2, Flu A&B, Strep A Tests, and RSV. 1. Direct observation at 1350 hours on 11/8/2021 in the testing and storage area for the waived test kits, the facility did not have a temperature monitoring system in place for the following waived test kits: Alere BinaxNow RSV Card McKesson Consult diagnostics Influenza A&B Test McKesson Consult diagnostics Strep A Tests Dipstick BD Veritor System for the Rapid Detection of Flu A+B BD Veritor System for Rapid Detection of SARS-CoV-2 2. Review of the waived test kits IFU stated the following: Alere BinaxNow RSV Card (IN43002) under section 'Storage and Stability': Store kit at 2-30(degrees) C. McKesson Consult diagnostics Influenza A&B Test (MRF#181-36025) under section 'Storage and Stability': The McKesson Consult Influenza A&B Test may be stored at 35-86(degrees)F [2-30 (degrees)C] in the original sealed pouch, away from direct sunlight. McKesson

	Consult diagnostics Strep A Tests Dipstick (PVN C0218) under section 'Storage and Stability': The kit can be stored at room temperature or refrigerated [36-86(degrees)F/ 2-30(degrees)C]. BD Veritor System for the Rapid Detection of Flu A+B (8087667 (14)) under section 'Storage and Handling': Kits may be stored at 2-30(degrees)C. DO NOT FREEZE. BD Veritor System for Rapid Detection of SARS-CoV-2 (256082) under section 'Storage': Kits may be stored at 2-30(degrees)C. 3. Review of patient testing log for June 1-3rd and 13-14th 2021, and August 13th, 18th, and 25th 2021 the laboratory performed: 74-Rapid Covid 19 tests 19-Strep A, 4-Flu A+B 1-RSV Refer to Patient Alias list. 4. Review of the CMS116 section VI Waived Testing indicates the estimated total annual test volume for all waived tests performed to be approximately 10,000. 5. Interview at 1400 hours on 11/8/2021 in the breakroom with the primary testing personnel confirmed the above. Key: CMS - Centers for Medicare and Medicad Services C - Celcius
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of the instructions for use (IFU) for the Sysmex Eightcheck-WP X-TRA, the annual test volume, and confirmed in interview, the laboratory failed to document a revised expiration date for three of three quality control (QC) reagents in use for the Sysmex pocH-100i hematology analyzer. 1. Direct observation at 1400 hours on 11/8/2021 of Sysmex pocH-100i hematology 'in use' controls in the laboratory refrigerator, revealed the laboratory did not indicate a revised expiration date written on the labels. The controls in use are as follows: Abnormal High Lot No. 12230712 Exp 11.17.2021 Normal Lot No. 12230711 Exp 11.17.2021 Abnormal Low Lot No. 12230710 Exp 11.17.2021 2. Review of the Sysmex Eightcheck-3WP X-TRA IFU (ref no. 350493-5) subsection 'Storage and shelf life after first opening' states: 'Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 (degrees) C after being re-capped. 3. Review of the CMS116 for the specialty Hematology lists an estimated annual test volume of 2,500. 4. Interview with at 1420 hours on 11/8/2021 in the laboratory with the primary testing personnel confirmed the above. Key: CMS - Center for Medicare and Medicad Services C - Celcius
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by:

	Based on review of personnel competency records, the laboratories competency policy, the annual test volume, and confirmed in interview, the technical consultant failed to have personnel competencies for six of six testing personnel competed for one of one new Sysmex pocH-100i hematology analyzer (serial number G6653) before patient testing began in July 2021. 1. Review of the laboratories Competency Assessment Policy, signed by the laboratory director 2/4/2019 states: 'If test methodology or instrumentation changes, and individual competency must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient results. 2. Review of the personnel competency records show six of six testing personnel did not have competency assessments performed prior patient testing before the Sysmex pocH-100i hematology analyzer was put in use in July 2021. 3. Review of the CMS116 for the specialty Hematology lists an estimated annual test volume of 2,500. 4. Interview with the primary testing personnel at 1145 hours in the breakroom on 11/8/2021 confirmed the above. Key: CMS - Centers for Medicare and Medicad Services