Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2166421	05/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dmctx2, Llc	410 Gaslight Blvd, Lufkin, 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 at the entrance and exit conferences. The facility representative was 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 review of manufacturer's instructions, patient test records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to include all authorized fact sheets when performing Covid testing using the BD Veritor system for 5 of 5 patient test results. The findings were: 1. Review of the manufacturer's instructions for us under, "Conditions of Authorization for the Laboratory (Applicable in the USA) The BD Veritor (Trademark) System for Rapid Detection of SARS-CoV-2 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices /coronavirus-disease- 2019-covid-19-emergency- use-authorizations-medical-devices/ vitro-diagnostics-euas However, to assist clinical laboratories using the BD Veritor (Trademark) System for Rapid Detection of SARS-CoV-2 ("your product" in the conditions below), the relevant Conditions of Authorization are listed below ... Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for

	disseminating these Fact Sheets may be used, which may include mass media." 2. Review of 5 of 5 patient test results found the laboratory failed to follow the manufacturer's instructions to include BD Veritor authorized fact sheets with patient results. 3. The findings were confirmed in interview with testing personnel 1 (as listed on Form CMS-209) on May 11, 2021 at 10:15 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services BD - Becton Dickinson FDA - Food and Drug Administration
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of patient final reports and confirmed in interview of facility personnel, the laboratory failed to establish and follow written policies and procedures to ensure normal ranges are correct on patient records. The findings were: 1. Review of 10 patient final results found that the laboratory had two sets of reference ranges available for patient final reports: Male Reference Range 1: Hematocrit: 33.0 - 45.0 g /dL Hemoglobin: 11.0 - 18.0 g/dL MCHC: 30.0 - 37.0 d/dL WBC: 4.3 - 10.0 X 10/uL Granulocytes: 1.5 - 8.5 X 10/uL Granulocytes %: 58 Lymphocytes #: 1.7 - 8.5 X 10 /uL Lymphocytes %: 11.10 - 43.60 % Platelets: 140 - 450 X 10/uL Male Reference Range 2: Hematocrit: 42.0 - 50.0 g/dL Hemoglobin: 14.0 - 18.0 g/dL MCHC: 31.7 - 36.0 g/dL WBC: 4.3 - 10.0 X 10/L Granulocytes: 1.8 - 7.2 X 10/L Lymphocytes /Monocytes: 1.7 -4.9 X 10/L Platelets: 140 - 440 X 10/L Female Reference Range 1: Hematocrit: 33.0 - 45.0 g/dL Hemoglobin: 11.0 - 18.0 g/dL MCHC: 30.0 - 37.0 d/dL WBC: 4.3 - 10.0 X 10/uL Granulocytes: 1.5 - 8.5 X 10/uL Lymphocytes #: 1.7 - 8.5 X 10/uL Platelets: 140 - 450 X 10/uL Female Reference Range 2: Hematocrit: 36.0 - 45.0 g/dL Hemoglobin: 12.0 - 16.0 g/dL MCHC: 31.7 - 36.0 g/dL WBC: 4.3 - 10.0 X 10/L Granulocytes: 1.8 - 7.2 X 10/L Lymphocytes/Monocytes: 1.7 -4.9 X 10/L Platelets: 140 - 440 X 10/L 2. Review of the laboratory's verification study found the ranges available on the patient final reports were not the laboratory's established ranges. 3. The findings were confirmed in interview with testing personnel 1 (as listed on (Form CMS-209) on May 11, 2021 at 10:45 hours in the break room. She revealed that one set of the reference ranges were that of the manufacturer. Key: CMS - Centers for Medicare and Medicaid Services WBC - white blood cell MCHC - mean cell hemoglobin concentration g/dL - grams per deciliter uL - microliter L - liter # - absolute count
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's personnel records, and confirmed in staff interview, it was revealed the laboratory failed to have

	documentation of the technical consultant performing the competency assessments on 4 of 4 testing personnel competencies reviewed for 2019 and 2020. The findings were: 1. Review of the laboratory's policy titled, "Technical Consultant Responsibilities" approved by the laboratory director review date August 30, 2019 stated, " ...12. Personnel have appropriately trained and demonstrate competency prior to testing patient specimens." 2. A review of the laboratory's personnel records revealed competency assessment were performed on Testing personnel numbers 2 and 3 as follows: Testing personnel 2 (as listed on Form CMS-209) Date: 06-2019 The competency assessment was documented as being performed by testing personnel 1 Testing personnel 2 (as listed on Form CMS-209) Date: 11-2020 The competency assessment was documented as being performed by testing personnel 1 Testing personnel 3 (as listed on Form CMS-209) Date: 03-2020 The competency assessment was documented as being performed by testing personnel 1 Testing personnel 3 (as listed on Form CMS-209) Date: 12-2020 The competency assessment was documented as being performed by testing personnel 1 3. A review of the personnel records for testing personnel number 1 revealed she did not meet the requirements to be a technical consultant. She did not have a bachelor's degree in a biological, chemical, physical, or medical laboratory science field. 4. The laboratory was asked to provide documentation of the technical consultant performing the competency assessments. No documentation was provided. 5. An interview with testing personnel 1 (as listed on Form CMS-209) on May 11, 2021 at 09:30 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services