Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0938746	04/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Oakcliff Medical Treatment Clinic	1401 W Jefferson Blvd, Dallas, 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	Laboratory representatives were present at the entrance conference conducted 04/26 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 04/26 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Academy of Family Physicians (AAFP) proficiency testing(PT) records, and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing for 3 of 3 hematology events in 2020 (Events A, B, C). Findings: 1. Review of the laboratory's policy titled "Proficiency Testing (PT) Assessment Policy" revealed: "E. Evaluation of Survey ... 4. All proficiency testing results should be reviewed ... 9. The laboratory director or designee will review and sign all PT survey reports, evaluation forms, and corrective action forms on site at least quarterly and will document such review on the Laboratory Director Proficiency Testing Review Form." 2. Review of hematology PT records revealed the laboratory director or designee failed to review and evaluate the results obtained on proficiency testing in 2020 for Events A, B and C. 3. During an interview on 04/26/2021 at 10:23 am, the Technical Consultant and Compliance Officers confirmed the above findings.

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 direct observation, review of the manufacturer's instructions, and confirmed in interview, the laboratory failed to have documentation of the date Hemoglobin A1c reagent cartridges were placed at room temperature and/or the revised expiration date for 6 of 6 reagent cartridges. Findings: 1. Review of the DCA Systems Hemoglobin A Reagent Kit package insert revealed: "STORAGE: Store reagent cartridges refrigerated at 2-8C (36-46F). Capillary holders may be stored refrigerated or at room temperature (15-30C/59-86F). USE LIFE: Reagent cartridges can be kept for up to three months at room temperature anytime before the (EXP) expiration date. Record on the carton, the date the carton was placed at room temperature." 2. During a tour of the laboratory on 04/26/2021 at 11:07 am, the following Hemoglobin A1c reagent cartridges were observed to be stored on the shelf with no date indicating when the reagent cartridges were placed at room temperature and/or revised expiration date: 6 Hemoglobin A1c cartridges lot #0726, expiration date 09/2022 3. During an interview on 04/26/2021 at 11:13 am, the Compliance Officer stated that when Hemoglobin A1c reagent cartridges are received in the laboratory they are never stored in the refrigerator. She stated that the all cartons of cartridges are stored at room temperature and the received date along with the revised expiration date is documented on the carton. During the exit interview on 04/26/2021 at 12:01 pm, the Technical Consultant and Compliance Officers confirmed the above findings.
D6053	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 at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel files and confirmed in interview the technical consultant failed to evaluate and document the performance 4 of 9 Testing Persons (TP-2, TP-3, TP-7, TP-9) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens in 2019 and 2020. Findings: 1. Review of the laboratory's personnel policy revealed: "Technical Consultant Responsibilities (Test Complexity: Moderate) The technical consultant or technical supervisor is responsible for technical and scientific oversight of the laboratory. This person is not required to be on-site at all times, but must be available to provide consultation either on-site, by telephone, or electronically. In addition, the technical consultant/supervisor ... Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to

	reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." 2. Review of personnel records for 2019 and 2020 revealed the following: TP-2 personnel records revealed an initial training assessment was performed on 09/2018 and 6-month competency was performed on 02 /25/2019 for CBCs (complete blood count). There was no documentation of a semiannual performance for CBCs (due 09/2019). TP-3 personnel records revealed an initial training assessment was performed on 12/30/2019 and 6-month competency was performed on 06/29/2020 for CBCs. There was no documentation of a semiannual performance for CBCs (due 12/2020). TP-7 personnel records revealed an initial training assessment was performed on 10/24/2019 and 6-month competency was performed on 04/15/2020 for CBCs. There was no documentation of a semiannual performance for CBCs (due 10/2020). TP-9 personnel records revealed an initial training assessment was performed on 12/04/2019 and 6-month competency was performed on 06/01/2020 for CBCs. There was no documentation of a semiannual performance for CBCs (due 12/2020). The technical consultant did not ensure semi-annual competency assessments were evaluated and documented for the above TP's. 3. During an interview on 04/26/2020 at 9:50 am, the Technical Consultant and Compliance Officers confirmed the above findings.