Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2105383	12/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Terrell Urgent Care	104 Lee Street, Terrell, 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 entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives 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 NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1100 Facility Administration 493.1403 Laboratory Director, (moderate complexity). Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute(API) Proficiency Testing (PT) records (2019-2021) and confirmed in staff interview, the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 3 Hematology events in 2019 and 1 of 3 in 2020. Findings Included: 1. Review of the API Attestation Form revealed the following statement: "Attestation Statement Signatures Required- For all PT results, an

	attestation statement must be signed by the testing personnel and the laboratory director ..." Further review revealed the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for the 3rd Hematology event in 2019 and 1st event in 2020. 2. In an interview with the technical consultant (TC-1) at 10:15 AM on 12/21/2021, in the facility breakroom, TC-1 was asked to provide documentation of the laboratory director attesting to the routine integration of PT samples into the patient workload for the 3rd Hematology event in 2019 and 1st event in 2020. No documentation was provided. This confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on direct observation, laboratory records, and staff interview, the laboratory failed to retain documentation of Sysmex Hematology Analyzer Quality Control (QC), Sysmex QC lot rollovers, Levi-Jennings QC charts, environmental records, and staff competencies for 12 of 12 months (January 2020-December 2020). Findings Included: 1. During the entrance conference with the Technical Consultant (TC-1) on 12/21/2021 at 10:15 a.m. in the facility breakroom, the TC informed the inspector they could not locate all documentation for: Sysmex Hematology Analyzer Quality Control (QC), Sysmex QC lot rollovers, Levi-Jennings QC charts, environmental records, and staff competencies for the year 2020. 2. Review of laboratory records revealed no documentation for 12 of 12 months (January 2020-December 2020) could be located at the time of survey. 3. During an interview with Testing Person 1 (TP-1) on 12/21/2021 at 10:20 a.m. in the facility breakroom, TP-1 stated to have searched the laboratory, but they could not locate the documentation for 2020. This confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of Sysmex pocH-100i Operator's Manual, laboratory maintenance records, and confirmed in staff interview, the laboratory failed to ensure daily, weekly and monthly maintenance was performed as required by the manufacturer prior to patient testing for 12 of 12 months in 2020 and 11 of 11 months in 2021 (January 2021- November 2021). Findings Included: 1. Review of Sysmex pocH-100i Operator's Manual (Rev.) revealed the following: "Section 6: Maintenance Log To ensure proper functioning of the analyzer, it is necessary to periodically clean and maintain the analyzer. Perform maintenance according to maintenance schedule detailed in the pocH-100i instructions for use. Document maintenance on the maintenance log provided. a. Daily Maintenance- Shutdown.. b. Every two weeks or

	150 samples- Clean Transducer.. c. Every 3 months or 1500 samples- Clean Waste Chamber.." 2. Review of laboratory maintenance records revealed the following months when required maintenance was performed: December 2021 The laboratory failed to perform require maintenance for the Sysmex pocH-100i Hematology Analyzer for 12 of 12 months in 2020 and 11 of 11 months in 2021 (January 2021-November 2021). 3. During an interview with Testing Person 1 (TP-1) on 12/21/2021 at 11:12 a.m. in the facility breakroom, TP-1 confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory's policy, manufacturer's instructions, patient test records, and quality control records, the laboratory director failed provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure laboratory overall operations and test systems were in compliance with regulations. Refer to D6004.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy and confirmed in staff interview, the Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations as evidenced by: 1. The laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 3 Hematology events in 2019 and 1 of 3 in 2020. Refer to D2009. 2. Based on direct observation, laboratory records, and staff interview, the laboratory failed to retain documentation for 12 of 12 months (January 2020-December 2020). Refer to D3031. 3. The laboratory failed to perform require maintenance for the Sysmex pocH-100i Hematology Analyzer for 12 of 12 months in 2020 and 11 of 11 months in 2021 (January 2021- November 2021). Refer to D5429.