

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2105383	(X3) Date Survey Completed 08/15/2023
Name of Provider or Supplier Terrell Urgent Care	Street Address, City, State 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	<p>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 in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: I. Based on direct observation, review of pocH-100i Sysmex hematology analyzer instructions for use, laboratory environmental logs (January 2023-June 2023) and confirmed in staff interview, the laboratory failed to ensure the laboratory humidity</p>

range was within operating specifications for 6 of 6 months in 2023. Findings Included: 1. During a tour of the facility on 08/15/2023 at 11:30 a.m., the surveyor observed a pocH-100i Sysmex hematology analyzer (Serial Number: G6683) available for patient testing. 2. Review of, "pocH-100i Sysmex hematology analyzer-Instructions for Use" (Revised: June 2008) revealed the following: "1.2 Technical Information 1.2.1. Performance characteristic- Specifications Relative humidity: 30-85%" 3. Review of laboratory environmental logs for 2023 (January-June) revealed the following laboratory room humidity range: 15-80% The laboratory failed to ensure the laboratory humidity range was within operating specifications for 6 of 6 months in 2023. 4. During an interview with the Technical Consultant (TC-1) on 08/15/2023 at 11:40 a.m. in the facility break room, TC-1 confirmed the above findings. II. Based on direct observation, laboratory environmental logs (January 2023-June 2023) and confirmed in staff interview, the laboratory failed to ensure the laboratory temperature range was within storage specifications for the XM Clean Cell Hematology Reagent for 6 of 6 months in 2023. Findings Included: 1. During a tour of the facility on 08/15/2023 at 11:30 a.m., the surveyor observed a pocH-100i Sysmex hematology analyzer (Serial Number:G6683) available for patient testing. Further observation revealed the following reagent stored in the bottom cabinet of the laboratory: XW Clean Cell Hematology Reagent Lot Number: A3001 Expiration Date: 02/06/2024 Storage Temperature: 15-25 C 2. Review of laboratory environmental logs for 2023 (January-June) revealed the following laboratory room temperature range: 15-30 C (59-86 F) The laboratory failed to ensure the laboratory temperature range was within storage specifications for the XM Clean Cell Hematology Reagent for 6 of 6 months in 2023. 4. During an interview with the Technical Consultant (TC-1) on 08/15/2023 at 11:35 a.m. in the laboratory, TC-1 confirmed the above findings. Word Key C- Celcius F- Fahrenheit

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
 Based on direct observation and confirmed in staff interview, the laboratory failed to ensure hematology reagents were not used passed their expiration date for 42 of 42 days in 2023. Findings Included: 1. During a tour of the facility on 08/15/2023 at 11:30 a.m., the surveyor observed a pocH-100i Sysmex hematology analyzer (Serial Number: G6683) available for patient testing. Further observation revealed the following expired reagent stored in the bottom cabinet of the laboratory: XW Clean Cell Hematology Reagent Lot Number: A2003 Expiration Date: 07/05/2023 The laboratory failed to ensure hematology reagents were not used passed their expiration date for 42 of 42 days in 2023. 2. During an interview with the Technical Consultant (TC-1) on 08/15/2023 at 11:35 a.m. in the laboratory, TC-1 confirmed the above findings.