

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0673541	(X3) Date Survey Completed 01/05/2023
Name of Provider or Supplier East Texas Family Medicine Pa	Street Address, City, State 4201 South Loop 256, Palestine, 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 onsite survey conducted 01/05/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
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: Based on surveyor observations, review of manufacturers instructions for use, laboratory documents, and confirmed in interview the laboratory failed to monitor the storage temperature for SysmexXN-330 hematology quality controls (QC) for six of six months from June to December 2022. The findings include: 1. Review of the XN-L Check QC instructions for use (IFU) section "Storage and shelf life of unopened product" stated the following: "When stored at 2-8(degrees) Celsius(C), the unopened vial is stable for 100 days." 2. In a tour of the laboratory on 1/5/2023 at 1030a, testing person (TP) 3 lead the surveyor to a silver-faced miniature refrigerator labeled "PRIVATE PAY" as the storage location for QC intended to be used for the SysmexXN-330 hematology analyzer. Surveyor noted the following 2 boxes of controls in the door of the refrigerator: 1 unopened box of XN-L Check, Lot 2323, expiration 2/28/2023 Level 1 - 4 vials Level 2 - 4 vials Level 3 - 4 Vials 1 opened box of XN-L Check controls, Lot2323, expiration 2/28/2023 Level 1 - 1 vial Level 2 - 1 vial Level 3 - 1 vial 3. Review of temperature documentation for June to December 2022 did not include a record of the refrigerator labeled "PRIVATE PAY". 4. In an</p>

interview on 1/5/2023 at 10:55 hours, in the conference room, TP3 and the practice consultant confirmed that there was no record of the monitoring of acceptable temperatures for the refrigerator where QC for the SysmexXN-330 hematology analyzer was kept.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on a review of personnel records, laboratory policy, and confirmed in an interview the technical consultant (TC) failed to have documentation of training for one of one new testing personnel, hired in 2022, performing testing on the SysmexXN-330 hematology analyzer. The findings include: 1. Review of new hire personnel records for testing person (TP) 6, as listed on the Centers for Medicare and Medicaid (CMS) personnel form 209, with a hire date of 4/5/2022. Further review showed documentation of TP6's first annual competency assessment for the SysmexXN-330 hematology analyzer by the technical consultant (TC) on 6/31/2022. Surveyor queried for documentation of training on the SysmexXN-330 hematology analyzer prior to the competency assessment performed on 6/31/2022, and none was provided. 2. Review of the laboratory policy titled "Quality Assurance Policies and Procedures", subsection "General Quality Policies" stated the following: "1. Quality in the entire test system is of foremost importance to this laboratory" "2. All laboratory personnel are trained properly commensurate with their positions, duties, and responsibilities." 3. In an interview on 1/5/2023 at 09:35 hours, in the breakroom, the practice consultant confirmed that the TC did not have documented training for TP6 on the SysmexXN-330.