Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506605	03/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Parmer Medical Center	1307 Cleveland Avenue, Friona, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based upon review of policies and procedures and interview of the general supervisor, 25 of 26 procedures found in the procedure manual had not been approved by the current laboratory director. The findings included: 1. Review of the procedure manual found 25 of 26 procedures included were approved by the previous laboratory director. 2. During interview of the general supervisor conducted March 5, 2025 at 12: 05 PM, she confirmed that policies and procedures had not yet been approved by the current laboratory director hired January 1, 2025.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by:

	Based upon review of policies and procedures, manufacturer's instructions, quality control records and interview of facility personnel found the laboratory failed to ensure that quality control materials were tested with each now lot of Profile- V MEDTOX Drugs of Abuse Test cards before testing 3 of 14 patient specimens tested in July 2024. The findings included: 1. Review of the laboratory's own written procedure (approved December 30, 2015) found on page 3, under the heading Quality Control: "External controls are to be performed as follows: To practice the test with a know control. When a new lot of devices is opened. Once a week. If the operator suspects that the reader is not working properly. If the operator has a repeated unexpected result. If the operator suspects that the test devices have been stored improperly." 2. Review of the Profile- V MEDTOX Drugs of Abuse Test cards instructions found on page 4 under the heading Quality Control: " "External controls are to be performed as follows: To practice the test with a know control. When a new lot of devices is opened. Once a week. If the operator suspects that the reader is not working properly. If the operator has a repeated unexpected result. If the operator suspects that the test devices have been stored improperly." 3. Review of quality control records for July 2024 found the laboratory performed weekly quality control testing using 2 lots of Med Tox Drugs of Abuse Cards as follows: 07/03/2024 - lot TM038A26 07/10/2024 - lot TM038A26 07/13/2024 - lot TM048B26 07/17/2024 - lot TM038A26 07/24/2024 - lot TM048B26 4. Review of patient test records found 3 of 14 patients tested in July 2024 were tested using Drugs of abuse cards lot TM048B26 with no documentation of external quality control materials tested between 07/13/2024 and 07/24/2024. Patient 10052895 tested 07/19/2024 Patient 10052898 tested 07/20/2024 Patient 10052913 tested 07/21/2024 4. During interview of the General Supervisor conducted March 6, 2025 at 10:25 AM she confirmed there was no documentation of external quality control materials for lot TM048B26 tested between 07/13/2024 and 07/24/2024.