

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0506605	(X3) Date Survey Completed 01/20/2023
Name of Provider or Supplier Parmer Medical Center	Street Address, City, State 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based upon review of manufacturer's instructions for use, Immunohematology quality control records, patient test records and interview of facility personnel, the laboratory failed to ensure expired reagents were not used in testing 4 patients on 4 of 61 days in October and November of 2022. The findings included: 1. Review of the Ortho Reagent Red Blood Cells instructions for use found: a. 0.8% Affirmagen Reagent Red Blood Cells - under the heading Reagents: "Do not use beyond expiration date". b. 0.8% Selectogen Reagent Red Blood Cells - under the heading Reagents: "Do not use beyond expiration date". Review of the Micro Typing Systems (MTS) Anti- IgG Card instructions for use found on page 2 under the heading Precautions - " Do not use beyond expiration date." 2. Review of the Immunohematology quality control records and patient test records for October and November 2022 found the laboratory used expired Ortho reagents and MTS IgG cards to test patient specimens as follows: a. Patient 10036320 was tested October 19, 2022 using the expired Ortho 0.8% Affirmagen Reagent Red Blood Cells lot 8A485 (Expiration October 18, 2022). b. Patient 202922 was tested October 7, 2022 using the expired Ortho 0.8% Selectogen Reagent Red Blood Cells lot V5460 (Expiration October 4, 2022). c. Patient 10036320 was tested October 19, 2022 using the the expired Ortho 0.8% Selectogen Reagent Red Blood Cells lot V5460 (Expiration October 4, 2022), and the expired Ortho 0.8% Affirmagen Reagent Red Blood Cells lot 8A485 (Expiration October 18, 2022). d. Patient 10036570 was tested November 19, 2022 using the expired Micro Typing Systems (MTS) Anti- IgG Card lot 011322001-12 (expiration November 15, 2022). 3. During interview of the general supervisor listed on the CMS report 209</p>

Laboratory Personnel Report conducted January 19, 2023 at 11:09 AM she confirmed that the laboratory used expired reagents and supplies to test patient specimens for blood typing and antibody detection.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based upon review of policies and procedures, quality control records, patient test records and interview of facility personnel, the laboratory failed to test at least two levels of Hematology quality control material prior to testing patient specimens on two of thirty one days in October 2022. The findings included: 1. Review of the laboratory's own written quality control policy titled Quality Control Schedule found on page one: " Hematology - Three levels of control material (low, normal & high) are run every 24 hours. However, it is not required if there are no patients to run; for example: nights and weekends. Two of the three controls must be within performance range in order for patient results to be reported." 2. Review of Hematology quality control records for October 2022 found the laboratory failed to test quality control materials on October 12, October 15 and October 27 as written in their own policy. 3. Review of patient test records found the laboratory tested six patients on dates when quality control testing was not performed as follows: a. October 12, 2022 - patient 10036153 b. October 27, 2022 _ patients 10036352, 10036498, 10036503, 10036505, patient 10036506 4. During interview of the general supervisor listed on the CMS Report 209 conducted January 19, 2023 at 12: 18 PM she confirmed patient specimens were tested without testing at least two levels of quality control material on the two dates in October 2022.