Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0507318	08/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
W J Mangold Memorial Hospital Lab	320 N Main St, Lockney, 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	A recertification survey was completed on August 26, 2021. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2000 - 42 C.F.R. 493.801 Enrollment And Testing Of Samples
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of pre survey paperwork, proficiency testing records, interview, and test volumes, the laboratory failed to ensure they were enrolled in proficiency testing (PT) for Rheumatoid Factor (RF). Findings follow. A. Review of the pre-survey paperwork titled Listing of Tests Performed in the Facility showed the laboratory was performing Rheumatoid Factor. B. Review of the American Proficiency Institute (API) records from the 1st, 2nd, and 3rd events of 2020 and the 1st event of 2021 showed the laboratory was not enrolled in PT for RF. C. Interview with the technical consultant #2 on August 23, 2021 at 1140 hours confirmed the laboratory was not enrolled in PT for RF and had never done PT for that. D. Email from technical consultant #2 on August 26, 2021 acknowledged the laboratory performed 81 RF tests annually.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, proficiency testing records, and interview the laboratory failed to ensure one of 5 testing personnel participated in proficiency testing (PT). Findings follow. A. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #5 was performing routine chemistry, Complete Blood Count (CBCs), urine drug screens, and serum pregnancy testing in the laboratory. B. Review of the American Proficiency Institute (API) records from the 1st, 2nd, and 3rd events of 2020 and the 1st event of 2021 showed only testing personnel #1-4 rotated for the respective PT. C. Interview with the technical consultant #2 on August 23, 2021 at 1140 hours acknowledged the laboratory had MTs (Medical Technologists), and rotated PT among the MTs in the lab, and confirmed testing personnel #5 was the only person not rotated in for PT.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, blood gas test reports, interview, and observation, the laboratory failed to have a mechanism to document the accurate collection and received times for blood gases performed on the OPTI-CCA for 7 of 8 test reports. Findings follow. A. Review of the OPTI-CCA Operator's Manual under Specimen Collection and Handling for OPTI Medical ComfortSamplers stated, "After collection, the ComfortSampler should be caped and transported in a horizontal position to the instrument for analysis within 30 minutes, as with all specimens collected in capillary tubes." B. Review of the blood gas test reports from 04/05/2021 to 08/23/2021 showed 7 of 8 test reports collection and received times were entered incorrectly. 1. MR# 74726 ordered 8/12/2021 at 0338, collected 8/12/2021 at 0359, received 8/12/2021 at 0443, resulted 8/12/2021 at 0446. Review of the instrument print out showed the blood gas was performed on 8/12/2021 at 0342. 2. MR# 77658 ordered 7/22/2021 at 1942, collected 7/22/2021 at 2113, received 7/22/2021 at 2113, resulted 7/22/2021 at 2117. Review of the instrument print out showed the blood gas

	was performed on 7/22/2021 at 2056. 3. MR# 60454 ordered 6/15/2021 at 2221, collected 6/15/2021 at 2251, received 6/16/2021 at 0435, resulted 6/16/2021 at 0436. Review of the instrument print out showed the blood gas was performed on 6/15/2021 at 2236. 4. MR# 79058 ordered 6/08/2021 at 2311, collected 6/09/2021 at 0021, received 6/09/2021 at 0421, resulted 6/09/2021 at 0423. Review of the instrument print out showed the blood gas was performed on 6/09/2021 at 0009. 5. MR# 2352 ordered 5/15/2021 at 2247, collected 5/16/2021 at 0103, received 5/16/2021 at 0103, resulted 5/16/2021 at 0105, Review of the instrument print out showed the blood gas was performed on 5/15/2021 at 2311. 6. MR# 74391 ordered 4/19/2021 at 1854, collected 4/19/2021 at 1855, received 4/20/2021 at 0425, resulted 4/20/2021 at 0420, Review of the instrument print out showed the blood gas was performed on 4/19/2021 at 1839. 7. MR# 100727 ordered 4/05/2021 at 0914, collected 4/05/2021 at 1325, received 4/05/2021 at 1325, resulted 4/05/2021 at 1327, Review of the instrument print out showed the blood gas was performed on 4/05/2021 at 0932. C. Interview with technical consultant #2 on August 23 at 1700 hours in the laboratory acknowledged they received electronic orders in the lab for blood gases and go to the Emergency Room to run the samples. Interview with the technical consultant on August 24 at 0950 hours in the Common Room of the Emergency Room acknowledged the nursing staff drawing the blood gases do not provide the laboratory with the collection time, and after a review of the findings that "they [laboratory] could do a better job with the times." NOTE: On August 24 at 0940 in the Common Room, the surveyor observed the OPTI CCA blood gas analyzer was 6 minutes behind the actual time.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the blood banking temperature chart wheels, and interview, the laboratory failed to provide documentation that the blood bank refrigerator was monitored for 16 days over a period of 3 1/2 months. Findings follow. A. Review of the blood bank refrigerator temperature chart wheels from 05/04/2021 - 08/24/2021 showed a gap from 08/06/2021 - 08/17/2021, 07/01/2021 - 07/06/2021, and 05/25 /2021 @ 8am - 05/26/2021 at 12. B. Interview with the technical consultant #2 on August 24, 2021 at 1300 hours confirmed the gaps and confirmed they do not have a certain day of the week that they change the chart and had given the responsibility to the night shift to perform.