Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0507318	01/15/2019
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessment policy, testing personnel competency assessment records, and interview with facility personnel, the laboratory failed to follow the approved competency assessment policy to have a qualified technical consultant perform the annual competency on 4 of 9 testing personnel in 2018. The findings included: 1. Based on review of the laboratory's policy titled "COMPETENCY POLICY", revision approved by the laboratory director on 2/18 /2016, the policy stated the following: "POLICY: Competency is the ability of personnel to apply their skill, knowledge and experience to perform their laboratory duties correctly. Six procedure are required for each analyte or test platform. These include - 1. Direct Observation 2. Monitoring the recording and reporting of results. 3. Review of intermediate test results or worksheets, QC, proficiency testing records, etc. 4. Direct observation of maintenance. 5. Assessment of test performance with previous run samples or proficiency samples. 6. Assessment of problem solving abilities. Competency is required after orientation, at six months and annually thereafter. Competency will be added to the yearly checklist which is posted in laboratory. The Technical Consultant is responsible for assessing and documenting competency on testing person. Lab Director is responsible for assessing competency of Technical Consultant". 2. Based on a review of testing personnel competency records: The competency of Testing Person 6 was performed on 10/01/2018 The competency of Testing Person 7 was performed on 9/24/2018. The competency of Testing Person 8 was performed on 9/26/2018. The competency of Testing Person 9 was performed on 9/27/2018. Each of the 4 competency assessment documents

	indicate a column "Employee Self-Evaluation" with a check next to each component. The listed components do not contain the 6 required procedures of Direct Observations, Monitoring the recording and reporting of results, Review of intermediate test results or worksheets, QC, proficiency testing records, Direct observation of maintenance, Assessment of test performance with previous run samples or proficiency samples, or Assessment of problem solving abilities. Each of the 4 competency assessment documents was signed by Testing Person 5 in the "Instructor Initials" column. Testing Person 5 does not meet the personnel requirements at 42 CFR 493.1411 Technical Consultant Qualifications. 3. In an interview at 10:30 hours on 1/15/2019 in the conference room, the Technical Consultant stated that she had not performed the competency assessments for Testing Persons 6, 7, 8, and 9 for 2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Opti-CCA blood gas analyzer operator's manual, laboratory maintenance records, and interview with facility personnel, the laboratory failed to replace the peristaltic pump cartridge annually in 2018. As of the date of survey, January 15, 2019, the laboratory had not documented and replaced the peristaltic pump cartridge for one (1) year, seven (7) months, and fourteen (14) days between June 7, 2017 and January 15, 2019. The findings included: 1. Based on review of the Opti-CCA blood gas analyzer operator's manual (PD7202 Rev. B), on page 25, the operator's manual states the following: "Annually Replace the peristaltic pump cartridge and gas I/O port." 2. Based on a review of laboratory maintenance records, the peristaltic pump cartridge was replaced on June 1, 2017. Based on review of maintenance records for July 2017 through January 15, 2019, the laboratory did not document and replace the peristaltic pump, as required by the manufacturer. 3. In an interview at 14:10 hours on 1/15/2019 in the conference room, the Technical Consultant and General Supervisor confirmed there was no other documentation of the laboratory changing the peristaltic pump cartridge on the Opti-CCA blood gas analyzer.
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. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory Individualized Quality Control Plan (IQCP) for reduced quality control frequency on the Opti-CCA blood gas analyzer, quality control records, and interview with facility personnel, the laboratory failed to 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 for one (1) year and seven (7) months between June 2017 and January 15, 2019. The findings included: 1. Based on review of the laboratory's Individualized Quality Control Plan (IQCP) for reduced quality control frequency on the Opti-CCA blood gas analyzer, approved by the laboratory director on 4/28/2016, the document states: "Action: Laboratory Personnel will document: Room Temperature (22 - 28 Celsius) Internal Control - SRC done each day of use External Control - With each kit and each month on log sheet Instrument is not moved from the room THB calibration performed every 3 months and documented." The Quality Control Plan (QCP) did not indicate the number and type of controls, criteria for acceptability, actions to take if quality control materials did not meet established acceptability limits (including patient remediation), or a method to 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. 2. Based on a review of quality control records from June 2017 through January 15, 2019, the laboratory documented the following: June, July, and August of 2017, the laboratory documented "pass" for control levels 1, 2, and 3. September 2017, the laboratory documented "pass" for control levels 1 and 2. There is no level 3 "pass" for September 2017. For October 2017 through December 2018, the laboratory documented "pass" for control levels 1, 2, and 3. 3. In an interview at 14:10 hours on 1 /15/2019 in the conference room, the Technical Consultant stated the laboratory monitored the accuracy and precision of most control materials over time in a software program but the Opti-CCA control materials had not been a part of this program.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Acetest instructions for use, quality control records, patient records, and interview with facility personnel, the laboratory failed to use a control material of a similar matrix to serum for 3 of 3 patients tested between November 2017 and December 2018. The findings included: 1. Based on the laboratory's procedure "ACETEST REAGENT TABLETS", revision approved by the laboratory director on 8/6/2015, under QUALITY CONTROL, the document states: "For best results, performance should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Negative and positive specimens or controls may also be randomly hidden in each batch of specimens tested." 2. Based on review of the instructions for use for the Acetest Reagent Tablets, revised (08/10), under SUMMARY AND EXPLANATION, the document states: "ACETEST reagent tablets from Bayer are composed of several

	ingredients, and are primarily used to test for the presence of ketones (acetoacetic acid and acetone) in urine. Serum, plasma or whole blood may also be tested with ACETEST reagent tablets for the presence of ketones." 3. In an interview at 14:45 hours on 1/15/2019 in the laboratory, the General Supervisor stated that quality control was performed each day of patient testing. When the surveyor asked what quality control materials were used, the General Supervisor stated the laboratory used Bio-Rad qUAntify Plus Controls. Based on a review of the Bio-Rad qUAntify Plus Controls instructions for use (Rev 2018/05), under INTENDED USE the document states: "The qUAntify Plus Controls are intended for use as an assayed control material for the precision of urinalysis test procedures for the analytes listed in this package insert." 3. Based on review of quality control and patient records, the laboratory performed quality control with the Bio-Rad qUAntify Plus Controls each day of patient testing for 3 of 3 patients tested on the following dates: Date: 11/27 /2017 Specimen: SPC#1287164 Specimen type: Serum Date: 08/07/2018 Specimen: LAB 35652 Specimen type: Serum Date: 12/29/2018 Specimen: LAB 53520 Specimen type: Serum 4. In an interview at 14:45 hours on 1/15/2019 in the laboratory, the General Supervisor stated that the laboratory did not have a control material of a similar matrix to serum.