Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475880	07/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Holdenville General Hospital	100 Mcdougal Drive, Holdenville, OK	

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	The recertification survey was performed on 07/08/2021 and 07/09/2021. The findings were reviewed with the chief executive officer, general supervisor/technical consultant #2, the laboratory manager, testing person #3, testing person #4, testing person #5, and the phlebotomist during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for the Dimension EXL 200 analyzer. Findings include: (1) On 07/08/2021 at 10:05 am, the laboratory manager stated to surveyor #1 *CMP, *Lipid Profile, Amylase, Pro-BNP (B-Type Natriuretic Peptide), CK (Creatine Kinase), CKMB, Direct Bilirubin, Lactic Acid, Hemoglobin A1c, Magnesium, Phosphorus, PSA (Prostate Specific Antigen), Uric Acid, and Troponin I testing were performed on the Siemens Dimension EXL 200 analyzer; (2) On 07/09/2021, surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's weekly maintenance log titled, "Dimension EXL Weekly and Monthly Maintenance". The weekly requirements were as follows: (a) Clean Outside of R2 Probe (b) Clean Outside of HM Wash Probes (3) Surveyor #1 then reviewed maintenance records from February 2020 through June 2021. The weekly maintenance had not been documented as performed between: (a) 04/23/2020 and 05 /08/2020 (b) 03/25/2021 and 04/06/2021 (4) Surveyor #1 reviewed the findings with

	the laboratory manager who stated on 07/09/2021 at 12:45 the weekly maintenance had not been documented as performed as identified above. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein *Lipid Profile - Total Cholesterol, HDL Cholesterol, Triglyceride
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure IQCP's included the required components. Findings include: (1) On 07/08/2021 at 10:00 am, the laboratory manager stated to the following to surveyor #1: (a) The following testing was performed using 2 iSTAT 1 analyzers (Serial Numbers 390874 and 418361): (i) pH, pCO2, pO2, and Lactate testing using the CG4+ test cartridge; (ii) Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, Creatinine, Hemoglobin, and Hematocrit testing using the Chem 8+ test cartridge; (iii) Troponin I testing using the CTnI test cartridge. (b) An IQCP had been developed for the test systems. (2) Surveyor #1 reviewed the IQCP for the test systems and identified a QA plan had not been included in the IQCP (it consisted of a Risk Assessment and QCP only); (3) Surveyor #1 reviewed the records with the laboratory manager who stated on 07/08/2021 at 12:30 pm, a QA plan had not been included in the IQCP.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 a review of records, manufacturer's instructions, and interview with the general supervisor/technical consultant #2 and testing person #1, the laboratory failed

	to have procedures to detect an ABO incompatibility between the donor's cell type and the recipient serum or plasma type for 41 of 41 patients. Findings include: (1) On 07/08/2021 at 09:50 am, testing person #1 stated to surveyor #1 the Ortho MTS Anti-IgG gel card was used to perform patient antibody screen and compatibility testing; (2) On 07/09/2021, surveyor #2 reviewed the manufacturer's instructions contained in the package insert for the MTS Anti-IgG gel cards. The instructions stated, "The MTS Anti-IgG Gel Test System can be used in both direct and indirect antiglobulin test systems to detect the presence or absence of IgG on human red blood cells"; (3) Surveyor #2 then reviewed the blood bank log book for patient compatibility testing performed from 01/04/2021 through 07/07/2021. For 41 of 41 patients reviewed (76 of 76 units), the records indicated the laboratory only used the Anti-IgG gel cards to perform patient compatibility testing, and therefore, did not include a method to detect ABO incompatibilities based on IgM antibodies (in order to achieve this, an immediate spin crossmatch, containing the donor's red blood cells and the recipient's serum or plasma, or an electronic crossmatch must be performed in conjunction with the IgG crossmatch); (4) The findings were reviewed on 07/09/2021 with the general supervisor/technical consultant #2 and testing person #2. Both stated on 07/09/2021 at 12:35 pm they were not aware that an immediate spin crossmatch must be performed to detect IgM antibodies; (5) Days of patients in which an immediate spin crossmatch had not been performed were: (a) 01/04/2021 - 2 units crossmatched (b) 01/12/2021 - 2 units crossmatched (c) 01/13/2021 - 2 units crossmatched (d) 01/18/2021 - 2 units crossmatched (e) 01/23/2021 - 2 units crossmatched (f) 01/24/2021 - 2 units crossmatched (g) 02/12/2021 - 2 units crossmatched (h) 02/19/2021 - 2 units crossmatched (i) 02/24/2021 - 2 units crossmatched (j) 02/26/2021 - 1 unit crossmatched (k) 03/05/2021 - 2 units crossmatched (l) 03/08/2021 - 2 units crossmatched (m) 03/09/2021 - 2 units crossmatched (n) 03/13/2021 - 2 units crossmatched (o) 03/15/2021 - 2 units crossmatched (p) 03/17/2021 - 2 units crossmatched (r) 03/20/2021 - 1 unit crossmatched (s) 03/22/2021 - 2 units crossmatched (t) 03/23/2021 - 2 units crossmatched (u) 03/25/2021 - 2 units crossmatched (v) 03/28/2021 - 2 units crossmatched (w) 04/05/2021 - 2 units crossmatched (x) 04/06/2021 - 2 units crossmatched (y) 04/07/2021 - 2 units crossmatched (z) 04/14/2021 - 2 units crossmatched (aa) 04/16/2021 - 2 units crossmatched (bb) 04/19/2021 - 2 units crossmatched (cc) 04/28/2021 - 2 units crossmatched (dd) 05/04/2021 - 2 units crossmatched (ee) 05/10/2021 - 2 units crossmatched (ff) 05/20/2021 - 2 units crossmatched (gg) 05/24/2021 - 1 unit crossmatched (hh) 05/25/2021 - 2 units crossmatched (ii) 06/02/2021 - 1 unit crossmatched (jj) 06/14/2021 - 2 units crossmatched (kk) 06/15/2021 - 2 units crossmatched (ll) 06/17/2021 - 2 units crossmatched (mm) 06/18/2021 - 2 units crossmatched (nn) 06/19/2021 - 2 units crossmatched (oo) 07/07/2021 - 2 units crossmatched NOTE: The following reference was published in the CLIA Network Newsletter dated July-August 2009: "The gel card only detects incompatibility based on IgG antibodies. It does not detect incompatibility based on IgM antibodies, which is important in determining ABO compatibility. Therefore, the use of the gel card alone is not adequate to demonstrate incompatibility between the donor's cell type and the recipient's serum type, and the laboratory must also perform an immediate spin or electronic crossmatch to determine ABO compatibility." NOTE: The Interpretive Guidelines at 493.1271 requires standard operating procedures for compatibility testing: "Procedures to demonstrate incompatibility between the donor's cell type and the recipients's serum or plasma type. These procedures may consist of a serologic crossmatch, or a computer crossmatch."
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient report and interview with the general supervisor /technical consultant #2 and testing person #1, the laboratory failed to provide normal reference intervals for 1 of 1 Wet Prep test reports. Findings include: (1) On 07/08 /2021 at 09:5 am, testing person #1 stated to surveyor #1 Wet Prep testing was performed in the laboratory; (2) Surveyor #2 reviewed one Wet Prep report for a patient tested on 07/07/2021 at 12:14 pm. The report did not include a normal reference range for Clue Cells and Trichomonas; (3) Surveyor #2 reviewed the report with testing person #1, who stated on 07/08/2021 at 01:10 pm, Wet Prep reports did not include a normal reference range for Clue Cells and Trichomonas as indicated above.