Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472440	05/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Elkview General Hospital	429 West Elm, Hobart, 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 05/26,27,28/2021. The findings were reviewed with the laboratory director, laboratory manager, and hospital's chief executive officer during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. 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 implementing a new reagent. Findings include: (1) On 05/27/2020 at 10:05 am, the laboratory manager stated the following to the surveyor: (a) PTT (Partial Thromboplastin Time) was performed using the ACL Elite analyzer; (b) PTT reagent - Synthasil lot # N0101206 had been put into use on 07/31/2020. (2) The surveyor reviewed the manufacturer's implementation instructions for establishing a normal reference range which stated: (a) "Reference Intervals should be established or verified, as appropriate, whenever there is a change in:" (i) "Instrumentation and/or methodology" (ii) "Lot number of reagent" (iii) "Sample collection tubes" (iv) "At least once a year" (b) "Reference Interval ...refers to the 95% confidence limits of the Reference Range (ie. the means 2SD)."; (c) "Either 120 or 20 normal donors following these screening guidelines:" (i) "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments)." (ii) "Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen

	therapy (HRT), anticoagulants, high dose aspirin, etc." (iii) "Donors should span the adult age range. Pediatric ranges should be established separately." (iv) "Donors should be equally divided between male/female." (3) The survey reviewed the PTT reagent implementation records and identified the following: (a) The laboratory had established a PTT normal reference interval of 23.59 - 32.67 seconds. (4) The surveyor then reviewed a patient PTT report dated 05/23/2021 with a normal reference range of 29.4 - 37.9 seconds; (5) The surveyor surveyor reviewed the findings with the laboratory manager. On 05/28/2021 at 11:05 am, the laboratory manager stated that although the laboratory had established a PTT normal reference interval with a PTT reagent lot change, the laboratory had not implemented the change into the laboratory's computer information system.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's operators manual, manufacturer's product information for use, and interview with the laboratory manager, the laboratory failed to ensure the demonstrated reportable range was utilized for CK-MB, CRP (C-Reactive Protein), Troponin I, D-Dimer, Routine Complete Blood Count, and Arterial Blood Gas testing. Findings include: (1) On 05/27/2021 at 10:30 am, the laboratory manager stated the following to the surveyor: (a) Arterial Blood Gas (pH, pCO2, and pO2) testing was performed using the Nova Biomedical Stat Prime and available for patient use on 11/15/2019; (b) CK-MB, Troponin I, and D-Dimer testing was performed using the Quidel Triage Meter Pro replacement analyzer and available for patient use on 02/11/2020; (c) CRP (C-Reactive Protein) testing was performed using the Vitros 350 analyzer and available for patient use on 01/21/2021; (d) Routine CBC (Complete Blood Count) was performed using the Sysmex XN-350 analyzer and available for patient use on 02/06/2021. (2) The surveyor reviewed the performance specification records for the analyzers. The reportable range were verified as follows: (a) CK-MB (i) The laboratory verified 2.0 - 49.5 ng/mL (ii) The manufacturer's reportable range was 1.0 - 80 ng/mL (b) CRP (C-Reactive Protein) (i) The laboratory verified 6.0 - 89 mg/L (ii) The manufacturer's reportable range was 5.0 - 90 mg/L (d) Troponin I (i) The laboratory verified 0.10 - 21.8 ng/mL (ii) The manufacturer's reportable range was 0.05 - 30 ng/mL (e) D-Dimer (i) The laboratory verified 182 - 4400 ng/mL (ii) The manufacturer's reportable range was 100 - 5000 ng/mL (f) CBC (Hemoglobin, Hematocrit, Platelet, White Blood Cells, Red Blood Cells, and etc.) (i) Hemoglobin - The laboratory verified 0.0 - 24.8 g/dL (aa) The manufacturer's reportable range was 0.1 - 26.0 g/dL (g) Arterial Blood Gas (i) pH - The laboratory verified 6.74 - 7.57 (aa) The manufacturer's reportable range was 6.50 - 8.0 (ii) pCO2 - The laboratory verified 17.4 - 130.2 mmHg (aa) The manufacturer's reportable range was 23.0 - 200 mmHg (iii) pO2 - The laboratory verified 22.9 - 303.6 mmHg (aa) The manufacturer's reportable range was 5.0 - 765 mmHg (3) The surveyor reviewed the performance specification with the laboratory manager and asked the laboratory

	manager if there was documentation to prove the laboratory was utilizing the reportable ranges that had been demonstrated by the laboratory; (4) On 05/27/2020 at 10:15 am, the surveyor and laboratory manager then observed the linearity values in the LIS (laboratory information system) and identified the following: (a) There were no values in the LIS; (b) The laboratory manager stated on 05/27/2021 at 10:25 am that since there were no values in the LIS, the laboratory was using the manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory.
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 a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for coagulation testing for 2 of 2 lot numbers. Findings include: (1) On 05/27/2020 at 10:05 am, the laboratory manager stated the following to the surveyor: (a) PT/INR (Protime/International Normalized Ratio) and PTT (Partial Thromboplastin Time) were performed on the ACL Elite analyzer; (b) Two levels of Hemosil QC (Quality Control) materials (level 1 and level 3) were tested each eight hours of patient testing; (c) Established ranges were used for determining acceptability of QC results. (2) The surveyor reviewed QC records for the current lot numbers of control materials used for patient testing and identified the following: (a) Hemosil Level 1 (Lot# N0595853) and Level 3 (lot #N0696468) - put into use on 08/01/2020 and were currently in use; (b) Hemosil Level 3 - The laboratory had established the following mean and acceptance range for PT and PTT: (i) PT - Mean of 34.85 seconds with an acceptance range between 33.19 to 36.51 seconds; (ii) PTT - Mean of 52.54 seconds with an acceptance range between 50.42 to 54.66 seconds. (3) The surveyor reviewed QC records from the analyzer and identified the following: (a) Hemosil Level 3 - The laboratory had not implemented the established mean and acceptance range for PT and PTT; (b) The analyzer demonstrated the following means and acceptance ranges as follows: (i) PT- Target mean of 35.9 with an acceptance range between 31.9 to 39.9 seconds; (ii) PTT - Target mean of 54.9 seconds with an acceptance range between 52.1 to 57.7 seconds. (4) The surveyor reviewed the findings with the laboratory manager who stated on 05 /28/2021 at 11:05 am the laboratory had established their own means and limits of acceptability, but had not implemented the established means and limits of acceptability. The laboratory manager explained the current means and acceptance ranges for Level 3 PT and PTT quality control values were from the previous Level 3 quality control lot# N0177403.

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 perform quality control as stated in the IQCP for Urine Drug Screen and D-dimer testing. Findings include: URINE DRUG SCREEN (1) On 05/27 /2021 at 09:50 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed Urine Drug Screen testing using the MedTox analyzer; (i) Two levels of quality control materials were tested weekly, according to the laboratory IQCP (Individualized Quality Control Plan); (ii) The results for two levels of control materials must be acceptable in order to report patient results. (2) The surveyor reviewed Urine Drug Screen quality control records for testing performed from January 2019 through April 2021. For the review period, the following was identified for 9 of 28 months: (a) Weekly quality control results could not be located for the following: (i) Between 04/16/2019 and 05/13/2019 (ii) Between 06/12/2019 and 06/24/2019 (iii) Between 07/01/2019 and 07/15/2019 (iv) Between 09/16/2019 and 09/30/2019 (v) Between 04/06/2020 and 04/20/2020 (vi) Between 05/18/2020 and 06/01/2020 (vii) Between 06/01/2020 and 06/15/2020 (viii) Between 07/27/2020 and 08/10/2020 (ix) Between 11/03/2020 and 11/17/2020 (3) The surveyor reviewed the records with the laboratory manager, who stated on 05/27/2021 at 01:40 pm quality control had not been performed as stated in the IQCP. D-DIMER TESTING (1) On 05 /27/2021 at 09:55 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed D-Dimer testing using the Alere Triage analyzer; (i) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (ii) The results for two levels of control materials must be acceptable in order to report patient results. (2) The surveyor reviewed D-Dimer quality control records for testing performed from January 2019 through April 2021. For the review period, the following was identified for 1 of 28 months: (a) Monthly quality control results could not be located for the following: (i) Between 03/02/2019 and 05/02/2019 (3) The surveyor reviewed the records with the laboratory manager, who stated on 05/27/2021 at 02:57 pm quality control had not been performed as stated in the IQCP.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (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 perform control procedures each day of blood bank testing for 2 of 6 days of patient testing. Findings include: (1) On 05/27/2021 at 10:00 am, the laboratory manager stated to the surveyor the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)) using the tube method; (2) The surveyor reviewed records for blood bank testing performed between 10/29/2020 through 11/06/2020 and identified quality control had not been performed for 2 of 6 days when patient Type and Screen or Crossmatch testing had been performed as follows: (a) Patient #1 - A Type and Screen was performed on 10/31 /2020; (b) Patient #2 - A Type and Screen and Crossmatch was performed on 11/02 /2020. (3) The surveyor reviewed the records with the laboratory manager. On 05/27 /2021 at 04:30 pm, the laboratory manager stated quality control had not been performed as indicated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 3 of 4 testing persons. Findings include: (1) On 05/27/2021 at 09:50 am, the laboratory manager stated to the surveyor urine sediment examinations were performed in the laboratory; (2) The surveyor then reviewed personnel records for 4 persons performing urine sediment examinations in the laboratory. The records showed that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 05/11/2020 and 05/06/2021 (b) Testing Person #2 - Performed on 05/23 /2020 and 04/30/2021 (c) Testing Person #4 - Performed on 05/11/2020 and 02/15 /2021 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of the urine sediment examinations; (4) The surveyor reviewed the findings with laboratory manager, who stated on 05/27/2021 at 01:13 pm the above evaluations did not include urine sediment examinations.