

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472440	(X3) Date Survey Completed 11/18/2022
Name of Provider or Supplier Elkview General Hospital	Street Address, City, State 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 11/16,17,18/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with laboratory director and laboratory manager during an exit conference performed at the conclusion of the survey.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>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 implementation instructions to ensure the mean of the normal range was accurately entered into the analyzer for one of one PT reagent lot change. Findings include: (1) On 11/16/2022 at 02:45 pm, the laboratory manager stated PT/INR (Prothrombin Time/International Normalized Ratio) testing were performed using the ACL Elite analyzer (the INR was calculated using the PT reference interval mean); (2) On 11/17/2022 at 03:35 pm, the laboratory manager stated the PT reagent, HemosIL RecombiplasTIN 2G, was put into use on 01/31/2022; (3) A review of the ACL Elite/Elite Pro Operator's Manual in the section titled, "ACL Elite/Elite Pro Technical Bulletin Important INR Notice" stated: (a) "PT NORMAL = Mean of the Normal Range (on the ACL Elite/Elite Pro this is called the Reference Value)"; (b) "To assure appropriate reporting of INR results, you must follow these steps"; (c) "Select CALCULATION SETUP and the instrument will show in the right part of the screen the selection of the REFERENCE VALUE. This represents the Mean of Normal Population value in SECONDS, which is used as the DENOMINATOR in the RATIO and INR CALCULATION"; (d) Make</p>

sure that the value entered in this field represents the MEAN NORMAL POPULATION RANGE of the local PT population. This value is editable and can be modified to reflect the laboratory established mean normal range". (4) A review of the implementation records for the reagent lot change identified the mean of the normal range that had been calculated by the laboratory was 11.6; (5) Observation of the mean of the normal range (reference value) that had been programmed into the analyzer, with the assistance of the laboratory manager on 11/17/2022 at 03:50 pm, identified the value had been entered as 11.9; (6) The findings were reviewed with the laboratory manager who stated on 11/18/2022 at 09:40 am, the mean of the normal range of 11.9 that had been entered into the analyzer was not correct and should have been entered as 11.6.

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 and interview with the laboratory manager, the laboratory failed to utilize the demonstrated reportable ranges for three of ten analytes reviewed for the new Ortho Vitros 3400 analyzer. Findings include: (1) On 11/18 /2022 at 10:00 am, the laboratory manager stated the laboratory began performing routine chemistry testing, which included the analytes Amylase, AST (Aspartate Amino Transferase), and Glucose, using the Ortho Vitros 3400 analyzer in April 2022; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Amylase - 39.2-924.4 U/L (b) AST - 15.2-727 U/L (c) Glucose - 31.2-597.4 mg/dl (3) Review of the reportable ranges programmed into the LIS (Laboratory Information System) and interview with the laboratory manager on 11/18/2022 at 11:00 am, confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) Amylase - 30-1200 U/L (b) AST - 3-750 U/L (c) Glucose - 20-625 mg/dl

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 on one of two analyzers reviewed. Findings include: (1) On 11/16/2022 at 02:45 pm, the laboratory manager stated PT/INR

(Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the ACL Elite analyzer; (2) On 11/17/2022, a review of the "ACL Elite/Elite Pro Operator's Manual" in Section 5 titled "Diagnostics and Maintenance" required the following weekly maintenance procedures: (a) Instrument External Surfaces Cleaning (b) Rinse Reservoir Cleaning (3) A review of maintenance records from June 2021 through October 2022 identified the weekly maintenance had not been documented as performed between: (a) 07/04 /2022 and 07/18/2022 (b) 08/08/2022 and 08/24/2022 (4) The records were reviewed with the laboratory manager who stated on 11/17/2022 at 03:36 pm, the weekly maintenance had not been documented as performed.

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 and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for PT testing for eight of eight months. Findings include: (1) On 11/16/2022 at 02:45 pm, the laboratory manager stated PT/INR (Prothrombin Time/International Normalized Ratio) testing were performed using the ACL Elite analyzer; (2) On 11/17 /2022 at 03:50 pm, the laboratory manager stated the following two levels of control materials were performed each eight hours of patient testing and were put into use on 03/05/2022: (a) HemoSIL Normal Control level 1 Lot #N0202108 and HemoSIL Abnormal Control level 3 lot #N0101547. (3) On 11/18/2022, a review of QC (Quality Control) records for patient testing performed from 04/01/2022 through 11/17 /2022 identified the following for one of two levels of QC (HemosIL Abnormal Control 3): (a) A two SD (Standard Deviation) range of 34.68-37.72 had been established by the laboratory when the lot number had been put into use. A range of 28.0-46.7 had been used to evaluate QC results during the review period, which was beyond the established range; (4) The records were reviewed with the laboratory manager who stated on 11/18/22 at 10:20 am, the laboratory had used a range wider than the established range to evaluate QC results as shown above.

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 one of 34 days of patient testing reviewed; and failed to perform a positive AHG control 34 of 34 days of blood bank testing reviewed. Findings include: CONTROL PROCEDURES (1) On 11/16/2022 at 02:00 pm the laboratory manager stated Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)) was performed using the tube method; (2) On 11/17/2022, a review of records for blood bank testing performed between 01/16/2022 and 10/17/2022 identified QC (Quality Control) had not been performed for one of 34 days of patient Crossmatch testing. The specific day was 08/30/2022; (3) The records were reviewed with the laboratory manager who stated on 11/17/2022 at 02:28 pm, QC had not been performed on 08/30/2022. POSITIVE AHG CONTROL (1) On 11/16/2022 at 02:00 pm, the laboratory manager stated the laboratory utilized the AHG (Anti-Human Globulin) reagent to perform Antibody Screen and Compatibility testing using the tube method; (2) On 11/17/2022, a review of records for testing performed from 01/16/2022 through 10/17/2022 identified a positive AHG control had not been performed 34 of 34 days of patient testing reviewed. The specific days were 01/16,19,31/2022; 02/01,09,10,14,22,24/2022; 03/09,16,30/2022; 04/01,10,20,27/2022; 05/05,12,16,22/2022; 06/27/2022; 07/03,17,27/2022; 08/03,11,23,30/2022; 09/08,15,19/2022; 10/09,13,17/2022 (3) The records were reviewed with the laboratory manager who stated on 11/17/2022 at 02:40 pm, a positive AHG control was not being performed.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a review of records, MedTox Scan Drugs of Abuse test system package insert, and interview with the laboratory manager, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for one of one patient report. Findings include: (1) On 11/18/2022 at 10:35 am, the laboratory manager stated Urine Drug Screen testing was performed using the Profile V Medtox Scan Drugs of Abuse test system; (2) A review of the Profile V Medtox Scan Drugs of Abuse test package insert stated, "The Profile-V MedTox Scan Drugs of Abuse test system provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass

spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained." (3) A review of one patient report with Urine Drug Screen test results reported on 11/17/2022 identified the report did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the laboratory manager who stated on 11/18/22 at 11:00 am, the patient report did not include the disclaimer.