

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0475409	<b>(X3) Date Survey Completed</b>  02/17/2023
<b>Name of Provider or Supplier</b>  Pushmataha Hospital	<b>Street Address, City, State</b>  510 E Main St, Antlers, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 02/15,16,17/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2 at the conclusion of the survey.
<b>D3021</b>	<p><b>REQUIREMENTS FOR TRANSFUSION SERVICES</b> CFR(s): 493.1103(c)(1)</p> <p>Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with technical consultant #2, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator for five of five alarm checks performed from September 2021 through December 2022. Findings include: (1) On 02/15/2023 at 02:30 pm, technical consultant #2 stated the laboratory routinely maintained one unit of O negative and one unit of O positive packed red blood cells in the blood bank refrigerator. The units were available for emergency patient transfusions; (2) A review of the policy titled "Testing Refrigerator Alarm" required the alarm checks be performed on a quarterly basis and stated the following: (a) "Quarterly Refrigerator Low and High Temperature Sensor Activation Test: The recommended low temperature should not be any colder than 1.5 degrees Centigrade and the high temperature should not be any warmer than 5.5 degrees Centigrade". (3) A review of the alarm check records from September 2021 through December 2022 identified the high alarm checks sounded at temperatures beyond the acceptable limit for five of five alarm checks performed as follows: (a) 09/15/2021 - The documented high alarm temperature was 6.8 degrees C (Centigrade) (b) 03/16/2022 - The documented high alarm temperature was 6.5 degrees C (c) 06/08/2022 - The documented high alarm</p>

temperature was 6.3 degrees C (d) 09/07/2022 - The documented high alarm temperature was 6.3 degrees C (e) 12/07/2022 - The documented high alarm temperature was 6.5 degrees C (4) The findings were reviewed with technical consultant #2 who stated on 02/15/2023 at 04:05 pm the documented temperatures for the high alarm checks above were not acceptable.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:  
Based on a review of records and interview with technical consultant #2, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of four Hematology events reviewed. Findings include: (1) On 02/15/2023 a review of proficiency testing records for 2021 and 2022 and identified the following for one of four Hematology events: (a) Second 2022 Event for Educational Blood Cell Identification - One of five results had not been graded by the proficiency testing program; (i) DIF-02 Neutrophil, Band - The laboratory's reported result of 13 did not agree with the "Expected Result" of 0-2. There was no documentation to indicate corrective action had been taken for the unacceptable response. (2) The records were reviewed with technical consultant #2 who stated on 02/16/2023 at 04:10 pm, the laboratory had not evaluated the result that was not graded by the proficiency testing program and corrective action had not been taken as stated above.

**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 technical consultant #2, the laboratory failed to follow the manufacturer's instructions for implementing two of two coagulation reagents. Findings include: (1) On 02/15/2023 at 02:50 pmt technical consultant #2 stated the laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing using the ACL Elite analyzer; (2) On 02/16/2023 at 10:40 am, technical consultant #2 stated the current lot number of reagents were put into use on 06/01/2022: (a) PT Reagent - HemosIL RecombiPlasTIN 2G lot #N1117938 (b) PTT Reagent - HemosIL SynthaSIL lot #N0129380 (3) A review of the manufacturer's instructions contained in the "Hemostasis Performance Manual" stated the following: (a) The section titled, "Establishing A Normal Reference Interval" under the heading "Specimen Collection and Preparation" stated the following for a 20 donor study: (i)

"Donors should be equally divided between male/female". (b) The section titled, "Comparison Study" stated the following: (i) "Normal and abnormal samples are tested"; (ii) "The new methodology or reagents is assessed against the comparative (usually the current) methodology or reagents"; (iii) At least 50% of the samples should be outside of the laboratory normal reference interval, if possible". (4) A review of the implementation records for the PT and PTT reagents identified the following: (a) Normal Reference Interval - The donors were not equally divided between male and female. The laboratory had used 13 male donors and seven female donors; (b) Comparison Study - Although 20 abnormal samples had been tested using the new lot number of reagent, they had not been tested using the new current number of reagent; (5) The records were reviewed with technical consultant #2 who stated on 02/16/2023 at 11:59 am, the laboratory had not followed the manufacturer's instructions for the lot number changes as stated above.

**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 technical consultant #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of three analyzers reviewed from 07/01/2021 through 12/31/2022. Findings include: SYSMEX XP-350 (1) On 02/15/2023 at 02:40 pm, technical consultant #2 stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-350 analyzer; (2) On 02/17/2022, a review of the manufacturer's maintenance log showed the following required weekly maintenance procedure: (a) "Clean SRV Tray" (3) A review of maintenance logs from 07/01/2021 through 12/31/2022 identified weekly maintenance had not been documented as performed between: (a) 08/30/2021 and 09/13/2022 (b) 10/30/2021 and 11/08/2022 (c) 01/14/2022 and 01/25/2022 (d) 08/06/2022 and 08/19/2022 (e) 08/26/2022 and 09/06/2022 (4) The records were reviewed with technical consultant #2 who stated on 02/18/2023 at 09:46 am, the weekly maintenance had not been documented as performed as above. DIMENSION EXL 200 (1) On 02/15/2023 at 02:45 pm, technical consultant #2 stated the laboratory performed Albumin, Ammonia, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Amylase, Total Bilirubin, BUN, Calcium, Chloride, CK (Creatine Kinase), CKMB (Creatine Kinase Isoenzyme), CO2, Creatinine, Glucose, Magnesium, Potassium, Total Protein, Sodium, Troponin I, Uric Acid, Acetaminophen, Direct Bilirubin, Alcohol, Digoxin, Lactic Acid, HCG (Human Chorionic Gonadotropin), Phenytoin, Phosphorus, Salicylate, TSH (Thyroid Stimulating Hormone), and Vancomycin testing using the Siemens Dimension EXL 200 analyzer; (2) On 02/16/2023 a review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) Clean outside of R2 Probe (b) Clean outside of HM Wash Probe (3) A review of maintenance logs from 07/01/2021 through 12/31/2022 identified weekly maintenance had not been documented as performed between: (a) 03/07/2022 and 03/20/2022 (b) 07/29/2022 and 08/08/2022 (4) The records were reviewed with technical consultant #2 who stated on 02/16/2023 at 01:15 pm, the weekly maintenance had not been documented as performed as shown above.

## 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, quality control package inserts, and interview with technical consultant #2, 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 Albumin, Amylase, Calcium, and Magnesium testing for 12 of 12 months reviewed. Findings include: (1) On 02/15/2023 at 02:45 pm, technical consultant #2 stated the following: (a) The laboratory performed Albumin, Amylase, Calcium, and Magnesium testing using the Siemens Dimension EXL 200 analyzer; (2) On 02/16/2023 at 12:45 pm, technical consultant #2 stated the following: (a) Two levels of Bio-Rad Assayed Multiquel QC materials were performed each day of patient testing. (b) When new lot numbers of control materials were put into use, the laboratory established means for each analyte and utilized historic two SD (Standard Deviation) ranges. (3) A review of the manufacturer's instruction (package insert) for the above control materials stated, "The mean values and the corresponding +/-3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides"; (4) A review of QC records for two lot numbers of control materials used during the review period of January 2022 through December 2022 identified the following: (a) Bio-Rad Liquid Assayed Multiquel controls materials, level one lot #45891 and level three lot #45893 - The laboratory was using ranges wider than the package insert guideline ranges for two of two levels of QC materials: (i) Albumin (aa) Level Three - The laboratory was using a range of 3.77-4.57 which was wider than the package insert guideline range of 3.84-4.39; (ii) Amylase (aa) Level One - The laboratory was using a range of 40.2-49.05 which was wider than the package insert guideline range of 41.4-48.2; (iii) Calcium (aa) Level One - The laboratory was using a range of 4.45-7.65 which was wider than the package insert guideline range of 5.43-6.67; (bb) Level Three - The laboratory was using a range of 10.77-14.77 which was wider than the package insert guideline range of 12.2-14.3; (iv) Magnesium (aa) Level Three - The laboratory was using a range of 3.16-5.16 which was wider than the package insert guideline range of 3.64-4.36. (5) The records were reviewed with technical consultant #2 who stated on 02/16/2023 at 02:20 pm, the laboratory was using ranges wider than the package insert guideline ranges and those ranges were currently being used to determine patient acceptability.

