Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1036892	05/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Drumright Community Hospital, Llc	610 West Bypass, Drumright, 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 05/02/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager, testing person #2, and chief executive officer during an exit conference performed at the conclusion of the survey.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with testing person #1, the facility failed to ensure written policies were followed for preventing transfusion reactions for six of six units of packed red-blood cells transfused. Findings include: (1) On 05/2/2025 at 10:00 am, testing person #1 stated blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Administration of blood and blood components" stated: (a) "Vital signs are taken prior to transfusion" (b) "15 minutes after infusion start"; (c) "30 minutes after infusion start"; (d) "One hour after infusion start"; (e) "Two hours after infusion start"; (f) "Three hours after infusion start"; (g) "At the end of the transfusion"; (h) "1-hour post transfusion"; (i) "4 hours post transfusion", (j) "Blood must be infused within four hours of issue". (3) A review of transfusion records for six units transfused, identified the policy had not been followed for six of six units as follows: (a) Unit #W091024425471 - The transfusion started on 12/02/2024 at 10:40 pm. Vital signs had not been documented as follows: (i) One hour post-transfusion vital signs - Not documented; (ii) Four hour post-transfusion vitals - Not documented. (b) Unit #W091024389665 - The transfusion started on 12/02/2024 at 07:14 pm. Vital signs had not been taken as

	follows: (i) One hour post transfusion vital signs - not documented; (ii) Four hour post transfusion vital signs - not documented. (c) Unit #W091024132327 - The transfusion started on 02/08/2024 at 10:50 am. Vital signs had not been taken as follows: (i) One hour post transfusion vital signs - not documented; (ii) Four hour post transfusion vital signs - not documented. (d) Unit #W091024135897 - The transfusion started on 02/08 /2024 at 03:17 pm. Vital signs had not been taken as follows: (i) One hour post transfusion vital signs - not documented; (ii) Four hour post transfusion vital signs - not documented. (e) Unit #W091025111809 - The transfusion started on 03/26/2025 at 05:25 am. Vital signs had not been taken as follows: (i) One hour post transfusion vital signs - not documented; (ii) Four hour post transfusion vital signs - not documented. (f) Unit #W091025164453 - The transfusion started on 03/26/2025 at 01: 55 pm. Vital signs had not been taken as follows: (i) One hour post transfusion vital signs - not documented; (ii) Four hour post transfusion vital signs - not documented. (4) The records were reviewed with the chief executive officer and testing person #1 who stated on 05/02/2025 at 10:00 am, the vital signs had not been documented according to policy.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for two of four Chemistry proficiency testing events reviewed in 2024 and 2025. Findings include: (1) On 04/30/2025, a review of Chemistry proficiency testing records for 2024 (first, second, and third events) and 2025 (first event) identified the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program) for one of five events: (a) 2024 - Chemistry Core 3rd Event (i) Total Bilirubin - five of five results exhibited a negative bias (aa) Sample CH-01 - SDI of -3.1 (bb) Sample CH-02 - SDI of -6.4 (cc) Sample CH-03 - SDI of -8.6 (dd) Sample CH-04 - SDI of -3.3 (ee) Sample CH-05 - SDI of -2.5 (b) 2025 - Chemistry Core 1st Event (i) Total Bilirubin - five of five results exhibited a negative bias (aa) Sample CH-01 - SDI of -5.8 (bb) Sample CH-02 - SDI of -5.4 (cc) Sample CH-03 - SDI of -2.9 (dd) Sample CH-04 - SDI of -2.6 (ee) Sample CH-05 - SDI of -5.2 (2) There was no evidence in the records to prove the biases had been identified and addressed; (3) The records were reviewed with testing person #1 who stated on 04/30 /2025 at 01:40 pm, the biases had not been identified and addressed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the

	laboratory manager and testing person #2, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for 12 of 12 lot numbers used during the review period of May 2024 through February 2025. Findings include: (1) On 04/29/2025 at 01:15 pm, the laboratory manager stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 analyzer; (b) Three levels of Sysmex Eightcheck-3WP X-Tra QC (Quality Control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of the "Laboratory Procedure Manual" identified a policy titled "Complete Blood Count (CBC) Sysmex", in the procedure section which stated "Parallel test new controls by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated and values are running within assay ranges, the lot may be placed into production. The new lot will be validated prior to the current lot expiration." (3) A review of records for 12 lot numbers used from May 2025 through February 2025 identified no documentation to prove 12 of 12 lot numbers had been implemented per policy: (a) Low-level lot #41360710, normal-level lot #41360711, and high-level lot #41360712 - The controls had been parallel tested once on 05/29 /2024 prior to implementation on 05/30/2024; (b) Low-level lot #42200710, normal-level lot #42200711, and high-level lot #42200712 - The controls had been parallel tested once on 08/22/2024 prior to implementation on 08/23/2024; (c) Low-level lot #43040710, normal-level lot #43040711, and high-level lot #43040712 - The controls had been parallel tested once on 11/13/2024 prior to implementation on 11/14/2024; (d) Low-level lot #50220710, normal-level lot #50220711, and high-level lot #50220712 - The controls had been parallel tested once on 02/05/2025 prior to implementation on 02/06/2025. (4) The findings were reviewed with the laboratory manager and testing person #2 who stated on 05/01/2025 at 01:155 pm, the laboratory did not follow their written policy as stated above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 and interview with the laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Sysmex XP-300 analyzer during the review period of March 2024 through March 2025. Findings include: (1) On 04/29 /2025 at 01:15 pm, the laboratory manager stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Weekly: (i) Cleaned SRV tray (b) Monthly: (i) Cleaned TD (ii) Clean waste chamber (3) A review of maintenance records from March 2024 through March 2025 identified weekly and monthly maintenance had not been documented as performed as follows: (a) Weekly: (i) Between 04/25/2024 and 05/05/2024 (ii) Between 05/22/2024 and 06/05/2024 (iii) Between 07/24/2024 and 08/07/2024 (iv) Between 11/02/2024 and 11/11/2024 (v) Between 11/18/2024 and 12/04/2024 (vi) Between 12/25/2024 and 01/08/2025 (b) Monthly: (i) Between 09/15/2024 and 12/27 /204 (TD cleaning not performed) (ii) Between 10/06/2024 and 12/27/2024 (Waste chamber cleaning not performed) (4) Interview with the laboratory manager on 05/01

	/2025 at 01:15 pm confirmed the maintenance procedures had not been documented as performed as stated above. 48517 Based on a review of records and interview with testing person #1, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Beckman Coulter AU 480 chemistry analyzer during the review period of September 2024 through November 2024. Findings Include: (1) On 05/01/2025 at 10:00 am, testing person #1 stated that chemistry testing was performed using the Beckman Coulter AU 480 analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Weekly; (i) Clean sample pre-dilution bottle; (ii) Perform a W2; (iii) Perform a photocal. (3) A review of maintenance logs from September 2024 through November 2024 identified no documentation maintenance had been performed as follows: (a) Weekly - There was no documentation that weekly maintenance was performed between 09/11/2024 through 09/25/2024 and 10/09/2024 through 10/23/2024; (4) The records were reviewed with testing person #1 who stated on 05/01/2025 at 10:00 am, the analyzer maintenance had not been documented as performed as stated above.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 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 competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person. Findings include: (1) On 04/29/2025, a review of personnel records for one person performing moderate complexity testing identified the following: (a) Testing Person #4 - The initial training was completed on 07/16/2023. There was no evidence an evaluation had been performed between 07/16/2023 and 06/11/2024. (2) The records were reviewed with the laboratory manager who stated on 04/29/2025 at 03: 35 pm, a semiannual competency evaluation had not been performed.