Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	37D0473327	05/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pawhuska Hospital Inc	1101 East 15th Street, Pawhuska, 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 05/13,14,15,16/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the administrator, technical consultant, laboratory manager, and chief clinical officer during an exit conference performed at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant and laboratory manager, the laboratory failed to assess the competency of the technical consultant based on the position responsibilities as listed in subpart M, and the policy failed to define the frequency of assessments were to be performed. Findings include: (1) A review of the laboratory policy and procedure manual identified a written policy for assessing the competency of the technical consultant based on the position responsibilities. The policy did not define the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of February 2022 through the current date identified competencies based on the position responsibilities, had not been performed for the technical consultant listed on the CMS-209; (3) The findings were reviewed with the technical consultant and laboratory manager who stated on 05/15/2024 at 4:45 pm, competency assessments had not been performed for the technical consultant during the review period, and the policy failed to define the frequency of assessments as stated above.

D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and testing person #3, the laboratory failed to provide written instructions to clients collecting and referring specimens for testing performed in the laboratory. Findings include: (1) On 05/13/2024 at 02:15 pm, the laboratory manager and testing person #3 stated the following testing were performed and specimens were transported to the laboratory from nursing homes and home health care agencies: (a) CBC testing using the Sysmex KX-21N analyzer; (b) Routine Chemistry testing using the Siemens Dimension EXL 200 analyzer; (2) Interview with the laboratory manager and testing person #3 on 05/13/2024 at 02:20 pm confirmed the laboratory did not provide written instructions (i.e., client service manual) to the clients to explain the laboratory's specimen collection and transportation policies.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, central supply manager, and ER (emergency room) nurse the laboratory failed to ensure eight of eight types of blood collection tubes were stored as required by the manufacturer in the central supply room, and failed to ensure seven of seven types of tubes were stored as required by the manufacturer in the ER #3. Findings include: CENTRAL SUPPLY ROOM: (1) Observation of the central supply room and interview with the central supply manager and laboratory manager on 05/14/2024 at 09:00 am, identified the following: (a) Three packages of BD Vacutainer PST Gel and Lithium Heparin tubes, lot 3318898, storage temperature of 4-25 degrees (C) centigrade; (b) One package of BD Vacutainer K2 EDTA 10.8mg tubes, lot # 3318891, storage temperature of 4-25 degrees C; (c) Three packages of BD Vacutainer K2 EDTA 7.2mg tubes, lot # 3289512, storage temperature of 4-25 degrees C; (d) One package of BD Vacutainer K2 EDTA 3.6mg tubes, lot # 3257669, storage temperature of 4-25 degrees C; (e) One package of BD Vacutainer Blood Collection tubes, lot # 3215487, storage temperature of 4-25 degrees C; (f) Two packages of BD Vacutainer SST Blood Collection tubes, lot # 3333244, storage temperature of 4-25 degrees C; (g) One package of BD Vacutainer Sodium Fluoride 10mg Potassium Oxalate 8mg tubes, lot 3222752 storage temperature of 4-25 degrees C; (h) One package of Vacuette 9NC Coagulation Sodium Citrate 3.2% tubes, lot B240133R, storage temperature of 4-25

	degrees C. (2) Interview with the laboratory manager and the central supply manager on 05/14/2024 at 09:15 am confirmed the laboratory was not monitoring the temperature of the Central Supply Room. EMERGENCY ROOM #3: (1) Observation of the emergency room and interview with the ER nurse and the laboratory manager on 05/14/2024 at 10:00 am, identified the following: (a) Two BD Vacutainer PST Gel and Lithium Heparin tubes 83 units, lot 3163707, storage temperature of 4-25 degrees (C) centigrade; (b) Two BD Vacutainer PST Gel and Lithium Heparin tubes 56 units, lot 3318898, storage temperature of 4-25 degrees C; (c) One Vacuette 9NC Coagulation Sodium Citrate 3.2% tube, lot B231133Y, storage temperature of 4-25 degrees C; (d) One BD Vacutainer K2 EDTA 10.8 mg tube, lot # 2292095, storage temperature of 4-25 degrees C; (e) Two BD Vacutainer K2 EDTA 3.6 mg tubes, lot # 3074254, storage temperature of 4-25 degrees C; (f) One BD Vacutainer Sodium Fluoride 10mg Potassium Oxalate 8mg tubes, lot 3016650 storage temperature of 4-25 degrees C; (g) One BD Vacutainer Sodium Fluoride 10mg Potassium Oxalate 8mg tubes, lot 3257749 storage temperature of 4-25 degrees C; (h) Two BD Vacutainer SST tubes, lot # 333244, storage temperature of 4-25 degrees C. (2) Interview with the ER nurse and the laboratory manager on 05/14/2024 at 10:15 am confirmed temperature was not monitored in the ER room. 48517 Based on observation and interview with the laboratory manager the laboratory failed to ensure one of one Vacutainer brand tubes was stored as required by the manufacturer in the laboratory freezer. Findings include: (1) Observation of the laboratory freezer and interview with the laboratory director on 05/13/2024 at 2:25 pm, identified the following: (a) One Vacutainer K2, EDTA tube, lot # 2347066, storage temperature of 4-25 degrees Celsius. (2) Interview with the laboratory manager on 05/13/2024 at 2:25 pm confirmed the tube was being stored below the manufacterer's stated temperature.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager and testing person #3, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 05/13/2024 at 02:30 pm, identified the following expired supplies that appeared to be available for use: (a) 15 BD Vacutainer PST Gel and Lithium Heparin tubes 56 Units, lot 3074294, expired 03 /31/2024; (b) Three BD Vacutainer K2 EDTA 10.8 mg tubes, lot 2259083, expired 02 /29/2024; (c) Two Vacuette 9NC Coagulation Sodium Citrate 3.2% tubes, lot B230433L, expired 03/31/2024. (2) Interview with the laboratory manager and testing person #3 on 05/13/2024 at 02:35 pm confirmed the expired supplies were available for use.
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 technical consultant and laboratory manager, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of four persons during the review period of 02/01/2022 through the current date. Findings include: (1) A review of personnel records for four persons performing moderate complexity testing from February 2022 through the current date identified no evidence annual competency evaluations had been performed for one of four persons as follows: (a) Testing Person #4 - Not performed between 02/01/2022 and 09/28/2023 (2) The records were reviewed with the technical consultant and laboratory manager who stated on 05/14/2024 at 10:55 am, the annual evaluations had not been performed as stated above.