

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0506682	(X3) Date Survey Completed 09/17/2025
Name of Provider or Supplier Pampa Regional Medical Center	Street Address, City, State One Medical Plaza, Pampa, TX	
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	A validation survey was conducted on 09/16/2025 to 09/17/2025. The laboratory was found not in compliance with the CLIA regulations with the following CONDITION: 42 C.F.R. 493.1240 Condition: Preanalytic systems;
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's patient test records, laboratory's policies, manufacturer's instructions, and interview, the laboratory failed to meet the requirements for the overall quality of preanalytic system as evidenced by: 1. The laboratory failed to follow its laboratory policy and manufacturer's instructions (Siemens Dimension) for specimen collection and handling with the 15 minute centrifugation time frame prior to analysis for 13 of 49 lactic acids (See D5311-I). 2. The laboratory failed follow their own policies and document the transportation storage conditions from specimens received from their clients in 2025 (See D5311-II) 3. The laboratory failed to have a written client service manual for their clients when they received specimens (See D5317)</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each</p>

of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:

Lactic Acids: I. . Based on review of manufacturer's instructions package insert, lack of laboratory policies for lactic acid, patient test reports, and interview with Technical Supervisor #1, the laboratory failed to follow its laboratory policy and manufacturer's instructions (Siemens Dimension) for specimen collection and handling with the 15 minute centrifugation time frame prior to analysis for 13 of 49 lactic acids reviewed from June 15, 2025 to June 30, 2025. A. In review of the manufacturer's instructions (Siemens Dimension) package insert for the Lactic Acid under Specimen Collection and Handling it stated, "Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by chilling of the specimen and separation of the cells with 15 minutes." B. In review of the laboratory's policy it stated, "Specimen Rejection Criteria" under Specimen condition stated for reasons to reject, "excessive delays in processing the specimens that would effect specimen integrity." C. In review of patients tests reports for lactic acid, from June 15, 2025 to June 30, 2025, the following patients were past the 15 minute time frame: a. Patient #V892199, date /collection time: 06/17/2025 at 0220, date/ time receipt in the laboratory: 06/17/2025 0247, 12 minutes over the 15 minute time frame. b. Patient #V0892451, date /collection time: 06/17/2025 at 1618, date/ time receipt in the laboratory: 6/17/2025 1650, 17 minutes over the 15 minute time frame. c. Patient #V0892465, date /collection time: 06/17/2025 at 2122, date/ time receipt in the laboratory: 06/17/2025 at 2140, 3 minutes over the 15 minute time frame. d. Patient #V892448, date /collection time: 06/17/2025 at 0145, date/ time receipt in the laboratory: 06/17/2025 at 0201, 1 minute over the 15 minute time frame. e. Patient #V092510, date/collection time: 06/18/2025 at 1115, date/ time receipt in the laboratory: 06/18/2025 at 1139, 9 minutes over the 15 minute time frame. f. Patient #V892572, date/collection time: 06 /18/2025 at 1855, date/ time receipt in the laboratory: 06/18/2025 at 1917, 7 minutes over the 15 minute time frame. g. Patient #V892586, date/collection time: 06/19/2025 at 0605, date/ time receipt in the laboratory: 06/19/2025 at 0624, 4 minutes over the 15 minute time frame. h. Patient #V891708, date/collection time: 06/20/2025 at 0940, date/ time receipt in the laboratory: 6/20/2025 at 1013, 18 minutes over the 15 minute time frame. i. Patient # V892784, date/collection time: 06/21/2025 at 0420, date/ time receipt in the laboratory: 06/21/2025 at 0615, 100 minutes over the 15 minute time frame. j. Patient #V892784, date/collection time: 06/22/2025 at 0050, date/ time receipt in the laboratory: 06/22/2025 at 0126, 21 minutes over the 15 minute time frame. k. Patient #V892917, date/collection time: 06/23/2025 at 1305, date/ time receipt in the laboratory: 06/23/2025 at 1349, 29 minutes over the 15 minute time frame. l. Patient #V893098, date/collection time: 06/24/2025 at 2100, date/ time receipt in the laboratory: 06/24/2025 at 2122, 7 minutes over the 15 minute time frame. m. Patient #V893211, date/collection time: 06/26/2025 at 0124 date/ time receipt in the laboratory: 06/24/2025 at 0201, 22 minutes over the 15 minute time frame. D. In interview with technical Supervisor #1 on 9-16-2025 at 0959 confirmed that the laboratory had not addressed Lactic Acids and their short turnaround time. E. The laboratory performed 1272 in 2025 lactic acid tests to the date of the survey and 1469 in 2024. Transportation Conditions: II. Based on review of laboratory policies, specimen log, direct observation, and interview with technical supervisor #1, the laboratory failed follow their own policies and document the transportation storage

conditions for specimens received from their clients in 2025 as evidenced by: A. Based on review of the laboratory's policies, it stated the following: 1. The policy of Urinalysis - QA Collection and Handling stated for urines and microscopic urines, "Prompt Transport of the specimen to the laboratory is essential... If a delay is inevitable, the specimen should be refrigerated at 2-8 degrees within 2 hours of collection and delivered as soon as possible." 2. The policy of Microbiology Specimen Collection stated for creatinine clearance, "Creatinine is stable for 4 days when stored at 2-8 degrees C." 3. The policy of Specimen Collection within the hematology manual for Complete blood count (CBC) stated, "analyze venous blood samples within 24 hours of collection if stored at room temperature (23.9 degrees C or 75 degrees F). Run blood samples within 48 hours after collection if refrigerated at 2 to 8 degrees C (35.6 to 46.4 degrees F)." 4. The policy of Specimen Rejection Criteria stated under Specimen Condition one of the causes for rejection were: "Improper specimen transportation or storage." B. Based on review of the specimen log titled "Please Log in All Samples," from 9-1-2025 to 9-17-2025, the following patient transport conditions were not documented: a. Patient #V899712 received on 9-16-2025 at 0735 from a client test ordered: Urinalysis (UA) with reflex to microscopic. b. Patient #V899749 received on 9-16-2025 at 1047 from a client, test ordered: UA with reflex to microscopic . c. Patient #V899762 received on 9-16-2025 at 1227 from a client, test ordered: Creatinine clearance. d. Patient #V899764 received on 9-16-2025 at 1228 from a client, test ordered: CBC. C. In direct observation on 9-16-2025 at 1235 patient # V899762 technical supervisor #2 did not write down the conditions of transport. The blood specimen and urine came into the laboratory at room temperature. D. In interview with technical supervisor #2 9-16-2025 at 1236, she stated that they don't document the condition of transports on the patient log. Additionally, she stated that they only keep the logs for 3 months and could not show documentation of condition of transport for June 2025. E. The laboratory performs 1871 microscopic urines, 5 creatinine clearances and 9145 CBC in 2025 to the date of the survey.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
 CFR(s): 493.1242(d)

(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 review of the laboratory's patient logs, lack of client service manual, and interview with Technical Supervisor # 1, the laboratory failed to have a written client service manual for their clients when they received specimens for 2024 and 2025 as evidenced by: 1. The laboratory could not provide a written client service manual (for those outside of the hospital sending specimens to the laboratory) with the following components: - patient preparation - specimen collection - specimen labeling - specimen storage and preservation - conditions for specimen transportation - specimen processing - specimen acceptability and rejections 2. In review of the patient log, the laboratory received the following from outside facilities: a. Patient #V899712 received on 9-16-2025 at 0735 from a client test ordered: Urinalysis (UA) with reflex to microscopic. b. Patient #V899749 received on 9-16-2025 at 1047 from a client, test ordered: UA with reflex to microscopic . c. Patient #V899762 received on 9-16-2025 at 1227 from a client, test ordered: Creatinine clearance d. Patient #V899764 received on 9-16-2025 at 1228 from a client, test ordered: CBC. 3. In interview with the

Technical Supervisor #1 on 9-16-2025 at 1006 confirmed that laboratory did not have client service manual or anything written. She also stated that the laboratory has never had a client service manual for outside facilities and that when the facilities have an issue or question about preparation of specimens to send to the laboratory, they just call the laboratory.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

(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:

I. Based on review of the manufacturer's instructions, direct observation and interview with technical supervisor #1, the laboratory failed to follow manufacturer's instructions (KOVA system) for centrifugation of microscopic urines in 2025 as evidenced by: 1. In review of the manufacturer's instructions it stated, "Centrifuge the KOVA Tubes (each containing 12 mls of urine specimen) at a relative centrifugal force (RCF) of 400 for five minutes." 2. In direct observation on 9-17-2025 at 1320 using the Horizon 25VOR the laboratory had the setting at 872 RCF. 3. In interview with Technical Supervisor #1 at 1330 stated that she wasn't sure where the 872 RCF came from. She later confirmed after reviewing the KOVA package insert that they were not following manufacturer's instructions. 4. The laboratory performed 1871 microscopic urines in 2025 to the date of the survey and 2647 microscopic urines in 2024. 27526 II. Based on review of the laboratory's procedure, manufacturer's instructions for use and interview with staff, the laboratory failed to follow the manufacturer's instructions for the CAMCO QUIK STAIN II for manual staining of blood smears. 1. Review of the laboratory's Smear Staining procedure (HEM 4.0) revealed the laboratory uses CAMCO QUIK STAIN II for manual staining of blood smears. The procedure states the following: ..."Dip slide in stain for 10 seconds ...Dip slide in distilled water (pH 6-7) for 20 seconds or more ..." 2. Review of the CAMCO QUIK STAIN II instructions for use located on the side of the stain bottle found the following: "2) Dip slide in stain for 10 seconds. 3) Dip slide in distilled water (pH 6-7) for 20 seconds or more ..." 3. During interview on September 17, 2025, at approximately 10:30 am, TS #1 stated water used for manual staining was de-ionized water made by the laboratory's Millipore System AFS (analyzer feed system) and the pH of the water was not measured prior to use. The laboratory performs 957 manual complete blood count differentials annually. III. Based on review of the laboratory's procedure, manufacturer's instructions for use, tour of the serology area of the laboratory and interview with staff, the laboratory failed to follow the manufacturer's instructions for performing Rapid Plasma Reagin (RPR) testing. 1. Review of the laboratory's Rapid Plasma Reagin procedure (SER 5.0) revealed the laboratory uses Cardinal Health RPR Card test for Syphilis. The procedure states the following on page 8: "READING AND REPORTING THE MACRO-VUE RPR CARD TESTS: Individual reactions should be evaluated in the "wet" state, under a high intensity incandescent lamp." 2. Review of the Cardinal Health RPR Card for Syphilis found the following: "Assay Protocol - Qualitative ...6. Immediately read results macroscopically in the "wet" state under a high-intensity light source." 3. During tour of the Serology area of the laboratory on September 17, 2025, at approximately 11:30 am, no high-intensity light source was observed. 4. During interview on September

17, 2025, at approximately 11:30 am, TS #1 confirmed the laboratory does not use a high-intensity light source when reading the RPR test cards. The laboratory performs 107 qualitative RPRs annually. Word Key: pH - Potential of Hydrogen

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of laboratory temperature logs, manufacturer instructions for use, interview with staff and direct observation, the laboratory failed to ensure Remel BactiDrop Oxidase reagent droppers were stored at a room temperature range defined by the manufacturer for three of three months (April thru June 2025). 1. Review of the laboratory's room temperature logs for the Microbiology area indicated an acceptable range of 15-25C. 2. Review of the Remel BactiDrop Oxidase reagent manufacturer's instructions for use found the following: "Storage ...Store product in its original container at 20-25C ...Protect from light." 3. During interview on September 16, 2025, at approximately 3 pm, Technical Supervisor #1 (TS#1) stated the room temperature range on the temperature logs did not align with the manufacturer's storage instructions for Remel BactiDrop Oxidase reagent droppers. 4. During tour of the laboratory on September 17, 2025, at approximately 8:30 am, two unopened and one opened box of Remel BactiDrop Oxidase reagent droppers (Lot number 295119, Expiration 2027-04-10) were observed in a drawer in the Microbiology area of the laboratory. The boxes indicated a storage temperature of 20-25C.