Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0469387	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier Rural Wellness Anadarko, Inc	**Street Address, City, State** 1002 E Central Blvd, Anadarko, 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 05/15,16/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, chief nursing officer, quality manager, laboratory director, and laboratory manager during an exit conference performed at the conclusion of the survey.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory director and laboratory manager, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator during the review period of June 2021 through the current date. Findings include: (1) On 05/15/2023 at 10:04 am, the laboratory manager stated three units of O positive packed red blood cells and one unit O negative packed red blood cells were routinely maintained in the blood bank refrigerator. The units were available for emergency patient transfusions; (2) A review of the laboratory's written policy titled, "Blood Bank Refrigerator Quality Control" required the low and high temperatures of activation for the alarm system be checked on a quarterly basis; (3) A review of alarm check records from 06/01/2021 through the current date identified that during 2022, the alarm checks had not been performed during the second quarter of 2022 (they had been performed 03/22/2022, 07/01/2022, and 10/06/2022); (4) The records were reviewed with the laboratory director and laboratory manager. Both stated on 05/15/2023 at 03:30 pm, the alarm checks had not been performed quarterly during 2022.

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 interview with the laboratory manager, the laboratory failed to provide written instructions to clients collecting and referring routine Hematology, Bacteriology, Virology, Chemistry and Urinalysis testing. Findings include: (1) On 05/15/2023 at 09:50 am, the laboratory manager stated the following: (a) Routine Chemistry testing was performed using the Ortho Vitros 5600 analyzer; (b) Routine CBC (Complete Blood Count) testing was performed using the Sysmex XN-450 analyzer; (c) PT/INR (Prothrombin Time/International Normalized Ratio) testing were performed using the Hemochron Jr analyzer; (d) Testing for Respiratory Panel Pathogens and Gastrointestinal Panel Pathogens were performed using the Biofire Torch analyzer; (e) Urine sediment examinations were performed; (f) Specimens were transported to the laboratory from a local home health agency. (2) Interview with the laboratory manager on 05/15/2023 at 10:10 am confirmed the laboratory did not provide written instructions (i.e.,client service manual) to the client to explain the laboratory's specimen handling policies.
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 director and laboratory manager, the laboratory failed to utilize the demonstrated reportable ranges for five of five analytes reviewed on the Ortho Vitros 5600 analyzer. Findings include: (1) On 05/16/2023 at 11:50 am, the laboratory manager stated the laboratory began using the Ortho Vitros 5600 analyzer to perform routine chemistry testing, which included the analytes Amylase, BUN (Blood, Urea, Nitrogen), CK (Creatine Kinase), Lipase, and Triglyceride using the Ortho Vitros 5600 analyzer on 10/04/2021; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Amylase - 47.8-1006.5 U/L (b) BUN - 18.8-114.8 mg/dl (c) CK - 49.1-1669 U/L (d) Lipase - 22.5-2000.7 U/L (e) Triglyceride - 30.8-476.3 mg/dl (3) Interview with the laboratory manager on 05/16/2022 at 01:25 pm, 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) BUN - 2-120 mg/dl (c) CK - 20-1600 U/L (d) Lipase - 10-2000 U/L (e) Triglyceride - 10-525 mg/dl

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the laboratory failed to perform calibration verification procedures at least once every 6 months for two of two analytes requiring calibration verification using the Ortho Vitros 5600 analyzer. Findings include: (1) On 05/16/2023 at 11:50 am, the laboratory manager stated the laboratory began using the Ortho Vitros 5600 analyzer to perform Procalcitonin and Vitamin D testing on 10/04/2021; (2) A review of calibration records for 2023 identified the calibration procedures for the above analytes were performed with less than three levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of records from 08/22/2021 through the current date identified calibration verification had not been performed at least once every six months as follows: (a) Procalcitonin (i) Not performed between 08/22/2021 (performed with installation of analyzer) and 09 /08/2022 (ii) Not performed after 09/08/2022 (b) Vitamin D (i) Not performed between 09/08/2022 and 05/16/2023 (4) The records were reviewed with the laboratory manager who stated on 05/16/2023 at 01:05 pm, calibration verification procedures had not been performed every six months.
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, QC (quality control) package inserts, and interview with the laboratory director and 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 BUN (Blood Urea Nitrogen) and Lactate testing for one of one month reviewed. Findings include: (1) On 05/16/2023 at 11:50 am, the laboratory manager stated the following: (a) The laboratory began using the Ortho Vitros 5600 analyzer to perform BUN and Lactate testing on 10/04/2021; (b) Two levels of Bio-Rad Assayed Multiqual QC materials were performed each day of patient testing. (c) When new lot numbers of control materials were put into use, the laboratory established means and two SD (Standard Deviation) ranges for each analyte. (2) A review of the manufacturer's instruction (package insert) for the 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"; (3) A review of QC records for two lot numbers of control materials used during the review period of 04/01/2023 through 05/03/2023 identified the following: (a) Level one lot #45931 and level three lot #45933 were in use - The laboratory was using ranges wider than the package insert guideline ranges as follows: (i) BUN (aa) Level One - The laboratory was using a range of 8.38-20.6, which was wider than the package insert guideline range of 12.6-15.1. (ii) Lactate (aa) Level Three - The laboratory was using a range of 3.47-7.35 which was wider than the package insert guideline range of 4.93-5.69. (4) The records were reviewed with the laboratory director and laboratory manager. Both stated on 05/16/2023 at 12:50 pm, the laboratory had used ranges wider than the package insert guideline ranges 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 director and laboratory manager, the laboratory failed to perform a negative and positive control material one of 20 days of patient serum Ketone testing reviewed from January 2023 through the current date. Findings include: (1) On 05/15/2023 at 09:50 am, the laboratory manager stated the following: (a) Serum Ketone testing was performed using the

	Germaine Laboratories AimTab Ketone tablets and serum samples; (b) Negative and positive QC (quality control) materials were performed each day of patient testing. (2) A review of QC and patient testing records for testing performed from January 2023 through the current date identified negative and positive QC materials had not been documented as performed each day of patient testing for one of 20 days. The specific day of patient testing was 02/15/2023; (3) The records were reviewed with the laboratory director who stated on 05/15/2023 at 12:07 pm, negative and positive QC materials had not been documented as performed as stated above.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director and laboratory manager, the laboratory failed to ensure the manuafacturer's specifications had been followed for three of three lot numbers reviewed from 06/01/2021 through the current date. Findings include: (1) On 05/15/2023 at 09:56 am, the laboratory manager stated the following: (a) The Hemochron Jr. Signature + analyzer was used to perform PT (Prothrombin Time)/ INR (International Normalized Ratio) testing using the Citrate PT cuvettes; (b) Normal and abnormal controls were tested on a monthly basis and with new lot numbers of cuvettes. (2) A review of the manufacturer's instructions (package inserts) for the control materials stated, "Accriva recommends that each institution establish its own expected range of response based on the mean +/- 2 standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a coefficient of variation of approximately 14% or less for coagulation control tests"; (3) A review of quality control records for lot changes performed in 2021 and 2022 identified the laboratory had not followed the manufacturer's instructions as follows: (a) Abnormal Control Lot #M0DAC007, put into use on 06/01/2021 - The laboratory had established their ranges using 16 repeated test results instead of 20 as required by the manufacturer. In addition, there was no evidence the laboratory had calculated the %CV (coefficient of variation) to determine the intra-laboratory variation in test results; (b) Normal Control Lot#H0DNC006, put into use on 06/01/2021 - The laboratory had established their ranges using 16 repeated test results instead of 20 as required by the manufacturer. In addition, there was no evidence the laboratory had calculated the %CV to determine the intra-laboratory variation in test results; (c) Normal Control Lot #E1DNC005, put into use on 11/01/2021 - The laboratory had established their ranges using 14 repeated test results instead of 20 as required by the manufacturer. In addition, there was no evidence the laboratory had calculated the %CV to determine the intra-laboratory variation in test results; (d) Normal Control Lot #B2DNC003, put into use on 10/04/2022 - The laboratory had established their ranges using 16 repeated test results instead of 20 as required by the manufacturer. In addition, there was no evidence the laboratory had calculated the %CV to determine the intra-laboratory variation in test

	results. (4) The findings were discussed with the laboratory director and laboratory manager. Both stated on 05/15/2023 at 03:05 pm, the laboratory had not followed the manufacturer's instructions for the control materials.