

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0469387	(X3) Date Survey Completed 05/18/2021
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 05/17,18,2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the hospital administrator, technical consultant #1, technical consultant #2, and the laboratory manager during an exit conference performed at the conclusion of the survey.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory failed to ensure that proficiency testing samples were tested by personnel who routinely performed patient testing for 3 of 4 Chemistry Miscellaneous events. Findings include: (1) On 05/17 /2021 at 10:00 am, the laboratory manager stated to the surveyor the laboratory performed Ammonia testing using the Ortho Vitros 350 analyzer; (2) The surveyor reviewed the Laboratory Personnel Report (Form CMS-209), that had been completed by the laboratory prior to the survey, with the laboratory manager and technical consultant #1 The laboratory manager and technical consultant #1 stated that 9 persons performed the above patient testing in the laboratory (laboratory manager /testing person #1 testing person #2, testing person #3, testing person #4, testing person #5, testing person #6, testing person #7, testing person #8, and testing person #9); (3) The surveyor then reviewed proficiency testing records for the first 2019, second 2019, first 2020, and second 2020 Chemistry Miscellaneous events and identified that 3 of 4 events performed (first 2019, first 2020, and second 2020) had been tested by the same person (testing person #3); (4) The findings were reviewed</p>

with the laboratory manager, technical consultant #1, and technical consultant #2. All stated on 05/17/2021 at 01:00 pm, the proficiency testing samples had been tested by testing person #3, as indicated above.

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 the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 2 of 6 Hematology events reviewed. Findings include: (1) On 05/17/2021, the surveyor reviewed proficiency testing records for 2019, 2020, and to date in 2021. The following was identified for 2 of 6 Hematology events: (a) Second 2019 Hematology Event for Blood Cell ID (Educational) - 5 of 5 results had not been graded by the proficiency testing program as follows: (i) For 2 of 5 results (ECI-06 and ECI-10), the program's expected results were included on the report, which showed the following: (aa) ECI-06 - The laboratory's reported result of Neutrophil, hyposegmented did not agree with the "Expected Result" of Neutrophil, segmented. There was no documentation to indicate corrective action had been taken for the unacceptable response; (bb) ECI-10 - The laboratory's reported result of Microcytic Red Blood Cell did not agree with the "Expected Result" of Spherocyte. There was no documentation to indicate corrective action had been taken for the unacceptable response. (b) First 2021 Hematology Event for Blood Cell ID (Educational) - 5 of 5 results had not been graded by the proficiency testing program as follows: (i) For 2 of 5 results (ECI-02 and ECI-04), the program's expected results were included on the report, which showed the following: (aa) ECI-02 - The laboratory's reported result of Lymph, reactive (atyp,variant) did not agree with the "Expected Result" of Lymphocyte, normal. There was no documentation to indicate corrective action had been taken for the unacceptable response (bb) ECI-04 - The laboratory's reported result of Monocyte did not agree with the "Expected Result" of Neutrophil, band (stab). There was no documentation to indicate corrective action had been taken for the unacceptable response. (ii) For 1 of 5 results (ECI-03), the following was identified: (aa) ECI-03 - Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The surveyor reviewed the records with the laboratory manager, technical consultant #1, and technical consultant #2. All stated on 05/17/2021 at 02:05 pm, the laboratory had not evaluated the results that were not graded by the proficiency testing program and corrective action had not been taken as indicated.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(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 the policy and procedure manual and interview with the laboratory manager, the laboratory failed to have written procedures that explained the current practices and procedures being performed in the laboratory. Findings include: (1) On 05/17/2021 at 10:10 am, the laboratory manager stated to the surveyor Ketone testing was performed using the Germaine Laboratories AimTab and serum or plasma specimens; (2) The surveyor reviewed written policies and procedures. The procedure titled, "Acetest" did not explain the current procedure for performing Ketone testing. The procedure described using the Bayer Acetest reagent tablets; (3) The surveyor reviewed the findings with the laboratory manager who stated on 05/17/2021 at 04:00 pm, the laboratory did not use the Bayer Acetest reagent tablets and the procedure in the manual did not reflect the laboratory's current method of performing Ketone testing using the Germaine Laboratories AimTab tablets.

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, procedure manual, and interview with the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory failed to ensure the verified reportable ranges were used by the laboratory for a new test method. Findings include: (1) On 05/17/2021 at 10:10 am, the laboratory manager stated to the surveyor the laboratory began performing pH, pCO₂, and pO₂ testing using the CG8+ cartridge and the iSTAT 1 analyzer on 02/20/2020; (2) On 05/18/2021, the surveyor reviewed the performance specification records for the new test method and the blood gas procedure. The laboratory manager stated to the surveyor on 05/18/2021 at 10:15 am, the reportable ranges in the procedure manual were being used by the laboratory. The surveyor identified the reportable ranges that had been demonstrated by the laboratory did not match the reportable ranges listed in the procedure manual as follows: (a) pH - The laboratory had demonstrated a reportable range of 6.6-8.0 and the reportable range listed in the procedure manual was 6.5-8.2; (b) pCO₂ - The laboratory had demonstrated a reportable range of 16.4-91.6 and the reportable range listed in the procedure manual was 5-130; (c) pO₂ - The laboratory had demonstrated a reportable range of 77-360 and the reportable range listed in the procedure manual was 5-800. (4) The surveyor reviewed the records with the laboratory manager, technical consultant #1, and technical consultant #2. All stated to the surveyor on 05/18/2021 at 10:40 am, the procedure manual did not reflect the reportable ranges that had been demonstrated by the laboratory.

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 the laboratory manager, technical consultant #1, and technical consultant #2, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On 05/17/2021 at 10:00 am, the laboratory manager stated to the surveyor the laboratory performed TSH (Thyroid Stimulating Hormone), Free T4 (Thyroxine), Troponin I, and CKMB testing using the Ortho Vitros ECiQ analyzer; (2) On 05/18/2021, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log for the analyzer, which required the following every 2 month maintenance: (a) Change the vapor adsorption cartridge (3) The surveyor then reviewed maintenance records for 16 months (January 2020 through April 2021). The every 2 month maintenance had not been documented as performed between: (a) 07/01/2020 and 10/02/2020 (4) The surveyor reviewed the records with the laboratory manager, who stated on 05/18/2021 at 02:00 pm, the maintenance had not been performed as stated above.