Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656682	06/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rural Wellness Stroud, Inc	2308 W Hwy 66, Stroud, 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 06/01,02/2021. The laboratory was found out of compliance with the following CLIA regulation: 493.1403; D6000: Laboratory Director The findings were reviewed with the chief executive officer, chief operating officer, quality/risk manager, chief nursing officer, director of operations, chief clinical officer, laboratory director, technical consultant #1, technical consultant #2, laboratory supervisor, and lead technologist during an exit conference performed at the conclusion of the survey.
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 technical consultant #2, the laboratory failed to review and evaluate proficiency testing results for one of 33 events. Findings include: (1) On 06/01/2021, surveyor #2 reviewed 2020 and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2020 Chemistry Core Event (i) Lipase - 3 of 5 results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.1 (bb) Sample CH-09 - SDI of 2.1 (cc) Sample CH-10 - SDI of 2.1 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) Surveyor #2 reviewed the findings with technical consultant #2. Technical consultant #2 stated on 06/01/2021 at 02:53 pm the biases had not been addressed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory supervisor and technical consultant #1, the laboratory failed to define a function check policy to ensure the urine centrifuge was functioning properly. Findings include: (1) On 06/01/2021 at 11:30 am, the laboratory supervisor stated the following to surveyor #1: (a) The laboratory performed microscopic urine sediment examinations; (b) The urine specimens were processed at a speed of 1500-1800 rpm (revolutions per minute) for 5 minutes using the following centrifuges: (i) The Ultra 8V LW Scientific centrififuge was in use prior to 09/2020; (ii) The Fisherbrand Drucker Model 642E centrifuge was put into use 09/2020. (2) The surveyor asked the laboratory supervisor if the laboratory had a function check protocol that defined the frequency of urine centrifuge speed and timer checks and the acceptable limits for the checks. On 06/01/2021 at 11:50 am, the laboratory supervisor stated to surveyor #1 the laboratory did not have a written function check protocol but the centrifuges were checked approximately every 6 months; (3) Surveyor #1 reviewed the centrifuge maintenance records for 2019 and 2020 with the following identified: (a) Ultra 8V LW Scientific centrifuge - Although speed and timer checks had been performed on 07 /10/2019 and 04/29/2020, the results for the speed and timer checks had been documented as "Pass" instead of the actual speed and times that had been obtained for the checks; (b) Fisherbrand Drucker Model 642E centrifuge - The speed and timer check had been performed on 09/08/2020 (prior to putting into use for patient testing). The speed had been checked at 3289.6 rpm, which was not the speed that urines were processed, and the result for the timer check had been documented as "Pass" instead of the actual time that had been obtained for the check. (4) Surveyor #1 reviewed the findings with technical consultant #1 who stated on 06/01/2021 at 02:00 pm that the laboratory did not have a written function check protocol for the urine centrifuge and the laboratory did not ensure the urine centrifuge was functioning properly as shown above.
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 supervisor and technical consultant #1, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On 06/02/2021 at 01:00 pm, the laboratory supevisor stated to surveyor #1, Chloride, Potassium, Sodium testing were performed using the Ortho Vitros 350 analyzer; (2) Surveyor #1 reviewed calibration verification records for Chloride, Potassium, and Sodium (since routine calibration procedures were performed using less than three calibrators for the above analytes, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). There was no evidence calibration verification procedures had been performed between 10/20/2020 and 05/25/2021 (due 04/2021); (3) Surveyor #1 reviewed the records with technical consultant #1 who stated on 06/02/2021 at 03:05 pm, calibration verification had not been performed every 6 months.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 supervisor and technical consultant #1, the laboratory failed to ensure IQCP's included the required components. Findings include: HEMOCHRON (1) On 06/01/2021 at 02:00 pm, the laboratory supervisor stated to the following to surveyor #1: (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing were performed using the Hemachron Jr. analyzer; (b) An IQCP (Individualized Quality Control Program) had been developed for the test system and had been updated and approved by the new laboratory director on 05/26/2021. (2) Surveyor #1 reviewed the IQCP for the test system and identified a QA (Quality Assessment) plan had not been included in the IQCP (it consisted of a Risk Assessment and QCP (Quality Control Plan) only); (3) Surveyor #1 reviewed the records with technical consultant #1 who stated on 06/01/2021 at 03:50 pm, a QA plan had not been included in the IQCP. I-STAT (1) On 06/01/2021 at 02:00 pm, the laboratory supervisor stated to the following to surveyor #1: (a) pH, pCO2, and pO2 testing were performed using the iSTAT 1 analyzer and the

	CG8+ cartridge; (b) An IQCP (Individualized Quality Control Program) had been developed for the test system and had been updated and approved by the new laboratory director on 05/26/2021. (2) Surveyor #1 reviewed the IQCP for the test system and identified a QA (Quality Assessment) plan had not been included in the IQCP (it consisted of a Risk Assessment and QCP (Quality Control Plan) only); (3) Surveyor #1 reviewed the records with technical consultant #1 who stated on 06/01 /2021 at 03:55 pm, a QA plan had not been included in the IQCP.
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 testing person #1, the laboratory failed to follow the manufacturer's specifications for quality control materials for one of two lot numbers. Findings include: (1) On 06/01/2021, testing person #1 stated to surveyor #2 that CKMB testing was performed on the Ortho Vitros ECI analyzer; (2) On 06/02/2021 at 09:45 am, testing person #1 stated the following to surveyor #2: (a) Two levels of Bio-Rad Liquichek Cardiac Marker Plus Control control materials were tested each day of patient CKMB testing. (3) Surveyor #2 then reviewed the manufacturer's instructions (package insert) for the control materials, which stated: (a) Bio-Rad Liquichek Cardiac Marker Plus Control - "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"; (4) Surveyor #2 reviewed quality control records for 2 lot numbers of control materials used from 02/02/2021 through the second day of the survey (06/02/2021). It was identified that the laboratory had used the manufacturer's ranges for determining acceptability of the results for CKMB testing. The lot numbers were: (a) Bio-Rad Liquichek Cardiac Markers Plus Contol (i) Level 1C lot #67646 and level 3 lot #67643 - put into use on - 02/02/2021and was currently being used. (5) Surveyor #2 reviewed the above findings with testing person #1, who stated on 06/02/2021 at 02:24 pm, the laboratory did not establish their own ranges. Instead, they had utilized the manufacturer's package insert ranges for determining acceptability of control results.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by:

	Based on a review of records, CLIA database, FDA database, and interview with the laboratory supervisor, technical consultant #1, testing person #1, director of quality, and the chief nursing officer, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory director, met the qualifications. Refer to D6003; (2) The laboratory director failed to ensure a new urine drug test introduced into the laboratory had the capability of providing quality results for patient care. Refer to D6012; (3) The laboratory director failed to ensure proficiency testing attestations, stating samples were tested as required under Subpart H, were signed by an individual meeting the regulatory qualifications for nine of 35 attestation statements. Refer to D6016.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the

laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:
Based on a review of records, CLIA database, and interview with the director of quality and chief nursing officer, the laboratory director failed to ensure the individual who performed the duties and responsibilities of the laboratory director, met the

	qualifications. Findings include: (1) On 06/01/2021, surveyor #2 reviewed proficiency testing records and identified attestation statements that had been signed by an individual who was not identified by the surveyors as a previous laboratory director; (2) On 06/02/2021 at 10:30 am, the director of quality and chief nursing officer stated to the surveyors a previous laboratory director served in the position from 11/24/2018 through 08/31/2020; (3) The surveyors reviewed the CLIA database and identified the state agency had not received documentation from the laboratory as notification that this individual would be serving as the laboratory director during that timeframe (see note below). The surveyors looked up the credentials of the individual on the Oklahoma Medical Board License verification and identified the individual was an MD, licensed in the state, however there was no documentation of one of the following to prove the individual met the following regulatory qualifications: (a) Have at least one year directing or supervising laboratory testing as stated at 493.1405(b)(2)(ii)(A) or; (b) Have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilites as stated at 493.1405(b)(2)(ii)(B). (4) Surveyor #1 and surveyor #2 reviewed records and identified the individual had signed the following as the laboratory director: (a) Approval of the performance specifications on 12/12/2018 for the new Vitros ECi analyzer (refer to D6013); (b) Nine of 35 proficiency testing attestation statements (refer to D6016). (5) The surveyors reviewed the finding with the director of quality and chief nursing officer. Both stated on 06/02/2021 at 01:24 pm: there was no documentation to prove the individual serving as the laboratory director from 11/24/2018 through 08/31/2020 met the regulatory qualifications as stated above. NOTE: The laboratory must notify the state agency of a laboratory director change within 30 days as stated at 493.51 - Notification requirements for laboratories issued a certificate of compliance.
D6012	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: Based on a review of records, FDA database, and interview with the technical consultant #1 and testing person #1, the laboratory director failed to ensure a new urine drug test introduced into the laboratory had the capability of providing quality results for patient care. Findings include: (1) On 06/01/2021 at 10:00 am, testing person #1 stated to surveyor #2 the lab had recently obtained and had not used the Healgen Scientific 12 Panel Drug Test for patient testing, but it was available for patient use; (2) Surveyor #1 and surveyor #2 had not encountered this test previously and therefore, attempted to verify the classification of the test. Since classification of test systems are performed by the FDA (Food and Drug Administration), the surveyors reviewed the FDA test classification database. The database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the classification of the test as high complexity or LDT-Laboratory Developed Test); (3) On 06/01/2021 at 12:26 pm, surveyor #1 and surveyor #2 explained to the laboratory director and laboratory manager the test was classified as LDT, which required the performance

	specifications of accuracy, precision, reportable range, analytical sensitivity, analytical specificity, and reference intervals (normal values), as applicable, be established and that personnel meet the high complexity regulatory requirements. Technical consultant #1 and testing person #1 stated to the surveyors on 06/01/2021 at 01:00 pm the laboratory thought the urine drug test was classified as waived and was not aware it had not gone through the FDA classification; (4) Surveyor #2 reviewed records for the test system and there was no evidence the test kit had been used for patient testing; (5) Following the survey, surveyor #2 received an email on 06/03 /2021 at 03:36 pm from a FDA policy analyst stating the Healgen Scientific 12 Panel Drug test had not been reviewed by the FDA and therefore there was no CLIA categorization determination for this test, defaulting it to a high complexity test system.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant #1 and testing person #1, the laboratory failed to ensure proficiency testing attestations, stating samples were tested as required under Subpart H, were signed by an individual meeting the regulatory qualifications for nine of 35 attestation statements. Findings include: (1) On 06/01/2021, surveyor #2 reviewed 2018, 2019, 2020 and 2021 proficiency testing records and identified that nine of 35 attestation statements had been signed by an individual who served as the laboratory director from 11/24/2018 through 08/31/2020, but did not meet the regulatory requirements of a laboratory director as stated at 493.1405 (refer to D6003) as follows: (a) Second 2018 Chemistry Miscellaneous Event (b) Third 2018 Hematology Event (c) Third 2018 Chemistry Core Event (d) Third 2018 Microbiology Event (e) Third 2018 Immunology Event (f) First 2019 Microbiology Event (g) First 2019 Hematology Event (h) First 2019 Chemistry Miscellaneous Event (i) First 2019 Immunology Event (2) Surveyor #1 and Surveyor #2 reviewed the records with technical consultant# 1. On 06/02/2021 at 02: 53 pm, technical consultant #1 and testing person #1 stated the attestation statements, as indicated above, had been signed and dated by an individual who did not meet the regulatory qualification requirements of a laboratory director.