Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2169508	04/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pro-Care Family Health Of Oklahoma, Llc	1013 Dewey Ave, Poteau, 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 initial survey was performed on 04/19/2021. The findings were reviewed with the laboratory director, technical consultant, testing person #1, and testing person #2 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 testing person #1, the laboratory failed to provide written instructions to clients collecting and referring urine drug specimens. Findings include: (1) On 04/19/2021 at 11:30 am, testing person #1 stated the following to the surveyor: (a) The laboratory performed Amphetamine, Benzodiazepine, Buprenorphine, Fentanyl, Methadone, Methamphetamine, Opiate, Oxycodone, Phencyclidine, and Tetrahydrocannabinol testing for urine specimens on the Beckman Coulter AU480 analyzer; (b) The urine specimens were transported to the laboratory from two outside clinics. (2) The surveyor asked testing person #1 if instructions (e.g., client service manual) had been written and provided to the client which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The testing person stated on 04/19/2021 at 12:35 pm, specimen handling instructions had not been written and provided to the client.
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 records and interview with testing person #1, the laboratory failed to follow specimen requirements for urine drug screen testing for 16 of 16 patient specimens. Findings include: (1) On 04/19/2021 at 11:30 am, testing person #1 stated the following to the surveyor: (a) The laboratory performed Amphetamine, Benzodiazepine, Buprenorphine, Fentanyl, Methadone, Methamphetamine, Opiate, Oxycodone, Phencyclidine, and Tetrahydrocannabinol testing for urine specimens on the Beckman Coulter AU480 analyzer. (2) The surveyor reviewed the laboratory's written procedure titled, "Assay for AU Systems" under the section titled, "2.0 SPECIMEN REQUIREMENTS:" stated: (a) "Use random urine. Samples within a Ph Range of 3 to 11 are suitable for testing with this assay."; (3) The surveyor reviewed patient test reports between 09/24/2020 through 04/14/202 and identified the following: (a) For 16 of 16 patient test reports there was no documentation to ensure each patient specimen was within a pH range of three to 11. (4) The surveyor reviewed the findings with testing person #1. Testing person #1 stated on 04/19/2021 at 12:55 pm, patient pH levels were not documented as indicated above.
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 testing person #1, the laboratory failed to demonstrate the performance specifications for one of one new test methods. Findings include: (1) On 04/19/2021 at 11:30 am, testing person #1 stated the following to the surveyor: (a) The laboratory began using the Beckman Coulter AU480 analyzer to perform Methamphetamine and Opiate testing for urine specimens on 09/22/2020. (2) The surveyor reviewed the performance specification records for the new test system and identified the following: (a) For Methamphetamine and Opiate there was no documentation to prove the laboratory had demonstrated the performance specifications for each analyte. (3) The surveyor reviewed the findings with testing person #1, who stated on 04/19/2021 at 12:35 pm, the laboratory did not have the documentation to prove the laboratory had demonstrated the performance specifications as stated above.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces

	a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, records and interview with testing person #1, the laboratory failed to establish analytical sensitivity and analytical specificity for urine drug testing for one of one analyte. Findings include: (1) On 04/19 /2021 at 11:30 am, testing person #1 stated the following to the surveyor: (a) The laboratory performed Benzodiazepine testing for urine specimens on the Beckman Coulter AU480 analyzer; (b) The laboratory began performing patient urine drug testing on 09/22/2020. (2) The surveyor reviewed the performance specification records and manufacturer's instructions and identified the following: (a) Immunalysis Benzodiazepines Urine Enzyme Immunoassay manufacturer's instructions stated, "The Immunalysis Benzodiazepines Urine Enzyme Immunoassays is a homogeneous enzyme Immunoassay with a cutoff of 200 ng/mL." (b) The laboratory performance specification records demonstrated accuracy, precision, reportable range, and reference range. However, the laboratory was using 300 ng/mL as the lowest cutoff value, which determined positive or negative patient results. (3) Since the laboratory had modified the manufacturer's cutoff concentration levels, the surveyor asked testing person #1 if analytical specificity and analytical sensitivity establishment studies had been performed. The laboratory director stated on 04/19/2021 at 01:10 pm analytical specificity and analytical sensitivity establishment studies had not been performed.
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, manufacturer's instructions, and interview with testing person #1, the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance procedures for the hematology analyzer. Findings include: (1) On 04/19/2021 at 11:30 am, testing person #1 stated the following to the surveyor: (a) The laboratory performed Amphetamine, Benzodiazepine, Buprenorphine, Fentanyl, Methadone, Methamphetamine, Opiate, Oxycodone, Phencyclidine, and Tetrahydrocannabinol testing for urine specimens on the Beckman Coulter AU480 analyzer. (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log. The maintenance requirements were as follows: (a) Daily (i) Inspect the syringes for leaks (ii) Inspect the Wash Solution Roller pump for leaks (iii) Inspect, Clean, and Prime the Sample Probe, Regent Probe, and Mix Bars (iv) Inspect the Wash Solution and Replenish a needed (v) Inspect the printer and paper (vi) Replace the DI H20 or diluent in the Pre-dilution Bottle (vii) Inspect the stability of the Upper Cover (viii) Prepare the Sample Probe Wash Solutions (b) Weekly (i) Clean the Sample Probe and Mix Bars (ii) Perform W2 (iii) Perform Photocal (iv) Clean the Pre-dilution Bottle (3) The surveyor then reviewed maintenance records from January 2021 through March 2021. The daily and weekly had not been documented as performed during the review period; (4) The surveyor reviewed the findings with testing person #1. Testing person #1 stated on 04/19/2021 at 01:10 pm the daily and weekly maintenance was performed but had not been documented as performed as indicated above.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records and an interview with the laboratory director and technical consultant, the laboratory failed to ensure the accuracy of patient test reports for one of one patient test report. Findings include: (1) On 04/19/2021, the surveyor reviewed a qualitative urine drug screen patient report tested on 12/14/2020 at 01:16 pm and identified the following: (a) The address on the report did not match the address on the CLIA certificate. (i) The address on the test report was 105 North Pocola Boulevard Suite B; (ii) The on the test report was 105 N. Pocola Blvd., Ste 2. (2) The surveyor reviewed the findings with the laboratory director and technical consultant. Both stated on 04/19/2021 at 01:40 pm the address on the test report did not match the CLIA certificate as indicated above.