

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2169508	(X3) Date Survey Completed 11/02/2023
Name of Provider or Supplier Pro-Care Family Health Of Oklahoma, Llc	Street Address, City, State 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 recertification survey was performed on 11/02/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the general supervisor and testing person #1 at the conclusion of the survey.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the general supervisor, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 11/02/2023 at 09:45 am, identified the following expired supplies that appeared to be available for use; (a) One gallon of LC-MS Grade Methanol - with an expiration date of 04/16/2023; (b) One gallon of LC-MS Grade Water - with an expiration date of 10/25/2023. (2) Interview with the general supervisor on 11/02/2023 at 09:45 am confirmed the expired supplies were available for use.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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</p>

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 general supervisor, the laboratory failed to have a function check protocol that ensured the Scilogex centrifuge was functioning properly for one of one function check performed during the review period of January 2023 through the current date. Findings include: (1) On 11/02/2023 at 09:45 am, the general supervisor stated the following: (a) The laboratory performed confirmatory urine drug testing using the AB Sciex Triple Quad 4500 analyzer; (b) Sample preparation included centrifuging specimens in the Scilogex centrifuge at a speed of 15,000 rpm (revolutions per minute) for 12 minutes. (2) A review of the policy titled, "Centrifuge Maintenance and Calibration Policy" did not specify the laboratory's method for ensuring the centrifuge timer would be checked for accuracy and stated, "Annually - Each centrifuge will be tested to verify speed accuracy (RPMs)"; (3) A review of the centrifuge function check records during 2023 identified the following for one of one check performed: (a) 06/22/2023 - The speed had been checked at 15,000 rpm. There was no documentation the timer had been checked. (4) The records were reviewed with the general supervisor who stated on 11/02/2023 at 10:55 am, the centrifuge timer had not been checked for accuracy.