

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0475146	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Payne And Rice Clinic, Inc	Street Address, City, State 116 Sw 2nd, Checotah, 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 04/10/19. The laboratory was found to be in compliance with a standard-level deficiency cited. The findings were reviewed with the laboratory manager and testing person #1 at the conclusion of the survey.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, observation, and interview with testing person #1 and testing person #2, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed urinalysis using the Multistix 10SG reagent dipsticks and the Clinitek 50 dipstick reader; (2) The surveyor observed the laboratory and identified the canister of the urine reagent dipsticks in use on the day of the survey (Lot #810024). There was no open date documented on the canister; (3) The surveyor asked reviewed the manufacturer's instructions for the reagent dipsticks, which stated the following: (a) "Record the opening date on the label."; (b) "Test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days." (4) The surveyor then asked testing person #1 to explain the laboratory's quality control procedure for the urine reagent dipsticks. Testing person #1 explained positive and negative urine controls were tested when a new canister of reagent dipsticks was opened, and before a new lot number was put into use; (5) The surveyor reviewed the manufacturer's instructions with testing person #1 and explained because the laboratory did not follow the manufacturer's instructions to document the open date on</p>

the canister, it could not be verified that quality control had been performed each 30 days of storage as the manufacturer required; (6) Testing person #1 stated to the surveyor, the laboratory failed to follow the manufacturer's instructions to record the open date on the label of the canister of reagent dipsticks to ensure the manufacturer's quality control requirement had been met.