

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0475146	<b>(X3) Date Survey Completed</b> 04/20/2021
<b>Name of Provider or Supplier</b> Payne And Rice Clinic, Inc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 04/20/2021. The findings were reviewed with testing person #1 and testing person #2 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person, the laboratory failed to ensure attestation statements were signed by the laboratory director or designee for 5 of 6 events. Findings include: (1) On 04/20/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records, with the following identified: (a) Third Hematology Event (FH2-C) 2019 - The attestation statement had not been signed by the laboratory director or designee; (b) First Hematology Event (FH2-A) 2020 - The attestation statement had not been signed by the laboratory director or designee; (c) Second Hematology Event (FH2-B) 2020 - The attestation statement had not been signed by the laboratory director or designee; (d) Third Hematology Event (FH2-C) 2020 - The attestation statement had not been signed by the laboratory director or designee; (e) First Hematology Event (FH2-A) 2021 - The attestation statement had</p>

not been signed by the laboratory director or designee. (2) The surveyor reviewed the records with testing person #1. On 04/20/2021 at 02:26 pm, the attestation statements had not been signed by the laboratory director as indicated above.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

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 ensure materials were stored as required by the manufacturer. Findings include: (1) On 04/20/2021 at 01:25 pm, testing person #1 stated the following to the surveyor: (a) Blood collection tubes, stored in the laboratory draw room, were used for the following: (i) Routine CBC (Complete Blood Count) testing performed on the Beckman Coulter analyzer. (2) The surveyor reviewed the manufacturer's environmental requirements for the blood collection tubes, which required a room temperature 4-25 degrees C (Celsius). The following were examples of blood collection tubes stored in the rooms: (i) BD Vacutainer K2 EDTA (50 tubes of lot# 0316343). (3) The surveyor reviewed laboratory temperature records from January 2021 through March 2021. There was no evidence that the temperature, where the blood collection tubes were stored, had been monitored at an acceptable range of 4-25 degrees C to accommodate the blood collection tubes; (4) The surveyor asked testing person #1 if the room temperature, where the blood collection tubes were stored, was being monitored. Testing person #1 stated on 04/20/2021 at 01:49 pm the room temperature was not being monitored.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on a review of records and interview with testing person #1, the laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training. Findings include: (1) On 04/20/2021, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #2 - This person was hired to perform patient testing on 11/02/2020. There was no documentation this

person had been initially trained; (2) The surveyor reviewed the findings with testing person #1. On 04/20/2021 at 02:15 pm testing person #1 stated there was no additional documentation to prove the above person had been initially trained to perform moderate complexity testing.