

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D1088990	<b>(X3) Date Survey Completed</b> 06/26/2019
<b>Name of Provider or Supplier</b> Palmetto Pain Management, Llc	<b>Street Address, City, State</b> 2611 Forest Drive, Columbia, SC	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 06/26/2019, based on laboratory procedure manual review, chemistry analyzer operator's manual review, lack of documentation, and testing personnel interview, it was determined that the laboratory failed to document and monitor room humidity readings for 3 of 3 years reviewed (2017, 2018, and 2019). Findings include: 1. The laboratory procedure manual stated a required room humidity range of 40 to 80% would be documented daily. 2. The operator's manual for the AU400 chemistry analyzer stated that the instrument should be operated at an ambient humidity of 40 to 80% humidity. 3. Documentation of acceptable humidity readings and of humidity being routinely monitored was unavailable for review on the day of the survey for the years 2017, 2018, and 2019. 4. Testing personnel confirmed during an onsite interview on 06/26/2019 at 2:00pm that the laboratory had failed to ensure that acceptable humidity ranges were monitored and documented for the laboratory.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

During an onsite recertification on 06/26/2019, based on instrument operator manual review, instrument maintenance record review and testing personnel interview, it was determined that the laboratory failed to document quarterly maintenance on the chemistry instrument for three of three years reviewed (2017, 2018, and 2019).

Findings include: 1. Review of the AU400 chemistry analyzer operator's manual revealed that all operators should routinely perform scheduled maintenance to ensure optimum performance of the instrument including a quarterly cleaning of the air filters and replacement of the wash solution. 2. Review of the AU400 chemistry analyzer maintenance logs on 06/26/2019 at 2:00pm revealed that quarterly maintenance had not been documented for three of three years reviewed (2017, 2018, and 2019). 3. Testing personnel confirmed during an onsite interview on 06/26/2019 at 2:30pm that the quarterly maintenance had not been performed for the reviewed years.

**D5777**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(b)(c)

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

During an onsite recertification survey on 06/26/2019, based on the laboratory procedure manual, lack of documentation and testing personnel interview, the laboratory failed to ensure that documentation of urine drug test result comparison procedures was performed for 3 of 3 years reviewed (2017, 2018, and 2019). Findings include: 1. The laboratory procedure manual stated that the records of 10 patients who had urine drug testing laboratory procedures requested would be selected and reviewed by the laboratory quarterly to ensure the following criteria were consistent: (1) patient age, (2) sex, (3) diagnosis or pertinent clinical data, (4) distribution of patient test results, (5) relationship with other test parameters. 2. Documentation of a quarterly patient record review for CBC testing was unavailable for review on the day of the survey for the years 2017, 2018, and 2019. 3. Testing personnel confirmed during an onsite interview on 06/26/2019 at 2:00pm that the laboratory had failed to ensure that a urine drug test result comparison was performed as required.