

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2107857	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier L5 Medical Holdings Llc DbA Pain Care Center Of	Street Address, City, State 6580 Valley Center Drive, Suite 108, Radford, VA	
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	An announced CLIA Recertification survey was conducted at the L5 Medical Holdings on March 28, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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: A. Based on the tour of the laboratory, manufacturer package inserts (PI), and an interview with the technical consultant, the laboratory failed to ensure that the calibration materials for the DRI THC, CEDIA Buprenorphine, and Immunalysis Oxydocdone analytes were within the stated manufacturer expiration date ranges at the date of survey on March 28, 2019. Findings include: 1. Tour of the laboratory and review of the PI's revealed the following calibration materials (located in the lab refrigerator) and expiration dates for the DRI THC, CEDIA Buprenorphine, and Immunalysis Oxydocdone analytes: DRI THC 50 (lot number 72862307) and 100 ng/mL (lot number 72862304) exp date 01/30/2019, Immunalysis Oxydocdone 100 mg/mL (lot number E32733) exp date 02/28/2019, CEDIA Buprenorphine Negative (lot number 72630057) open vial exp date 60 days (opened 10/4/2018), CEDIA Buprenorphine 5 ng/mL (lot number 72630061) open vial exp date 60 days (opened 10/4/2018), CEDIA Buprenorphine 20 ng/mL (lot number 72630064) open vial exp date 60 days (opened 10/4/2018), CEDIA Buprenorphine 50 ng/mL (lot number 72630068) open vial exp date 60 days (opened 10/4/2018) and, CEDIA Buprenorphine 75 ng/mL (lot number 72630071) open vial exp date 60 days (opened 10/4/2018). 2. An interview with the technical consultant at approximately 4:15 PM</p>

confirmed that the calibration materials specified above were expired at the date of survey. B. Based on the tour of the laboratory, manufacturer package inserts (PI), patient testing data, and an interview with the technical consultant, the laboratory failed to ensure the DRI THC and CEDIA Buprenorphine calibration materials were not used beyond the stated manufacturer expiration dates when performing calibration procedures on January 20, 2019 and February 28, 2019. The laboratory tested three hundred and forty-nine (349) patients with the DRI THC assay and nine hundred and seventy-six (976) patients with the CEDIA Buprenorphine assay from January 20, 2019 and up to the date of survey on March 28, 2019. Findings include: 1. Tour of the laboratory and review of PI's revealed that the following calibration materials (located in the lab refrigerator) and expiration dates for the DRI THC and CEDIA Buprenorphine: DRI THC 50 (lot number 72862307) and 100 ng/mL (lot number 72862304) exp date 01/30/2019, CEDIA Buprenorphine Negative (lot number 72630057) open vial exp date 60 days (opened 10/4/2018), CEDIA Buprenorphine 5 ng/mL (lot number 72630061) open vial exp date 60 days (opened 10/4/2018), CEDIA Buprenorphine 20 ng/mL (lot number 72630064) open vial exp date 60 days (opened 10/4/2018), CEDIA Buprenorphine 50 ng/mL (lot number 72630068) open vial exp date 60 days (opened 10/4/2018) and, CEDIA Buprenorphine 75 ng/mL (lot number 72630071) open vial exp date 60 days (opened 10/4/2018). The laboratory utilized the above-specified calibration materials to perform calibration procedures on January 20, 2019 and February 28, 2019. 2. Review of the patient testing data revealed 349 patients assayed with the DRI THC test and 976 patients assayed with the CEDIA Buprenorphine test from January 20, 2019 and up to the date of survey on March 28, 2019. 3. An interview with the technical consultant at approximately 4:15 PM confirmed that the findings.

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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures (P&P), lack of documentation, and an interview with the testing personnel, the laboratory director failed to ensure that testing personnel (TP) A had documented training and competency assessment for the new Thermo Scientific Indiko Plus analyzer prior to testing patients on January 20, 2019. Findings include: 1. Review of CLIA CMS- 209 form revealed TP A performed patient testing (see attached testing personnel code sheet). 2. Review of TP A records revealed a lack of documentation of training and competency assessment for the new Thermo Scientific Indiko Plus analyzer installed on January 17, 2019. Patient testing began on January 20, 2019. 3. Review of the Personnel Competency Assessment P&P (signed by the lab director on 01/13/2017) revealed the following statements: "To ensure all laboratories testing personnel meet the qualifications as determined by CLIA. These regular assessments will also ensure personnel understand their testing responsibilities

and insure they have appropriate training and comprehension to perform testing procedures in an accurate and reliable manner. Training checklist- one form for each analyzer/test the tech is performing." The inspector requested to review the training checklist and competency assessment for the new chemistry analyzer. The documentation was not available for review. 4. An interview with TP A at approximately 4: 15 PM confirmed the lack of training documentation and competency assessment for the new analyzer installed on January 17, 2019.