Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2050971	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Pain Care Center Of Lynchburg, L5 Medical, Llc	**Street Address, City, State** 4262 S Amherst Hwy Suite 200, Madison Heights, 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 Pain Care Center of Lynchburg on August 16, 2018 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:
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 the tour of the laboratory, review of manufacturer package inserts (PI), and interviews, the laboratory failed to monitor and document the freezer temperatures to ensure proper storage of the urine samples for the drugs of abuse panel testing according the manufacturer instructions for the calendar year of 2017 and up to the date of survey on August 16, 2018. Findings include: 1. Tour of the laboratory and an interview with the testing personnel at approximately 12:00 PM revealed that the lab stores patient urine samples for drugs of abuse panel testing in the freezer for initial test and confirmation testing. 2. Review of the Thermo Scientific PI's for the assays of amphetamines, benzodiazepines, buprenorphine, cannabinoids, cocaine metabolite, methadone, opiates, and oxycodone revealed the following statements: "For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20 degrees Celsius." 3. The inspector requested to review the freezer

	temperature records for the calendar year of 2017 and up to the date of survey on August 16, 2018. The documents were not available for review. 4. An interview with the primary testing personnel at approximately 1:30 PM confirmed that the lab did not monitor and document the freezer temperatures for the proper storage of urine samples.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of daily quality control (QC) records, QC policy, patient testing logs and interviews, the laboratory failed to perform a negative and positive QC material on October 5, 2017 prior to reporting eighteen (18) patients as described within the policy. Findings include: 1. Review of daily QC records from January 1, 2017 and up to the date of survey on August 16, 2018 for the assays of amphetamines, benzodiazepines, buprenorphine, cannabinoids, cocaine metabolite, methadone, opiates, and oxycodone tested on the Indiko Plus Thermo Scientific instrument revealed that on October 5, 2017, positive and negative QC materials were not assayed. 2. Review of the laboratory's "Quality Control Policy" revealed the following statements: " Purpose: To ensure accuracy of laboratory testing equipment and integrity of results generated to be performed daily and shown to general supervisor. Toxicology- Two levels of assayed quality control material are utilized. If control levels fail then mix control, vial and repeat, if fails then use new control vial. If still fails then check reagent level and calibration status. Fill and recalibrate then repeat. If still fails then no testing will be done until the problem is resolved." 3. Review of daily patient testing logs revealed the following patients were assayed on October 5, 2017: Accession number 0035, Accession number 4513, Accession number 5136, Accession number 2829, Accession number 4711, Accession number 4029, Accession number 3152, Accession number 2182, Accession number 5128, Accession number 1548, Accession number 4205, Accession number 4011, Accession number 0125, Accession number 5127, Accession number 4520, Accession number 4699, Accession number 4821 and Accession number 4172. A total of 18 patients. 4. An interview with the primary testing personnel at approximately 1:30 PM confirmed that the laboratory did not assay QC materials on October 5, 2018 while reporting patients listed above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of CMS 209 Laboratory Personnel Report Form (CLIA), testing personnel (TP) records, the quality assurance (QA) policy and interviews, the

	technical consultant failed to perform and document annual competency assessments for one (1) of one (1) TP in 2017. Findings include: 1. Review of the CMS-209 form revealed that TP A performs patient testing. See attached personnel code list. 2. Review of the TP A records revealed no documentation of competency assessments performed by the technical consultant in 2017 and up to the date of survey on August 16, 2018. The inspector requested the competency assessments. The documentation was not available for review. 3. Review of the QA policy revealed the following statement: " VIII Competency- B. Existing employees are checked annually and periodically as needed. Competency may be checked by: 1. director observation (use SOP or a check list to ensure no steps are omitted). 2. Quality Control review. 3. Repeat testing. 4. Unusual patient or unusual control review. 5. Proficiency testing review. 6. Blind specimen analysis. 7. Oral examination." 4. An interview with the primary testing personnel at approximately 1:30 PM confirmed that the technical consultant failed to perform the competency assessment for TP A in 2017.