

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2107857	(X3) Date Survey Completed 06/29/2021
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 on-site survey was conducted at the L5 Medical Holdings on June 29, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on June 4, 2021 with off-site record review of documentation on June 28, 2021. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6000 - 42 C.F.R. 493-1403 Condition: Moderate Complexity Laboratory Director.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), lack of documentation, and interviews, the laboratory did not have a P&P for performing competency assessments on individuals performing the job duties of technical supervisor (TS), general supervisor (GS), and technical consultant (TC) at the date of the survey on 06/29/21. Refer to D5407. Findings include: 1. Review of the available P&P's revealed lack of documentation of a policy for performing competency assessments on individuals performing the job duties of TS, GS, and TC. The inspector requested to review the P&P for competency assessments. The document was not available for review at the date of survey. 2. An exit interview with TP A on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings.</p>
D5407	PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure (P&P) manual, lack of documentation and interviews, the laboratory director failed to review, approve, and sign the P&P at the date of survey on 06/29/21. Findings include: 1. An interview with the testing personnel (TP) A on 06/29/21 at approximately 10:00 AM revealed that the new lab director accepted responsibilities as of 06/30/21. 2. Review of the P&P located in the laboratory binder and presented to the inspector at the date of survey (signed by the previous lab director on 01/13/17) lacked documentation of review and approval by the current laboratory director. Review of the P&P presented to the inspector at approximately 2:45 PM on the date of survey revealed lack of documentation by the current lab director indicating review and approval. In addition, TP A stated that the second P&P was the current P&P in use by laboratory staff. 3. An exit interview with the TP on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory 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:

Based on the review of operator's guide, instrument data, lack of documentation, and interviews, the laboratory failed to follow and document the weekly and monthly maintenance for the Thermo Fisher Indiko Plus Chemistry analyzer from 03/28/19 up to the date of survey on 06/29/21, a total of twenty-six (26) months. Findings include: 1. Review of the operator's guide revealed the following maintenance procedures to be done weekly to include cleaning cuvette waste bin, clean sample racks and reagent disk and clean wash well; and monthly maintenance to include cleaning of the incubator. 2. Review of the available data within the instrument revealed lack of documentation of performance of weekly and monthly maintenance procedures. Additional maintenance documentation was not available for review upon request at the date of survey. 3. An exit interview with TP A on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel

who performed the test(s).

This STANDARD is not met as evidenced by:

Based on the review of patient test records, personnel education records, and interviews, the laboratory failed to include the identity of the individual performing the Liquid chromatography/Tandem Mass Spectrometry (LG/MS) for three (3) of 3 patients reviewed at the date of survey on 06/29/21. Findings include: 1. The surveyor selected 3 patient test numbers and performed a patient tracing method at the date of survey. Patient 1- 133175 on 11/06/20, Patient 2- 134466 on 01/11/21 and Patient 3- 138003 on 05/24/21. 2. Review of the AB Sciex 4000 Quadrupole mass spectrometer instrument results did not provide the identity of the individual performing and reviewing patient test data, daily calibrations and quality control results. During the review of instrument data, TP A demonstrated that the instrument was able to include the identity of the individuals performing daily testing procedures. The function had not been enabled prior to the date of survey. 3. Review of the Labtrak Laboratory Information System (LIS) results for the above-mentioned patients' revealed TP B initials as indicating review and accepting results. In an interview with TP A and B at the date of survey at approximately 12:00, TP A stated that TP B was just reviewing other patient data and that their initials populated because TP B was logged into the Labtrak LIS. Review of TP B education records revealed TP B is not qualified to perform high complexity testing. 4. An exit interview with TP A on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the review of policy and procedures (P&P), available quality assurance (QA) documents, lack of documentation and interviews, the laboratory failed to demonstrate a QA mechanism to identify and address analytic issues in the sub-specialty of toxicology from 03/28/19 up to 06/01/20, a total of fourteen (14) months at the date of survey on 06/29/21. Findings include: 1. Review of the P&P located in the laboratory binder and presented to the inspector at the date of survey (signed by the previous lab director on 01/13/17) revealed the following statement: "Quality Management General Policy- the general laboratory systems are monitored on a monthly basis utilizing the "Monthly Quality Assessment Checklists". Each month's review is maintained in a monthly folder and stored for two years in the laboratory. When issues are identified we evaluate and determine corrective action. All issues and changes are documented and communicated to the staff via the "Monthly Issues /Action Log". The laboratory director and all pertinent laboratory staff will review and initial these forms on a monthly basis." The lab lacked documentation of the QA checklist from 03/28/19 up to 06/01/20 upon request at the date of survey on 06/29/21. 2. An exit interview with TP A on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings.

D6000**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION 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), quality control (QC) records, instrument data, patient results, personnel records, lack of documentation, and interviews, the laboratory director failed to: 1. Ensure initial and semi-annual competency assessments were documented for TP B (Refer to D6029 part A), and 2. Ensure annual competency assessments were documented for TP A (Refer to D6029 part B), 3. Delegate, in writing, the job duties and responsibilities of technical consultant (TC) and testing personnel (TP) (Refer to D6032).

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:

****REPEAT DEFICIENCY**** A. Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures (P&P), lack of documentation, and interviews, the laboratory director failed to ensure the performance and documentation of initial and semi-annual competency assessments prior to testing patients on 09/08/20 for testing personnel (TP) B. Findings include: 1. Review of CLIA CMS- 209 form revealed TP B performing patient testing (see attached testing personnel code sheet). 2. Review of TP B records revealed lack of documentation of initial and semi-annual competency assessments. Patient testing began on 09/08/20. The inspector requested to review the initial and semi-annual competency assessments for TP B. The documentation was not available for review. 3. An exit interview with TP A on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings. B. Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures (P&P), lack of documentation, and interviews, the laboratory director failed to ensure the performance and documentation of annual competency assessments performed in the calendar years of 2019 and 2020 for testing personnel (TP) A. Findings include: 1. Review of CLIA CMS- 209 form revealed TP A performing patient testing (see attached testing personnel code sheet). 2. Review of TP A records revealed lack of documentation of annual competency assessments in 2019 and 2020. The inspector requested to review the annual competency assessments for TP A. The documentation

was not available for review. 3. An exit interview with TP A on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test 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), quality control (QC) records, instrument data, patient results, personnel records, lack of documentation and interviews, the laboratory director did not delegate, in writing, the job duties and responsibilities of technical consultant (TC) and testing personnel (TP) to the individual performing the duties of TC and TP at the date of survey on 06/29/21. Findings include: 1. Review of the CLIA 209 form and interview with TP A on the date of survey at approximately 11:00 AM revealed TP A performing duties of TC and TP B performing duties of TP. (See attached TP Code Sheet.) 2. Review of the QC records, and instrument data for the Thermo Fisher Indiko Plus analyzer revealed that TP A was performing duties of TC in the calendar year of 2020 and up to the date of survey in 2021. In addition, TP B was performing testing of moderate complexity with the Thermo Fisher Indiko Plus analyzer from 09/08/20 up to the date of survey. 3. Review of TP records and P&P revealed lack of documentation of the delegation of duties of TC, in writing, by the current laboratory director to TP A and TP B. The inspector requested to review the above-mentioned documentation. The documentation was not available for review. 4. An exit interview with TP A on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test 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), quality control (QC) records, instrument data, patient results, personnel records, lack of documentation and interviews, the laboratory director did not delegate, in writing, the job duties and responsibilities of technical supervisor (TS) and general supervisor (GS) to the individual performing the duties of TS and GS at the date of survey on 06/29/21. Findings include: 1. Review of the CLIA 209 form and interview with TP A on the date of survey at approximately 11:00 AM revealed TP A performing duties of TS and GS. (See attached TP Code Sheet.) 2. Review of the QC records, and instrument data for the AB Sciex 4000 Quadrupole mass spectrometer revealed that TP A was performing duties of TS and GS in the calendar year of 2020 and up to the date of survey in 2021. 3. Review of TP records and P&P revealed lack of documentation of the delegation of duties of TS and GS, in writing, by the current laboratory director to TP A. The documentation was not available for review. 4. An exit interview with TP A on 06/29/21 at approximately 3:00 PM confirmed the findings. A phone interview with the lab director on 06/30/21 at approximately 12:45 PM confirmed the findings.