

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2022398	(X3) Date Survey Completed 08/14/2018
Name of Provider or Supplier Hudson Valley Pain Management Pllc	Street Address, City, State 1940 Commerce Street Suite 212, Yorktown Heights, NY	
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
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 a review of laboratory competency procedures and an interview with the laboratory testing person, the laboratory failed to follow their written policies and procedures to assess the competency of the laboratory testing personnel semi-annual and annual for the first year of patient testing. Findings Include: It was confirmed by the laboratory testing person on August 14, 2018, at approximately 11:45 am, that the director acting as the technical consultant failed to have documentation of semi-annual and annual competency for the testing person since testing began for toxicology in December 2016.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of laboratory records and an interview with the</p>

	<p>laboratory testing person, the laboratory failed to follow the Quality Assessment (QA) policy and perform general laboratory systems quarterly QA reviews for all phases of testing since testing began in December 2016.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of instrument maintenance records and an interview with the laboratory testing person, the laboratory failed to have documentation of the required manufacturer's daily, weekly, and monthly maintenance for the Biolis 24 i Toxicology Analyzer.</p>
<p>D5439</p>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of records and an interview with the laboratory testing person, the laboratory failed to perform calibration verification every six months after testing began in December 2016 through the date of this survey on the Biolis 24 i toxicology analyzer for urine Creatine, Amphetamine, Barbiturates, Cocaine Metabolites, Methadone, Methamphetamine, Opiates and Oxycodone. Approximately 875 patient specimens were tested and results released from December 2016 through the date of this survey.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

	<p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of calibration verification records and an interview with the laboratory testing person, the laboratory director failed to ensure that the QC program was maintained for toxicology testing. Refer to D5439</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures and an interview with the practice manager, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D5429</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor review of the personnel procedures and an interview with the laboratory testing person, the laboratory director, acting as the technical consultant, failed to perform and document the semi-annual evaluation for the testing person during the first year of patient testing in calendar year 2017. Refer to D5209.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of personnel records and an interview with the laboratory testing person, the laboratory director, acting as the technical consultant, failed to perform the annual competency evaluation for the testing person who performs high complexity toxicology testing in calendar year 2017. Refer to D5209.</p>