

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2000860	<b>(X3) Date Survey Completed</b> 08/13/2019
<b>Name of Provider or Supplier</b> Premier Brain And Spine Llc	<b>Street Address, City, State</b> 2500 Morris Avenue, Union, NJ	
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>D5315</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(c)</p> <p>The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Toxicology Records, Final Reports and interview with the Testing Personnel (TP) and Technical Supervisor (TS), the laboratory referred Urine Toxicology confirmation testing to a non-CLIA-certified laboratory from March 2019 to the date of survey. The findings include. 1. The TP #2 listed on CMS form 209 reviewed, verified and resulted toxicology results from a non-CLIA-certified laboratory. 2. The TP #2 listed on the CMS form 209 stated "TP read Toxicology results from home". 3. The TS confirmed on 8/13/19 at 2 pm that toxicology tests were reviewed and resulted from a non-CLIA-certified laboratory.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in</p>

the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to have all procedures needed for Urine Toxicology tests run on the Applied Biosystem Sciex Triple Quad 4500 from March 2019 to the date of the survey. The findings include: 1. The laboratory failed to have procedures for: a. Verification of new lots of reagents, prepared mobile phases and standards before they were put in use. b. Acceptance criteria for results with an "Ion Ratio Failure". 2. The TS confirmed on 8/13/19 at 1:50 pm that the laboratory did not have the above procedures.

**D5467**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual, Calibrators, Controls and interview with the Technical Supervisor (TS), the laboratory failed to prepare control material from different lot numbers of calibrators for Urine Toxicology confirmation and screening tests from March 2019 to the date of the survey. The TS stated on 8/13 /19 at 2:10 pm the laboratory did not use different lot numbers to prepare calibrators and controls.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that PS were adequate to perform Urine Toxicology tests on the Applied Biosystem Sciex Triple Quad 4500 system from March 2019 to the date of survey. The findings include: 1. There was no validation performed to establish the expiration date of reagents, working solutions, Internal Standard, controls and calibrators used. 2. The validation of the hydrolysis control did not include validation of: a. Optimal Enzyme Concentration b. Temperature of the Heat Block c. Time on the Heat Block 3. Sample

stability studies were not performed on frozen samples or samples over 5 days old. 4. The TS confirmed on 8/13/19 at 2:20 pm that the LD did not ensure the PS were adequate.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that Urine Drug Screen results for UDS A - 2019 PT performed with the College of American Pathologists (CAP) were reviewed and evaluated by the appropriate staff. The TS confirmed on 8/13/19 at 10:45 am that the LD did not ensure all PT reports were reviewed.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

The laboratory director must 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 surveyor review of Personnel Records (PR) and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that education and training records for one of two testing personnel were available from March 2019 to the date of the survey. The TS confirmed on 8/13/19 at 10:00 am that all education and training records were not available.