

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2117532	<b>(X3) Date Survey Completed</b>  06/18/2019
<b>Name of Provider or Supplier</b>  Premier Labworks Inc	<b>Street Address, City, State</b>  1388 Court St Ste A-1, Redding, CA	
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>D5467</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(9)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control and patient test records, policies and procedures, and interview with the laboratory Technical Supervisor and testing personnel, the laboratory failed to use the calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system as a control material. The findings include: a. The laboratory does drug confirmation test for 44 different analytes using HPLC/mass spectrometry methods. It has developed the test in the laboratory. The laboratory uses a calibration material from a manufacturer to calibrate the system. However, the laboratory uses the same calibration material from the same lot as a quality control material. b. The laboratory Technical Supervisor, on 6/18/2019 at 11:30 am, affirmed that the laboratory uses the same lot from the manufacturer to calibrate the system and as a quality control material. c. The laboratory's testing declaration form, signed by the laboratory Director on 6/17/2019, stated that the laboratory performs 55,200 tests, annually.</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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>

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, quality control test records, and interview with the Laboratory Technical Supervisor, it was determined that the laboratory director failed to 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. The findings include: See D5467.