

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0978959	<b>(X3) Date Survey Completed</b>  07/19/2018
<b>Name of Provider or Supplier</b>  Pharmalogic Penn Ltd	<b>Street Address, City, State</b>  2608 Elmira Street, Sayre, PA	
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>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Instructions for Clay Adams Brand DYNAC Centrifuge Models Nos: 420101 and 420102, observation of the laboratory and interview with the Laboratory Director (LD), the laboratory failed to document maintenance for 1 of 1 Clay Adams Dynac Centrifuge (Model # 420101) used for Radioisotope testing of Chromium 51, from 2017 to the date of survey. Findings Include: 1. Review of the Instructions for Clay Adams Brand DYNAC Centrifuge Models Nos: 420101 and 420102, Maintenance section under Motor Brushes, States "Every six months the motor brushes should be inspected for wear. Brushes should be replaced when they are less than 1/4 of an inch (0.63 cm) long. Use only the replacement brushes specified in the PARTS LIST section." 1. On the day of survey, 07/19/2018, 1 Clay Adams Dynac Centrifuge (Model # 420101) used for Radioisotope testing for Chromium 51 was observed in the laboratory. The laboratory could not provide 2017 and 2018 maintenance documentation for the centrifuge. 2. In 2017 (January 1st to December 31st) the laboratory performed 10 Radioisotope tests for Chromium 51. 3. In 2018 (January 1st to July 17th) the laboratory performed 2 Radioisotope tests for Chromium 51. 4. The LD confirmed on 07/19/2018 around 10:15 am, that the laboratory did not document maintenance for the Clay Adams Dynac centrifuge.</p>