

Laboratory Name: \_\_\_\_\_

Model #: \_\_\_\_\_

Date \_\_\_\_\_

Analyst \_\_\_\_\_

**ADVANCED INSTRUMENTS: ALP FLUOROPHOS QC CHECK LIST**

<u>VALUES</u>		<u>COMPLIANCE</u>	<u>ACTUAL</u>
<b>1. Heater Block Temperature</b>		37- 39°C	
<b>2. Zero Check: A/D set-up</b>		< 315 mU/L	
<b>3. Daily Instrument Check (DIC): A/D Set-up</b>		602 ± 15 mU/L	
<i>Calibrator C may be used instead of DIC to verify instrument accuracy.</i>			
DIC or Cal. C (circle one)	Lot #	Manufacturer Expiration Date	
<b>*If DIC or Calibrator C reading is out of range skip to #8 – Do not proceed with testing</b>			
<b>4. Reconstituted Substrate stability check: A/D Set-up</b>		< 1,200 mU/L	
Lot #		Manufacturer Expiration Date	
Date Prepared		Lab Expiration Date	
<i>Substrate is light and heat sensitive and must be checked before use.</i>			
<b>5. Reconstituted Substrate contamination check (on Empty Channel)</b>		<10 mU/L	
<i>If the working substrate value does not fall within the acceptable ranges (&lt;1,200 mU/L A/D, &lt;10 mU/L Empty Channel), do not use working substrate; re-test, reconstitute a new set of reagents and/or seek technical assistance before testing samples.</i>			
<b>6. Positive Control</b>			
PhosphaCheck Positive Control		500 ± 100 mU/L	
Lot #		Manufacturer Expiration Date	
<i>PhosphaCheck control expires 72 hours after preparation</i>	Date Prepared	Lab Expiration Date	
Laboratory Prepared Positive Control		500 ± 150 mU/L	
Date Prepared		Lab Expiration Date	
<b>7. Negative Control</b>			
PhosphaCheck Negative Control		<10 mU/L	
Lot #		Manufacturer Expiration Date	
<i>PhosphaCheck control expires 72 hours after preparation</i>	Date Prepared	Lab Expiration Date	
Laboratory Prepared Negative Control		<20 mU/L	
Date Prepared		Lab Expiration Date	
<b>8. Adjust potentiometer (if out-of-range) - using Calibrator C. *Recalibrate all channels when complete</b>			
Calibrator C reading		602 ± 6	Final Reading
<b>9. Check Calibrator ratio of Calibrators A, B and C (Prior to Calibration) - Set Up Empty Channel</b>			
Acceptable ratio		151 ± 7	Test Ratio
Lot #		Manufacturer Expiration Date	
<i>Calibrators expire 60 days after opening</i>		Date opened	
<b>Re-calibration is required if: 1. Controls are out of limit 2. Adjustments to potentiometer are needed 3. Any significant instrument service is performed. (as per FDA 2400 form)</b>			