

Laboratory Name: _____

Model #: _____

Date _____

Analyst _____

ADVANCED INSTRUMENTS: ALP FLUOROPHOS QC CHECK LIST

| <u>VALUES</u> | | <u>COMPLIANCE</u> | <u>ACTUAL</u> |
|--|---------------|------------------------------|---------------|
| 1. Heater Block Temperature | | 37- 39°C | |
| 2. Zero Check: A/D set-up | | < 315 mU/L | |
| 3. Daily Instrument Check (DIC): A/D Set-up | | 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 | |
| *If DIC or Calibrator C reading is out of range skip to #8 – Do not proceed with testing | | | |
| 4. Reconstituted Substrate stability check: A/D Set-up | | < 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> | | | |
| 5. Reconstituted Substrate contamination check (on Empty Channel) | | <10 mU/L | |
| <i>If the working substrate value does not fall within the acceptable ranges (<1,200 mU/L A/D, <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> | | | |
| 6. Positive Control | | | |
| 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 | |
| 7. Negative Control | | | |
| 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 | |
| 8. Adjust potentiometer (if out-of-range) - using Calibrator C. *Recalibrate all channels when complete | | | |
| Calibrator C reading | | 602 ± 6 | Final Reading |
| 9. Check Calibrator ratio of Calibrators A, B and C (Prior to Calibration) - Set Up Empty Channel | | | |
| Acceptable ratio | | 151 ± 7 | Test Ratio |
| Lot # | | Manufacturer Expiration Date | |
| <i>Calibrators expire 60 days after opening</i> | | Date opened | |
| 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) | | | |