**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k050790

**B. Purpose for Submission:** Notification of intent to manufacture and market a new device: SPOTCHEM II LDH assay.

**C. Measurand:**

LDH – Lactate Dehydrogenase

**D. Type of Test:**

Colorimetric

**E. Applicant:**

Akray, Inc. c/o Polymedco Inc.

**F. Proprietary and Established Names:**

Proprietary name – SPOTCHEM II Lactate Dehydrogenase (LDH)

Established name – Lactate Dehydrogenase (LDH)

**G. Regulatory Information:**

1. Regulation section:

   LDH – 21 CFR 862.1440 Lactate Dehydrogenase test system

2. Classification:

   LDH – Class II, meets the limitations of exemptions 21 CFR 862.9 (c) (4). The device is an in vitro device that is intended for assessing the risk of cardiovascular disease.

3. Product code:

   LDH – CFH

4. Panel:

   75, Chemistry

## H. Intended Use:

1. Intended use(s):

   See Indications for use below

2. Indication(s) for use:

   The SPOTCHEM II LDH test is intended to measure the activity of the enzyme lactate dehydrogenase in serum, plasma, and whole blood. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.

3. Special conditions for use statement(s):

   For professional use only

4. Special instrument requirements:

   The SPOTCHEM II LDH test is an in-vitro diagnostic procedures intended to measure LDH activity quantitatively in human serum and plasma (whole blood) on the SPOTCHEM EZ SP-4430 analyzer.

## I. Device Description:

The SPOTCHEM II LDH consists of 25 reagent strips and a test specific calibration card. The SPOTCHEM II LDH Reagent Strip is composed of a

plastic strip to which a multilayered test field is affixed. The layers consist of a sample-retention layer, a layer containing the reagents and a support layer.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

   PolyChem LDH kit, LDH500

2. Predicate 510(k) number(s):

   K020852

3. Comparison with predicate:

| LDH | | |
|---|---|---|
| Item | Device | Predicate |
| Methodology | Colorimetric, enzyme based | Colorimetric |
| Reagent Storage | 2-8$^0$C | 2-8$^0$C |
| Sample Types | Serum/plasma from whole blood samples | Serum |

**K. Standard/Guidance Document Referenced (if applicable):**

None referenced

**L. Test Principle:**

Enzyme based colorimetric

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Intra Assay precision was assessed at three levels. Twenty replicates of the same sample within one analytical run were evaluated at three levels. The mean, standard deviation (SD), and coefficient of variation (CV) in percent were calculated. An intra assay CV of <5% was determined to be acceptable.

| Analyzer SPOTCHEM LDH | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| n | 20 | 20 | 20 |
| Mean | 121.1 | 164.3 | 377.1 |
| SD | 4.03 | 4.57 | 12.77 |
| %CV | 2.1% | 3.3% | 2.1% |

Inter assay precision was determined by analyzing duplicates of three different samples in each of ten different runs over ten different occasions. An inter assay CV of <10% was determined to be acceptable.

| Analyzer SPOTCHEM LDH | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| Days | 5 | 5 | 5 |
| n | 20 | 20 | 20 |
| Mean | 116.1 | 159.0 | 359.6 |
| SD | 3.84 | 4.17 | 15.28 |
| %CV | 3.3 | 2.6 | 4.2 |

b. *Linearity/assay reportable range:*

Linearity/calibration curve fit data were generated for a pool that spanned the linear range of the test. Serial dilution sets were prepared using 7% BSA and made up fresh and assayed with each of three calibrated runs. The results at each level of analyte were averaged and the linear fit was assessed. The linearity claim is based on a percent deviation of ≤ 5% at the two highest analyte concentrations. The LDH test was found to be linear from 59.7 to 914 IU/L. Linear fit parameters were $y=1.009x -24.58$ $r^2=0.9976$.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Calibration on the magnetic calibration card was determined by an internal stability study. The initial shelf-life determinations were conducted by accelerated aging studies and backed up with real time aging studies. The shelf life of the magnetic calibration card was conducted after exposure to real shipping conditions and labeled storage conditions. The duration of the testing is 25% beyond the labeled expiration date for an 80% claim.

d. *Detection limit:*

The minimum detectable LDH activity with an acceptable level of precision was determined as 100 IU/L.

e. *Analytical specificity:*

Interfering substances:

| | LDH |
|---|---|
| Sample | Highest Level Tested with No Interference |
| Hemoglobin | 300 mg/dL |
| Bilirubin | 11.58 mg/dL |
| Triglycerides | 385.6 mg/dL |

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Correlation studies were performed comparing the LDH test results generated on the SPOTCHEM EZ SP-4430 analyzer against the results generated from legally marketed tests. The 41 serum samples spanned from 101 to 553 IU/L. The regression equation was y=0.955x + 2.946 and r=0.9964.

b. *Matrix comparison:*

Correlation studies were performed comparing the LDH test results

generated on the SPOTCHEM EZ SP-4430 for the specimen types of serum and whole blood. Eighteen matched samples of serum and whole blood were analyzed. The regression equation for the 18 serum and whole blood samples was y=0.983x+0.016 and $r^2$=0.9770.

3. Clinical studies:

   *a. Clinical Sensitivity:*

   Not applicable

   *b. Clinical specificity:*

   Not applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

   Not applicable

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

   Adult LDH levels in serum, lactate to pyruvate at $37^0$C – 100-190 IU/L

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.