

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

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

K032564

**B. Analyte:**

N-acetylprocainamide (NAPA)

**C. Type of Test:**

Quantitative

**D. Applicant:**

Dade Behring, Inc.

**E. Proprietary and Established Names:**

Dimension N-acetylprocainamide (NAPA) Flex reagent cartridge method

**F. Regulatory Information:**

1. Regulation section:  
862.3320
2. Classification:  
II
3. Product Code:  
LAN
4. Panel:  
Toxicology (91)

**G. Intended Use:**

1. Intended use(s):  
Refer to Indications for use.
2. Indication(s) for use:  
The NAPA method is used on the Dimension clinical chemistry system for the quantitative determination of N-acetylprocainamide in serum or plasma. N-acetylprocainamide measurements may be used in therapeutic drug monitoring to maintain adequate procainamide therapy.  
  
The device is for in vitro diagnostic use.  
It is intended for prescription use.
3. Special condition for use statement(s):  
Not applicable.
4. Special instrument Requirements:  
The device is for use on Dimension clinical chemistry systems.

Performance was demonstrated in this submission on the RxL Dimension analyzer.

#### H. Device Description:

The Flex® reagent cartridge method consists of prepackaged ready-to-use reagents in a flexible plastic cartridge for use only on the Dimension® clinical chemistry system.

#### I. Substantial Equivalence Information:

1. Predicate device name(s):  
Dade Behring aca NAPA test pack
2. Predicate K number(s):  
K833378
3. Comparison with predicate:

Both devices are for measurement of the same analyte(s) in the same matrix, and are run on automated analyzers.

The reagent formulations vary between the two devices.

Similarities		
Item	Device	Predicate
Manufacturer	Dade Behring	Dade Behring
Differences		
Item	Device	Predicate
Instrument	Dimension analyzer	aca analyzer
Technology	Petina, turbidometric	EMIT, colorimetric

#### J. Standard/Guidance Document Referenced (if applicable):

Refer to individual sections.

#### K. Test Principle:

The methodology for NAPA is based on a homogenous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique which uses a latex particle NAPA conjugate (PR) and monoclonal NAPA specific antibody (Ab). NAPA present in the sample competes with NAPA on the particles for available antibody, thereby decreasing the rate of aggregation. The rate of aggregation is inversely proportional to the concentration of NAPA in the sample. The rate of aggregation measured using bichromatic turbidimetric readings at 340 nm and 700 nm. The concentration is determined by means of a mathematical calculations that are extrapolated from a standard curve.

#### L. Performance Characteristics (if/when applicable):

1. Analytical performance:
  - a. Precision/Reproducibility:  
(All performance was established on the RxL Dimension analyzer.

The number of lots of product used in the study is not specified.

Typical precision observed for the Dimension® N-acetylprocainamide (NAPA) Flex® reagent cartridge method is summarized in the table below:

Sample	Mean		Standard Deviation (%CV)					
	µg/mL	[µmol/L]	Within Run			Total		
BioRad Liquichek® TDM Control Level 1	2.10	7.6	0.08	0.29	(3.8)	0.13	0.47	(6.0)
BioRad Liquichek® TDM Control Level 2	5.1	18.4	0.09	0.32	(1.8)	0.13	0.47	(2.5)
BioRad Liquichek® TDM Control Level 3	10.0	36.28	0.09	0.32	0.87	0.16	0.58	(1.6)
Low Pool (4.6 µg/mL)	4.59	16.57	0.07	0.25	(1.5)	0.12	0.43	(2.6)
Mid Pool (13.0 µg/mL)	13.05	47.11	0.11	0.40	(0.8)	0.18	0.58	(1.4)
High Pool (22.8 µg/mL)	22.8	82.31	0.47	1.70	(2.1)	0.52	1.88	(2.3)

Sample pools were analyzed in duplicate for 20 days. The within-run and total coefficients of variation (%CV) were calculated by the analysis of variance method according to the National Committee of Clinical Laboratory Standards (NCCLS) Guideline EP5-A (February 1999). Liquichek® is a registered trademark of BioRad, Bio-Rad Laboratories, Irvine, California 92618.

*b. Linearity/assay reportable range:*

The claimed assay range is 0.5 – 30.0 µg/mL.

Support for linearity is provided through visual examination of a graph contrasting expected versus observed results. Expected results are established through spiking of serum samples. Samples in the study ranged from 0 to 32.2 micrograms per mL. The sensitivity claim defines the lower end of the assay range.

Linearity claims are also supported through a visual exam of replicate measurements of the calibrators plotted against expected results.

*c. Traceability (controls, calibrators, or method):*

Calibrators are specified in the labeling but are not supplied in the kit. Calibrators were cleared under 510K number k032574.

Five levels of calibrator material, ranging in concentration from 0-30 micrograms /mL are intended for use with the assay.

Traceability of the assay is not discussed by the sponsor.

*d. Detection limit:*

Sensitivity of the assay is 0.5 micrograms/mL.

To determine analytical sensitivity, the sponsor assayed the negative calibrator 20 times. The mean concentration and standard deviation was calculated. The analytical sensitivity was estimated by adding 2 standard deviations to the average of the readings.

*e. Analytical specificity:*

Cross-reactivity of Desethyl N-acetylprocainamine is estimated to be 12%. The method used to establish this estimate is not described.

The sponsor evaluated over 50 endogenous and exogenous compounds and determined that their systemic bias was less than 10%. The compounds are listed in the package insert.

*f. Assay cut-off:*

Not applicable. This is a quantitative assay for a therapeutic drug.

2. Comparison studies:

*a. Method comparison with predicate device:*

A total of 73 split serum samples were evaluated by the candidate device and by the predicate device. The range of sample concentrations is 1-16 micrograms/mL, and concentrations are adequately distributed across the reportable range of the assay.

Sample selection: The method used to select samples for inclusion in the study was not specified.

Number of study sites: not specified

Description of the site(s): not specified

Type of study site: not specified.

Operator description: not specified

Number of instruments used: not specified

Regression analysis results of the method comparison are:

Slope = 0.96

Intercept = -0.03 micrograms/mL

Correlation Coefficient = 0.993

*b. Matrix comparison:*

In order to evaluate for potential bias between the claimed matrices, the sponsor analyzed 20 replicates of serum, sodium heparin, lithium heparin, and EDTA samples. Each set of plasma results were compared to serum results. The sample concentrations spanned the reportable range of the assay. There is no apparent bias between the claimed plasma types and serum.

3. Clinical studies:

*a. Clinical sensitivity:*

Not applicable. Clinical studies are not necessary for this device type.

*b. Clinical specificity:*

Not applicable. Clinical studies are not necessary for this device type.

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

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The therapeutic range for this assay to be interpreted when combined with procainamide is 10-30 micrograms/mL.

**M. Conclusion:**

I recommend that this device be found substantially equivalent to the predicate device.