510(k) SUMMARY

NOV 2 3 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K101574.

807.92 (a)(1): Name: **ARK Diagnostics, Inc.**

Address: 1190 Bordeaux Drive
Sunnyvale, CA 94089

Owner Operator Number: 10027663
Establishment Registration: 3005755244

Phone: (408) 747-0700
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Contact: Kenneth C. Kasper, PhD – (408) 747-0708
Executive Director of Quality and Regulatory Affairs

Date prepared: November 23, 2010

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name: ARK™ Gabapentin Assay
ARK™ Gabapentin Calibrator
ARK™ Gabapentin Control

Common Name: Homogeneous Enzyme Immunoassay

Classification: 21 CFR 862.3350 NWM Diphenylhydantoin Test System; Class II
(21 CFR 862.3200 DLJ, 21 CFR 862.3280 LAS)

807.92 (a)(3): Identification of the legally marketed predicate device

ARK™ Topiramate Assay	K083799 (bundled)
ARK™ Topiramate Calibrator	
ARK™ Topiramate Control	

807.92 (a)(4): Device Description

The ARK Gabapentin Assay is a homogeneous immunoassay based on competition between drug in the specimen and gabapentin labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for binding to the antibody reagent. As the latter binds antibody, enzyme activity decreases. In the presence of drug from the specimen, enzyme activity increases and is directly proportional to the drug concentration. Active enzyme converts the coenzyme nicotinamide adenine dinucleotide (NAD) to NADH that is measured spectrophotometrically as a rate of change in absorbance. Endogenous serum G6PDH does not interfere with the results because the coenyzme NAD functions only with the bacterial enzyme used in the assay.

The ARK Gabapentin Assay consists of reagents R1 anti-gabapentin polyclonal antibody with substrate and R2 gabapentin labeled with bacterial G6PDH enzyme. The ARK Gabapentin Calibrator consists of a six-level set to calibrate the assay, and the ARK Gabapentin Control consists of a three-level set used for quality control of the assay.

ARK Gabapentin products contain ≤0.09% sodium azide. As a precaution, affected plumbing should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides. No special handling is required regarding other assay components.

807.92 (a)(5): Intended Use / Indications for Use

The ARK™ Gabapentin Assay is a homogeneous enzyme immunoassay intended for the quantitative determination of gabapentin in human serum or plasma on automated clinical chemistry analyzers. Gabapentin concentrations can be used as an aid in management of patients treated with gabapentin.

The ARK™ Gabapentin Calibrator is intended for use in calibration of the ARK Gabapentin Assay.

The ARK™ Gabapentin Control is intended for use in quality control of the ARK Gabapentin Assay.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

SUBSTANTIAL EQUIVALENCE COMPARATIVE CHART

Comparison between the ARK™ Gabapentin Assay and the ARK™ Topiramate Assay

Characteristic	**Device** ARK™ Gabapentin Assay	**Predicate** ARK™ Topiramate Assay K083799
Intended Use	The ARK™ Gabapentin Assay is intended for the quantitative determination of gabapentin in human serum or plasma on automated clinical chemistry analyzers.	The ARK™ Topiramate Assay is intended for the quantitative determination of topiramate in human serum or plasma on automated clinical chemistry analyzers.
Indications for Use	Gabapentin concentrations can be used as an aid in management of patients treated with gabapentin.	The results obtained are used in the diagnosis and treatment of topiramate overdose and in monitoring levels of topiramate to help ensure appropriate therapy.
Sample	Serum or plasma	Serum or plasma
Methodology	Homogenous enzyme immunoassay (EIA)	Homogenous enzyme immunoassay (EIA)
Reagent Components	Two (2) reagent system: Anti- gabapentin Antibody/Substrate Reagent (R1) containing rabbit polyclonal antibodies to gabapentin, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers Enzyme Reagent (R2) containing gabapentin labeled with bacterial G6PDH, buffer, bovine serum albumin, sodium azide, and stabilizers	Two (2) reagent system: Anti-topiramate Antibody/Substrate Reagent (R1) containing rabbit polyclonal antibodies to an epitope of topiramate, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, preservatives, and stabilizers Enzyme Reagent (R2) containing topiramate epitope labeled with bacterial G6PDH, buffer, bovine serum albumin, preservatives, and stabilizers
Platform required	Automated clinical chemistry analyzer	Automated clinical chemistry analyzer
Accessory reagents	Calibrators (six levels) and controls (three levels)	Calibrators (six levels) and controls (three levels)
Testing environment	Routine clinical laboratory	Routine clinical laboratory
Reagent condition and storage	Liquid, 2-8° C	Liquid, 2-8° C

807.92 (b)(1) and 807.92 (b)(2):
Brief Description of Nonclinical and Clinical Data

Limit of Quantitation (LOQ)

The LOQ of the ARK Gabapentin Assay was determined according to CLSI EP17-A and is defined as the lowest concentration for which acceptable inter-assay precision and recovery is observed (≤20% CV with ±15% recovery). The LOQ was determined to be 0.75 µg/mL.

Recovery

Accuracy (analytical recovery) was performed by adding concentrated gabapentin drug into human serum negative for gabapentin. A stock concentrate of highly pure gabapentin was added volumetrically to human serum negative for gabapentin, representing drug concentrations across the assay range. Six replicates of each sample were assayed on an automated clinical chemistry analyzer. The results were averaged and compared to the target concentration and percent recovery calculated. Results are shown below.

$$\% \text{ Recovery} = 100 \times \frac{\text{Mean recovered concentration}}{\text{Theoretical concentration}}$$

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery
1.0	0.99	98.5
2.0	2.07	103.3
3.5	3.55	101.3
9.0	8.98	99.7
16.0	16.03	100.2
22.0	22.00	100.0
28.0	27.85	99.5
35.0	35.59	101.7
40.0	41.49	103.7

Mean percent recovery: 100.9%

Linearity

Linearity studies were performed as suggested in CLSI/NCCLS Protocol EP6-A. A 48.0 µg/mL serum sample was prepared and dilutions were made proportionally with human serum negative for gabapentin. Gabapentin concentrations ranged from 0.75 to 48.0 µg/mL. Linearity at specific dilutions was considered acceptable if the percent difference was ±10% between the predicted 1st and 2nd order regressed values or ±15% ≤ 1.0 µg/mL. A linear relationship was demonstrated between 0.75 and 48.0 µg/mL. Results are shown below.

Theoretical (µg/mL)	Results (µg/mL)	1st Order Predicted Results	2nd Order Predicted Results	% Difference
0.75	0.73	0.76	0.85	12.0
1.0	1.0	1.0	1.1	8.4
2.4	2.4	2.4	2.4	2.2
3.2	3.3	3.2	3.2	1.1
4.8	4.9	4.8	4.8	0.0
8.0	8.0	8.0	7.9	-0.7
12.0	11.9	12.0	11.9	-0.9
24.0	23.6	23.9	23.8	-0.6
32.0	31.8	31.9	31.8	-0.3
40.0	39.7	39.8	39.9	0.2
48.0*	48.1	47.8	48.1	0.6

*Concentration exceeds the reportable limit.

Assay Range

The range of the assay is 0.75 to 40.0 µg/mL. Report results below this range as <0.75 µg/mL or below the analyzer-specific lower LOQ established in your laboratory. Report results above this range as >40.0 µg/mL or above the analyzer-specific upper LOQ established in your laboratory.

Specimens testing initially above the assay range may be diluted in Calibrator A and retested. Multiply the assay result by the dilution factor to obtain the concentration of gabapentin in the undiluted specimen. A dilution factor of 4 is suggested.

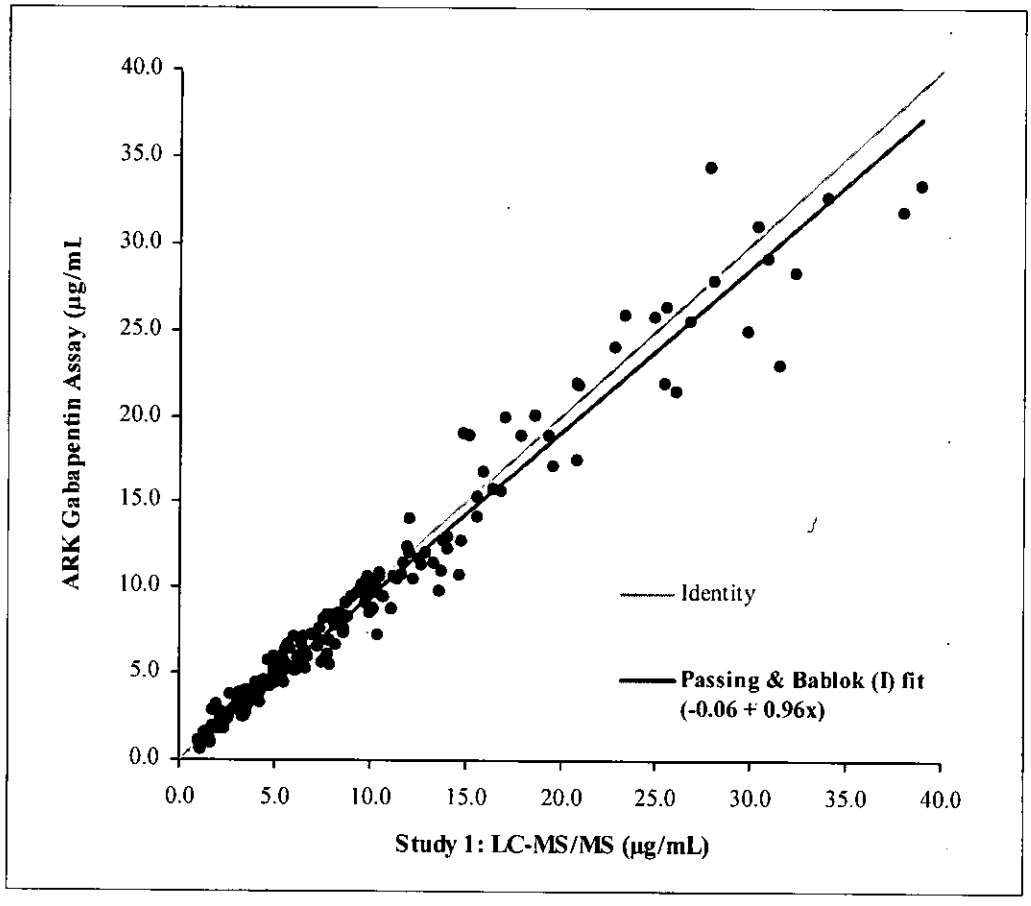
Method Comparison

Correlation studies were performed using CLSI/NCCLS Protocol EP9-A2. Results from the ARK Gabapentin Assay were compared with results from three study sites using high performance liquid chromatography – mass spectrometry methods (LC-MS/MS, Study 1), HPLC (Study 2) and LC-MS/MS (Study 3).

Study 1

Gabapentin concentrations by LC-MS/MS ranged 1.0 to 39.0 µg/mL. ARK gabapentin values ranged 0.6 to 34.4 µg/mL Results of the Passing-Bablok[25] regression analysis for the study are shown below (with 95% confidence limits).

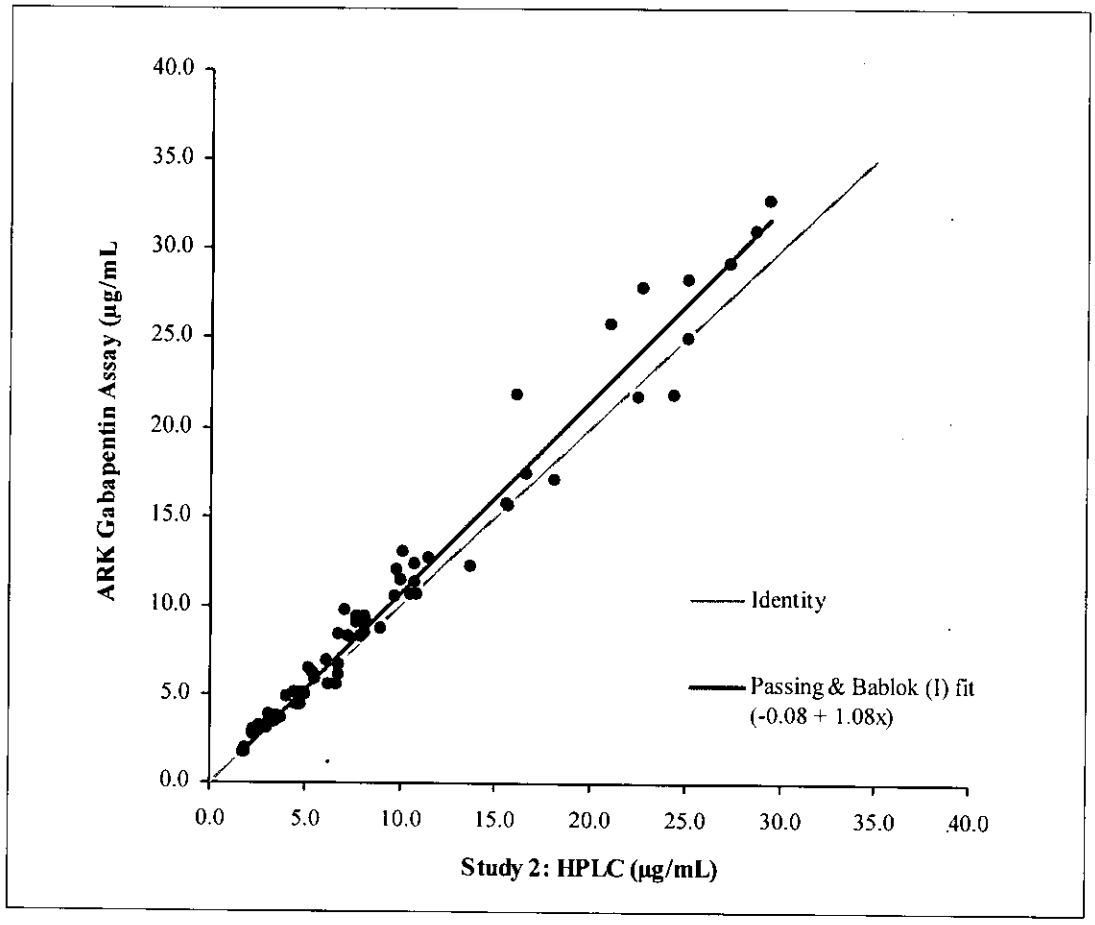
Slope	0.96	(0.92 to 0.99)
y-intercept	- 0.06	(- 0.28 to 0.18)
Correlation Coefficient (r^2)	0.96	(0.95 to 0.97)
Number of Samples	183	



Study 2

Gabapentin concentrations by HPLC ranged from 1.8 to 29.4 µg/mL. ARK gabapentin values ranged 1.6 to 32.6 µg/mL. Results of the Passing-Bablok[25] regression analysis for the study are shown below (with 95% confidence limits).

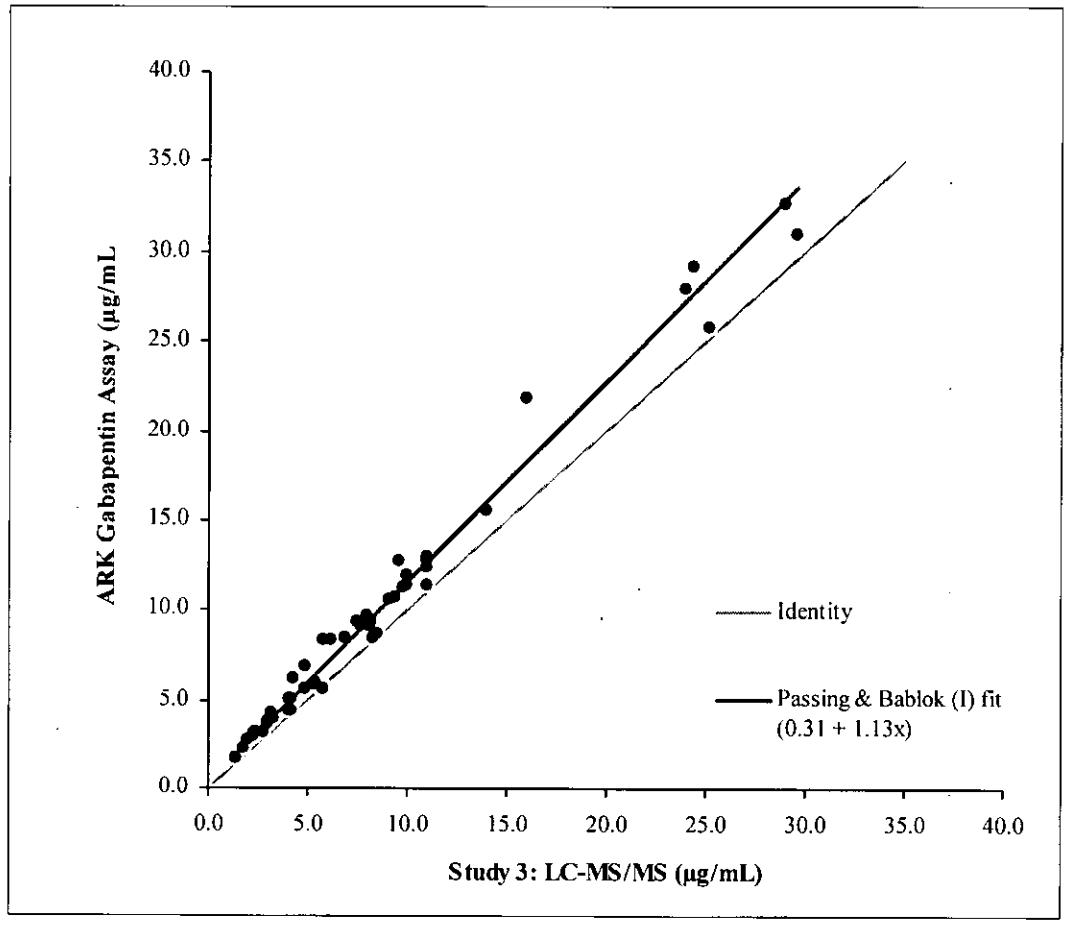
Slope	1.08	(1.03 to 1.13)
y-intercept	-0.08	(- 0.35 to 0.25)
Correlation Coefficient (r^2)	0.97	(0.95 to 0.98)
Number of Samples	64	



Study 3

Gabapentin concentrations by LC-MS/MS ranged 1.4 to 29.6 µg/mL. ARK gabapentin values ranged 1.6 to 32.6 µg/mL. Results of the Passing-Bablok[25] regression analysis for the study are shown below (with 95% confidence limits).

Slope	1.13	(1.08 to 1.17)
y-intercept	0.31	(0.06 to 0.52)
Correlation Coefficient (r^2)	0.98	(0.97 to 0.99)
Number of Samples	49	



Precision

Precision was determined as described in CLSI/NCCLS Protocol EP5-A2. Tri-level controls and three human serum pooled specimens containing gabapentin were used in the study. Each level was assayed in quadruplicate twice a day for 20 days. Each of the runs per day was separated by at least two hours. The within run, between day, total SD, and percent CVs were calculated. Results are shown below. Acceptance criteria: <10% total CV.

Sample	N	Mean (µg/mL)	Within Run SD	Within Run CV (%)	Between Day SD	Between Day CV (%)	Total SD	Total CV (%)
ARK Gabapentin Control								
LOW	160	2.5	0.08	3.3	0.10	3.9	0.14	5.6
MID	160	7.9	0.21	2.6	0.26	3.3	0.35	4.4
HIGH	160	24.6	0.48	1.9	0.65	2.7	0.88	3.6
Human Serum								
LOW	160	2.2	0.11	4.7	0.11	4.8	0.17	7.7
MID	160	7.3	0.58	2.4	0.25	3.4	0.33	4.6
HIGH	160	24.9	0.54	2.2	0.97	3.9	1.17	4.7

Interfering Substances

Interference studies were conducted using CLSI/NCCLS Protocol EP7-A2 as a guideline. Clinically high concentrations of the following potentially interfering substances in serum with known levels of gabapentin (approximately 2 and 20 µg/mL) were evaluated. Each sample was assayed using the ARK Gabapentin Assay, along with a serum control of gabapentin. Measurement of gabapentin resulted in ≤10% error in the presence of interfering substances at the levels tested.

		Percentage Recovery	
Interfering Substance	**Interferent Concentration**	**2 µg/mL Gabapentin**	**20 µg/mL Gabapentin**
Albumin	12 g/dL	102.1	98.2
Bilirubin Conjugated	70 mg/dL	95.2	98.3
Bilirubin Unconjugated	70 mg/dL	106.6	98.4
Cholesterol	623 mg/dL	101.6	98.0
Gamma-Globulin	12 g/dL	103.2	99.7
Hemoglobin	1000 mg/dL	102.5	101.6
Intralipid®	1500 mg/dL	97.0	99.2
Rheumatoid Factor	1100 IU/mL	97.0	97.1
Triglycerides	1220 mg/dL	105.6	99.6
Uric Acid	30 mg/dL	106.6	97.9

Specificity

Gabapentin is eliminated from the systemic circulation solely by renal excretion as unchanged drug and is not appreciably metabolized in humans.[1] Therefore, no metabolites are known to result that could interfere in the measurement of gabapentin.

Medications that may be routinely co-administered with gabapentin, anti-epileptic drugs or L-amino acids were tested to determine whether these compounds affect the quantitation of gabapentin concentrations using the ARK Gabapentin Assay. High levels of these compounds were spiked into serum pools containing low (2 µg/mL) and high (20 µg/mL) therapeutic levels of gabapentin. The samples were analyzed and the gabapentin concentrations of samples containing co-administered with gabapentin, anti-epileptic drugs or L-amino acids were compared to the serum control.

Drug Interference

Gabapentin-selective antibody did not crossreact with most other anti-epileptic or coadministered drugs tested. Due to structural similarities with gabapentin, high pregabalin levels may interfere. A high concentration of each compound was spiked into normal human serum with known levels of gabapentin (approximately 2 and 20 µg/mL) and assayed along with a serum control of gabapentin. Measurement of gabapentin resulted in ≤10% error in the presence of drug compounds at the levels tested.

Compound	Concentration (µg/mL)	Percentage Recovery	
		Gabapentin (2 µg/mL)	Gabapentin (20 µg/mL)
γ-Aminobutyric Acid	100	97.8	99.2
L-2-Aminobutyric Acid	100	98.6	99.2
Acetaminophen	200	98.7	98.1
Acetazolamide	100	99.2	98.6
Acetylsalicylic acid	1000	100.6	100.4
Amikacin	100	100.2	98.7
Amitriptyline	20	98.2	97.9
Amoxapine	40	98.9	99.6
Amphotericin B	100	98.2	98.2
Ampicillin	100	100.8	100.0
Ascorbic Acid	100	97.3	98.3
Baclofen	100	103.3	100.6
Buproprion	40	106.9	100.6
Caffeine	100	99.8	99.8
Carbamazepine	120	99.4	98.9
Carbamazepine- 10, 11 epoxide	120	98.9	98.9
10-Hydroxy carbamazepine	100	102.8	100.4
Chloramphenicol	250	101.4	96.7
Chlorpromazine	20	103.1	100.8
Citalopram	20	102.8	100.8
Clobazam	100	96.3	108.0
Clonazepam	20	101.2	101.4
Cyclosporin A	40	95.1	97.2
Diazepam	20	102.6	100.5
Digoxin	80	103.0	101.8
Doxepin	20	103.9	101.2
Erythromycin	200	97.9	98.9
Ethanol	4000 (0.4%)	105.2	99.3
Ethotoin	100	97.1	97.5
Ethosuximide	250	95.8	99.6
Felbamate	250	98.2	99.1
Fluoxetine	20	103.8	101.2
Furosemide	100	95.2	98.0

Compound	Concentration (µg/mL)	Percentage Recovery	
		Gabapentin (2 µg/mL)	Gabapentin (20 µg/mL)
Gentamicin	100	100.0	100.4
Haloperidol	20	102.5	101.7
Heparin	200 U/mL	94.8	96.2
Ibuprofen	500	96.5	96.9
Imipramine	20	101.2	101.1
Kanamycin B	200	96.7	101.3
Lamotrigine	250	102.9	95.9
Levetiracetam	400	97.4	96.0
Lidocaine	100	97.7	98.7
Lincomycin	1000	102.4	100.4
Mephenytoin	100	100.6	99.6
Mesoridazine	40	106.2	96.2
Methicillin	250	101.5	98.0
Naproxen	600	100.2	97.3
Neomycin	1000	97.8	102.1
Niacin	100	98.9	100.3
Nitrazepam	20	96.5	97.5
Nortriptyline	20	101.6	97.1
Olanzapine	20	99.9	98.5
Oxcarbazepine	200	100.9	100.8
Paroxetine	40	102.4	96.0
2-phenyl-ethyl--malonamide (PEMA)	1000	105.8	98.7
Penicillin V	100	95.8	99.0
Perphenazine	100	102.4	99.0
Phenobarbital	200	100.3	98.3
Phenytoin	200	96.9	93.6
Primidone	100	93.0	99.1
Procainamide	100	95.9	95.9
Prochlorperazine	40	97.8	98.7
Ranitidine	100	97.2	98.3
Rifampin	100	95.3	102.4
Risperidone	20	101.8	103.2
Sertraline	100	98.5	97.5
Spectinomycin	100	98.3	102.1
Stiripentol	100	95.9	96.7
Sulfamethoxazole	400	97.5	98.0
Theophylline	200	103.0	100.5
Thioridazine	20	102.6	102.5
Tobramycin	100	94.6	100.3
Tiagabine	200	91.6	97.9
Topiramate	250	96.9	96.9

Compound	Concentration (µg/mL)	Percentage Recovery	
		Gabapentin (2 µg/mL)	Gabapentin (20 µg/mL)
Trimethoprim	40	96.7	99.0
Valproic Acid	600	96.7	96.9
Vancomycin	250	100.3	99.8
Vigabatrin	150	101.3	99.9
Zonisamide	400	98.6	104.1

L-Amino Acid Interference

The L-amino acids listed below resulted in <10% error in detecting gabapentin at the concentrations tested.

Compound	Concentration (µg/mL)	Percentage Recovery	
		Gabapentin (2 µg/mL)	Gabapentin (20 µg/mL)
L-Arginine	100	96.9	104.4
L-Asparagine	100	95.1	101.8
L-Aspartic Acid	25	93.9	102.0
L-Cysteine	25	92.6	101.9
L-Glutamic Acid	100	95.7	101.4
L-Glycine	100	98.0	100.8
L-Histidine	100	92.2	102.5
L-Isoleucine	100	92.2	101.9
L-Leucine	100	96.3	101.5
L-Methionine	25	93.3	100.9
L-Phenylalanine	50	94.4	99.6
L-Serine	50	95.1	99.3
L-Threonine	100	95.6	100.7
L-Tyrosine	100	93.9	99.0
L-Alanine	150	98.9	97.0
L-Lysine	150	97.8	98.2
L-Proline	150	96.0	98.3
L-Valine	150	97.5	97.7
L-Tryptophan	150	98.0	99.1
L-Glutamine	350	97.3	96.9

Drug that Interferes - Pregabalin

Pregabalin was analyzed from 15 to 100 µg/mL in the presence of either Low (2 µg/mL) or High (20 µg/mL) gabapentin. High concentrations of pregabalin may interfere by elevating the measurement of gabapentin. Pregabalin plasma levels in patients under therapy have been reported to range from approximately 0.2 to 14.2 µg/mL. Excessive pregabalin levels up to 60

µg/mL in combination with lamotrigine in a self poisoning incident have been reported. The results of interference testing are shown below.

Pregabalin (µg/mL)	Percent Cross-Reactivity		Percent Recovery	
	Gabapentin (2 µg/mL)	Gabapentin (20 µg/mL)	Gabapentin (2 µg/mL)	Gabapentin (20 µg/mL)
100	1.10	1.95	156.9	109.7
50	1.18	2.06	130.6	105.1
15	1.13	- 1.47	108.9	98.9

Care should be taken when interpreting ARK Gabapentin results if pregabalin is also being administered to the patient.

Anticoagulants

Studies were conducted to determine the performance characteristics of the assay for both serum and plasma samples containing gabapentin. The results indicate that there is no significant difference between the recovery of gabapentin in serum or plasma.

Sample Stability

Testing of fresh specimens is preferred. Clarified specimens may be stored up to one week at 2 to 8°C. If testing will be delayed more than one week, specimens may be stored frozen (≤ -10°C) up to four weeks prior to being tested (acceptance criterion ± 10%). Care should be taken to limit the number of freeze-thaw cycles. Specimens were shown to withstand 3 freeze-thaw cycles when stored at -20°C.

On-Board Stability

Calibration Curve Stability: A stored calibration was effective up to 84 days based on supporting data. Curve stability may depend on individual laboratory performance.

Reagent on-board stability: Reagents were effective when stored after transfer to analyzer specific reagent containers for up to at least 84 days based on supporting data. In-use stability of calibrator and controls was also demonstrated.

Accelerated OPEN stability of calibrators and controls:
Calibrators and controls were shown to be stable OPEN in accelerated stability at 37°C for seven (7) days. Once opened vials may be stored at 2-8°C for 12 months.

807.92 (b)(3): Conclusions from Nonclinical Testing

As summarized above, the ARK Gabapentin Assay, the ARK Gabapentin Calibrator and the ARK Gabapentin Control are substantially equivalent to the ARK™ Topiramate Assay system. The ARK Gabapentin Assay system was shown to be safe and effective for its intended use based on performance studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

ARK Diagnostics, Inc.
c/o Johnny Valdez
President
1190 Bordeaux Drive
Sunnyvale, CA 94089

NOV 23 2010

Re: k101574
Trade/Device Name: ARK™ Gabapentin Assay, ARK™ Gabapentin Calibrator, and ARK™ Gabapentin Control
Regulation Number: 21 CFR 862.3350
Regulation Name: Diphenylhydantoin Test System.
Regulatory Class: Class II
Product Codes: OTF, DLJ, LAS
Dated: November 15, 2010
Received: November 16, 2010

Dear Mr. Valdez,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

K101574

510(K) Number (if known):

NOV 2 3 2010

Device Name:

ARK™ Gabapentin Assay
ARK™ Gabapentin Calibrator
ARK™ Gabapentin Control

Indications for Use:

The ARK™ Gabapentin Assay is a homogeneous enzyme immunoassay intended for the quantitative determination of gabapentin in human serum or plasma on automated clinical chemistry analyzers.

Gabapentin concentrations can be used as an aid in management of patients treated with gabapentin.

The ARK™ Gabapentin Calibrator is intended for use in calibration of the ARK Gabapentin Assay.

The ARK™ Gabapentin Control is intended for use in quality control of the ARK Gabapentin Assay.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101574