

## 510(k) SUMMARY

### The A/C Portable Enzymatic Homocysteine Assay on the A/C Diagnostics Reader

#### Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

#### 1. Submitter Information

Submitter: AntiCancer Inc.  
7917 Ostrow Str.  
San Diego, California 92111  
Phone: (858)654-2555  
FAX: (858)268-4175  
e-mail: [info@anticancer.com](mailto:info@anticancer.com)

Contact Person: Yuying Tan, M.D.  
Principal Investigator of the Device  
Research Manager of AntiCancer Inc.

Date of Summary Preparation: March 24, 2008  
Revised: Sep 16, 2008

#### 2. Device Information

510K:#: k080851  
Device Name: A/C Portable Enzymatic Homocysteine Assay  
Classification Name: Homocysteine Assay  
Class: II  
Product Code: LPS

#### 3. Predicate Device Information

Device Name: A/C Enzymatic Homocysteine Assay on Hitachi 912  
AntiCancer Inc.  
7917 Ostrow Str.  
San Diego, California 92111  
Phone: (858)654-2555  
FAX: (858)268-4175  
e-mail: [info@anticancer.com](mailto:info@anticancer.com)

510(k) Number: K030754

**4. Information of Manufacturers**

**Kit Manufacturer**

Contract Manufacturer: Bioserv Corporation  
5340 Eastgate Mall  
San Diego, CA 92121  
Telephone: (858) 450-3123  
FAX: (858) 450-0785  
FDA Establishment Registration Number: US FDA 2027352  
Contact Person : Mary Richardson  
Quality Assurance Manager

**Reader Manufacturer**

Contract Manufacturer: Wuxi Opulen Technologies Ltd.  
3-405, Originality Industrial Park  
Liyuan Economic Zone  
Wuxi, Jiangsu, 214072  
P.R. China  
Telephone: (86) 510-85160567  
FAX: (86) 510-85160369  
Establishment Registration Number: 04707Q10000268, P.R. China  
Contact Person : Jiasen Yan  
President

## 5. Statement of Intended Use

The A/C Portable Enzymatic Homocysteine Assay on the A/C Diagnostics Reader (HyTek-205) is intended for the quantitative determination of total homocysteine (tHCY) in human plasma or serum. The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia. The A/C Enzymatic Homocysteine Assay is for *in vitro* diagnostic use.

## 6. Description of Device

The A/C Portable Enzymatic Homocysteine Assay is calibrated with A/C Enzymatic Homocysteine Assay Calibrators. A/C Enzymatic Homocysteine Assay Controls are assayed for the verification of the accuracy and precision of the A/C Portable Enzymatic Homocysteine Assay.

The A/C Enzymatic Homocysteine Assay measures tHCY. The principle of the assay is that after reduction, tHCY is depleted by Homocysteinase (rHCYase) and produces hydrogen sulfide (H<sub>2</sub>S), which is determined using N,N-dibutyl phenylene diamine (DBPDA), the combination of which forms a chromophore, the fluorescence is measured by the A/C Diagnostics Reader (HyTek-205).

The A/C Portable Enzymatic Homocysteine Assay is a three-steps reaction, which runs at room temperature. The total assay takes 80 minutes, and the A/C Diagnostics Reader is the only equipment needed.

## 7. Method Comparison

To establish equivalence to an existing device, and thus establish the safety and effectiveness, The A/C Portable Homocysteine Enzymatic Assay (K080851) on the A/C Diagnostics Reader is compared to the Predicate Device, the A/C Automatic Enzymatic HCY Assay on Hitachi 912 (K030754) [Table 1].

The comparison of the A/C Portable Homocysteine Assay on the A/C Diagnostics Reader to the A/C Automatic Homocysteine Assay on the Hitachi 912 Automatic Analyzer [4-5] was carried for fifty plasma samples. The correlation and regression analysis yielded  $y = 1.01 + 0.91x$  with a correlation coefficient of  $R^2 = 0.95$ . The distribution of the difference vs mean of paired tHCY values were shown in Bland-Altman plot. The mean difference between the two assays was 1.05  $\mu\text{mol/L}$ . The samples both at low and high concentrations of tHCY agreed well.

**Table 1. Comparison of the A/C Portable Enzymatic HCY Assay and the A/C Automatic Enzymatic HCY Assay**

A/C Enzymatic HCY Assay		Differences	
		K 080851 Portable HCY Assay	K 030754 Automatic HCY Assay
<b>Similarities</b>	Principle	Enzymatic	
	Indication for Use	The A/C Enzymatic Assay is intended for the quantitative determination of total homocysteine (tHCY) in human plasma or serum. The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia. The assay is for <i>in vitro</i> diagnostic use.	
	Precision	CV for within assay ranged from 3.8% to 4.8%. CV for between assay ranged from 5.0% to 7.4%.	CV for within assay ranged from 3.0% to 4.8%. CV for between assay ranged from 4.9% to 7.8%.
<b>Differences</b>	Performance	Portable Manual	Fully Automatic
	Equipment	A/C Diagnostics Reader	Hitachi 912 Automatic Analyzer
	Application	Small Lab	Large Lab and Big Hospital
	High throughput	100 tests/hr	360 tests/hr

- K 080851 Portable Assay: A/C Portable Enzymatic HCY Assay is the assay for current 510k application.
- K 030754 Automatic Assay: A/C Automatic Enzymatic HCY Assay is the predicate device, which 510k application has been cleared by FDA in 2003.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

OCT 10 2008

AntiCancer, Inc.  
c/o Yuying Tan, M.D.  
Research Manager  
7917 Ostrow Road  
San Diego, CA 92111

Re: k080851  
Trade Name: A/C Portable Enzymatic Homocysteine Assay on the  
A/C Diagnostics Reader  
Regulation Number: 21 CFR 862.1377  
Regulation Name: Urinary Homocysteine Test System  
Regulatory Class: Class II  
Product Codes: LPS  
Dated: September 16, 2008  
Received: September 25, 2008

Dear Dr. Tan:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K080851

Device Name: A/C Portable Enzymatic Homocysteine Assay on A/C Diagnostics Reader

**Indications For Use:**

The A/C Portable Enzymatic Homocysteine Assay on the A/C Diagnostics Reader (HyTek-205) is intended for the quantitative determination of total homocysteine (tHCY) in human plasma or serum. The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia. The A/C Enzymatic Homocysteine Assay is for *in vitro* diagnostic use.

Prescription Use   \*   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

[Signature]  
Division of             
Office of In Vitro Diagnostic Device  
Evaluation and Safety

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