



510(k) Summary of Safety and Effectiveness

Intended use

The Wako LBA DCP immunological test system is an in vitro device that consists of reagents and an automated instrument used to quantitatively measure by immunochemical techniques DCP in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for progression to hepatocellular carcinoma in conjunction with other laboratory findings, imaging studies and clinical assessment.

Summary and explanation of the test

Prothrombin is a vitamin K dependent blood coagulation factor that is formed in the liver. It contains 10 γ -carboxy-glutamic acid (Gla) residues on its amino-terminal domain, which are synthesized from glutamic acid (Glu) residues by vitamin K dependent γ -glutamyl carboxylase in the posttranslational process. When the deficiency of vitamin K or the ingestion of vitamin K antagonists (Warfarin sodium), the Des- γ -carboxy-Prothrombin (DCP) is found in patients. DCP was reported by Liebman, H.A., in 1984 as a specific tumor marker that increases in patients with hepatocellular carcinoma (HCC). A number of reports have shown elevations in serum DCP level in patients with HCC and liver cirrhosis. And DCP does not correlate with AFP and AFP-L3. DCP and AFP-L3% are considered complementary assays for assessing for the risk of developing HCC. When used in combination, a greater number of patients at risk of developing HCC can be identified resulting in more treatment options for a larger number of patients.

The Wako LBA DCP assay is test kit for the quantitative determination of DCP based on a new method, LBA (Liquid-phase Binding Assay). The method uses a liquid-phase binding reaction between antigen and antibody and separates bound and free forms by column chromatography without a need for a solid phase. LBA DCP can offer fully automatic and highly precise DCP measurement by using an automated analyzer "LiBASys".

Principle of the method

This reagent consists of anti-DCP monoclonal antibodies and anti-Prothrombin monoclonal antibodies which are used as Fab' molecules and a substrate for fluorophotometric measurement. When DCP in a sample reacts with anion conjugated anti-Prothrombin monoclonal antibody and peroxidase (horseradish) labeled anti-DCP monoclonal antibody, which binds to all the present DCP molecules it forms an immune complex shown in Fig. 1.

Fig. 1

[Peroxidase (horseradish) labeled anti-DCP monoclonal antibody]



[Anion conjugated anti-Prothrombin monoclonal antibody]

The reaction mixture, which includes the above complex, is introduced into an anion-exchange column. The immune complex fractions are eluted into the reaction cup. Then the POD activity of the complex is measured. The POD activity is determined as the increase of fluorescence intensity of 5, 5'-diacetoamide-2'-2'-bisphenol formed by the reaction of hydrogen peroxide and 4-acetoamidophenol. These values are compared to fluorescence intensity of known standards for DCP concentration, in order to obtain the DCP values of samples.

Longitudinal data was collected on 441 subjects, 324 males and 117 females. The risk of developing HCC among patients with an elevation of DCP ≥ 7.5 ng/mL and among patients without such an elevation is calculated, along with their 95% confidence interval. The risk of developing HCC with an elevated DCP test is 36.5%. The risk of developing HCC with a negative DCP test result is 7.6%. Their ratio is 4.8, indicating a 4.8-fold increase of developing HCC given an elevated DCP test result.

		HCC	No HCC	Total	Suspicious*
DCP	≥ 7.5 ng/mL	19	33	52	7
	< 7.5 ng/mL	20	244	264	64
Total		39	277	316	71

Relative risk 4.8 (95% C.I.: 2.8 – 8.4)
 Risk of HCC given DCP positive 36.5% (95% C.I.: 23.5% - 49.6%)
 Risk of HCC given DCP negative 7.6% (95% C.I.: 4.4% - 10.8%)



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 Wako Diagnostics
 August 9, 2006
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Food and Drug Administration
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Rockville MD 20850

JUN 11 2007

Wako Chemicals, USA, Inc.
c/o Ms. Lori Creasy
Regulatory Affairs Specialist
1600 Bellwood Road
Richmond, VA 23237

Re: k062368

Trade/Device Name: Wako LBA DCP, Wako DCP Calibrator Set, Wako DCP Control Set

Regulation Number: 21 CFR 866.6030

Regulation Name: AFP-L3% Immunological Test System

Regulatory Class: Class II

Product Code: OAU, JIT, JJX

Dated: December 14, 2006

Received: December 21, 2006

Dear Ms. Creasy:

This letter corrects our substantially equivalent letter of January 31, 2007.

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 (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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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

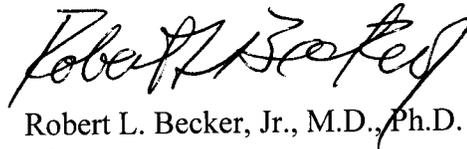
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Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue 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) 276-0450. 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 <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and

Safety

Center for Devices and Radiological Health

Enclosure

3. INDICATIONS FOR USE

510(k) Number (if known): K062368

Device Name: LBA DCP

Indications for Use:

The Wako LBA DCP immunological test system is an in vitro device that consists of reagents and an automated instrument used to quantitatively measure by immunochemical techniques DCP in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for progression to hepatocellular carcinoma in conjunction with other laboratory findings, imaging studies and clinical assessment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

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Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062368