

NOV - 9 1999

Wako

Wako Chemicals USA, Inc.
1600 Bellwood Road, Richmond, VA 23237 U.S.A.

510(K) Summary of Safety and Effectiveness

The Wako L-Type Triglyceride test is an in vitro assay for the quantitative determination of triglyceride in serum.

Summary:

Lipids in serum consist of triglyceride, cholesterol, phospholipids, free fatty acid and slight amount of fat-soluble compounds such as amount of fat-soluble vitamins and carotene. Triglycerides are water-insoluble lipids, consisting of fatty acids linked to glycerol. Determination of triglyceride in serum is an important clinical test in diagnosis of arterial sclerosis, coronary heart diseases and diabetes. The clinical method using acetylacetone has been traditionally used to measure triglyceride. However, the method requires complicated procedure such as absorption or extraction. Therefore, the chemical method has been replaced with the specific methods employing enzymes. The enzymatic method employing glycerol-3-phosphate oxidase (GPO) has been used extensively with growing popularity since it is superior on specificity and simplicity, and the measurement can be done under ordinary conditions. The Wako L-Type Triglyceride is an enzymatic method utilizing N-ethyl-N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline sodium salt (DAOS) that produces blue pigment.^{1,2}

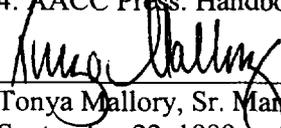
Principle:

Triglycerides in a sample are hydrolyzed to glycerol and free fatty acids in a reaction catalyzed by lipoprotein lipase (LPL). Glycerol is converted to glycerol-3-phosphate by glycerokinase (GK) in the presence of adenosine-5'-triphosphate(ATP). Glycerol-3-phosphate formed is oxidized by GPO in a reaction that produces hydrogen peroxide. The hydrogen peroxide produced causes DAOS and 4-aminoantipyrine to undergo a quantitative oxidative condensation catalyzed by peroxidase (POD), producing a blue pigment. The amount of triglycerides contained in the sample is determined by measuring the absorbance of the blue color

The safety and effectiveness of the Wako L-Type Triglyceride is demonstrated by its substantial equivalency to Wako Triglyceride 30R product. Both test systems are used to measure triglyceride in serum. In comparison studies against the predicate assay, a correlation coefficient of 0.9995 and a regression equation of $y = 0.970x + 2.2$ was obtained. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 1.2 mg/dL.

References:

1. Burtis, C.A. and Ashwood, E.R., Ed.: Tietz Textbook of Clinical Chemistry, 2nd Ed., Saunders, Philadelphia, 1994.
2. Spayd, R.W., Bruschi, B., et al.: Clin. Chem., 24, 1343-1350 (1978)
3. DG Klinische Chemie Mitteilungen 26 (1995) Heft 5.
4. AACC Press: Handbook of Lipoprotein Testing (1997).


Tonya Mallory, Sr. Manager Wako Diagnostics
September 22, 1999
1600 Bellwood Road
Richmond, VA 23237



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 9 1999

Ms. Tonya Mallory
Senior Manager
Wako Diagnostics
1600 Bellwood Road
Richmond, Virginia 23237

Re: K993466
Trade Name: Wako L-Type Triglyceride Test
Regulatory Class: I
Product Code: CDT
Dated: September 23, 1999
Received: October 13, 1999

Dear Ms. Mallory:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

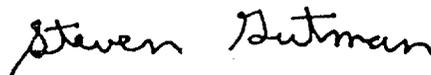
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known): K993466

Device Name: Wako L-Type Triglyceride Test

Indications For Use:

Measurements obtained by this test are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993466

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)