

JAN 15 1999

K984119

Wako

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

510(k) Summary of Safety and Effectiveness

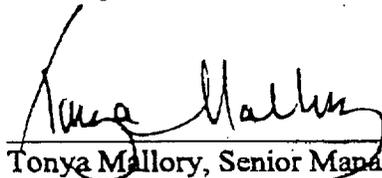
The Wako L-type Fe test is an in vitro diagnostic assay for the quantitative determination of iron in serum.

Approximately two thirds of iron in the body is in hemoglobin of red blood corpuscles (RBCs) and the rest is in liver, spleen, bone marrow and other tissues as stored in iron. Numerous cellular enzymes and coenzymes require iron, such as peroxidases and cytochromes. Transport of iron from one organ to another is accomplished by serum iron, bound to transferrin. Measurement of serum iron concentration is largely of use in the diagnosis of iron deficiency anemia, hemochromatosis, chronic inflammatory disorders and malignancies. There are several methods used for the measurement of iron concentration.¹ The Wako L-type Fe is a method utilizing bathophenanthroline as a chromogen.

When a sample is mixed with the Buffer, serum protein is denatured by the action of surfactant contained in the Buffer and transferrin-bound iron is liberated. All the Fe^{3+} ions released are reduced to Fe^{2+} by L-ascorbate and form a chelate with bathophenanthroline disulfonic acid disodium salt. The serum iron can be determined by measuring the absorbance of the red chelate solution.

The safety and effectiveness of the Wako L-type Fe assay is demonstrated by its substantial equivalency to the Wako Fe B test.

Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is estimated to be 1.2 mg/dL. The Wako L-type Fe assay had determined to be linear to 1000 mg/dL.



Tonya Mallory, Senior Manager, Diagnostics

January 12, 1999

Wako Chemicals USA, Inc.

1600 Bellwood Road

Richmond, VA 23237

References:

1. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 2nd ed., Saunders, Philadelphia, 1994.

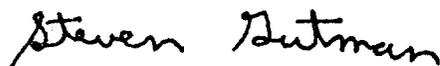
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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

510(k) NUMBER (IF KNOWN): K 984119

DEVICE NAME: WAKO L-type Fe, Wako Fe Calibrator

INDICATIONS FOR USE:

Iron measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis, and chronic renal disease.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 984119

(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)