

K973616

DEC - 5 1997

## 510K SUMMARY OF SAFETY AND EFFECTIVENESS

### **BAYER IMMUNO 1™ SYSTEM TROPONIN I METHOD, SETPOINT CALIBRATORS AND TESTPOINT CONTROLS FOR THE IMMUNO 1 SYSTEM. Bayer Corporation, 511Benedict Avenue, Tarrytown, New York 10591**

Listed below is a comparison of the performance between the Immuno 1 Troponin I method (T01-3887-51) and a similar device that was granted FDA determination of substantial equivalence; the Dade Stratus® Troponin I kit. The information used in this summary of Safety and Effectiveness was extracted from the Troponin I Method Sheet and from data on file at Bayer Corp.

#### **INTENDED USE**

This in vitro diagnostic procedure is a solid-phase enzyme immunoassay intended for the quantitative determination of Troponin I in human serum and plasma on the Bayer Immuno 1 system. When used in combination with other clinical data such as presenting symptoms and diagnostic procedures, measurement of Troponin I aids in the diagnosis of acute myocardial infarction.

#### **ASSAY DESCRIPTION**

The Bayer Immuno 1 Troponin I™ assay is an enzyme label sandwich assay using a monoclonal and a polyclonal antibody. A Troponin I specific monoclonal antibody is labeled with fluorescein and a Troponin I specific goat affinity purified antibody is labeled with alkaline phosphatase (ALP). The solid phase consists of a suspension of magnetizable particles coated with antibody to fluorescein (mIMP reagent). Sample or calibrator, R1 reagent containing fluorescein - antibody conjugate, R2 reagent containing ALP-antibody conjugate and mIMP reagent are mixed and incubated at 37°C. In the presence of Troponin I a (fluorescein-conjugate:Troponin I:ALP-conjugate) complex is formed and captured by the anti fluorescein antibodies on the magnetic particles. The particles are washed and para-nitrophenyl phosphate substrate solution is added. The ALP in the antibody conjugate reacts with the substrate to form para-nitrophenoxide and phosphate. Increasing absorbance due to the formation of para-nitrophenoxide is monitored at 405 nm and 450 nm. The dose response curve is directly proportional to the concentration of Troponin I in the sample. A linear point to point fit is used to construct the dose response curve. The Bayer Immuno 1 Troponin I™ assay has a range of 0 to 200 ng/ml and liquid calibrators are provided with values of 0, 5, 10, 20, 60 and 200 ng/ml Troponin I. Bayer Immuno 1 Troponin I TESTpoint controls are provided with values of 3, 7, 50 ng/mL Troponin I.

The Dade Stratus® Troponin I assay utilizes the binding of two Troponin I monoclonal antibodies in a two site "sandwich" immunoassay. Both the Dade Stratus® and Bayer Immuno 1™ Troponin I assays utilize an alkaline phosphatase enzyme conjugated antibody. The Bayer Immuno 1™ Troponin I assay uses a para-nitrophenyl phosphate substrate and measures

increasing absorbance due to the formation of para-nitrophenoxide at 405 nm and 450 nm, while the Dade Stratus® Troponin I assay uses 4-Methylumbelliferyl Phosphate as the substrate and measures front surface fluorescence. The Bayer Immuno 1™ Troponin I test uses liquid calibrators prepared with a buffered bovine serum albumin and cardiac Troponin I at specific levels while the Dade Stratus® Troponin I uses frozen liquid calibrators prepared from buffered bovine matrix and human cardiac troponin I at specified levels.

## PERFORMANCE CHARACTERISTICS

**Total imprecision** of Bayer Immuno 1™ Troponin I method ranges from 4.3% with a low human control having a mean troponin I value of 2.9 ng/mL to 2.1% for a high control having a mean troponin I value of 47.8 ng/mL. These estimates of imprecision were made by analyzing human serum samples in duplicate on two Immuno 1 instruments on each of 18 days. The results are calculated from a calibration curve generated on each instrument on the first day.

**Linearity recoveries** range from 88% to 110% determined by diluting human AMI patient pools with troponin I free normal human serum. Recoveries determined by diluting AMI patient pools with Immuno 1 Sample diluent B range from 85% to 116% with an average recovery of 97.9%.

**A Correlation study** at two clinical trial sites between the Bayer Immuno 1™ Troponin I method and the Dade Stratus® Troponin I method using a total of 279 patient samples yielded regression statistics of  $r = 0.98$ ,  $\text{Immuno 1} = 0.96 \times \text{Stratus} - 0.2$ . Troponin I in the 279 patient samples ranged from 0 to 77.1 ng/mL.

**Minimum Detectable Concentration** of the Bayer Immuno 1™ Troponin I method is 0.1 ng/mL. This is a multisystem estimate of two (2) times the with-in run standard deviation of the zero calibrator.

**Cross Reactivity** to human cardiac Troponin T, human cardiac Troponin C, human skeletal Troponin I, human skeletal Troponin T, bovine actin and bovine tropomyosin is minimal or undetectable.

## EXPECTED VALUES

Specimens from 197 healthy Red Cross blood donors were all found to give results below the minimum detectable concentration of 0.1 ng/mL. Specimens from 64 patients hospitalized with a clinical diagnosis of angina gave results less than the minimum detectable concentration for 60 patients and in the range 0.2 to 0.6 ng/mL for the other 4. Specimens from 41 hospitalized patients with a clinical diagnosis of AMI had results greater than or equal to 0.9 ng/mL.

The Bayer Immuno 1™ Troponin I method is substantially equivalent to the Dade Stratus® Troponin I method currently approved for clinical use in the United States.



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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Gabriel Muraca, Jr.  
. Manager Regulatory Affairs  
Bayer Corporation  
511 Benedict Avenue  
Tarrytown,, New York 10591-5097

Re: K973616  
Troponin I Assay for Immuno 1™ System  
Regulatory Class: II  
Product Code: MMI  
Dated: November 18, 1997  
Received: November 19, 1997

Dear Mr. Muraca:

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 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.

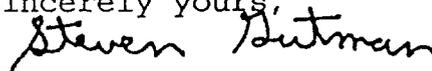
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

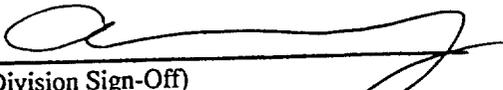
510(k) Number (if known): K973616

Device Name: **Bayer Immuno 1™ System**  
**Troponin I (TnI)**

Indications For Use:

This *in vitro* diagnostic method is intended to quantitatively measure the concentration of cardiac Troponin I (TnI) in human serum and plasma (lithium heparin) using the Bayer Immuno 1™ system. When used in conjunction with other clinical data such as presenting symptoms and diagnostic procedures, measurement of cardiac Troponin I aids in the diagnosis of acute myocardial infarction (AMI).

This diagnostic method is not intended for use on any other system.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K973616

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use