



## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

The safety and effectiveness of the liquid Crestat N-ASSAY L AST/GOT Reagent is demonstrated by its substantial equivalence to the Boehringer Mannheim Corporation AST liquid reagent (K861792) which is based on a similar enzymatic method as recommended by the IFCC. Both test systems are intended to quantitatively measure AST activity in human serum.

In comparison studies against the predicate assay (without the optional pyridoxal-5-phosphate or P5P activation), a correlation coefficient of 0.99178 and a regression equation  $y = 0.9754 x + -0.5665$  was obtained with serum samples. In comparison studies against the predicate assay (with the optional P5P activation), a correlation coefficient of 0.97146 and a regression equation  $y = 0.5807 x + 1.5184$  was obtained with serum samples. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 1 IU/L. The N-ASSAY L AST/GOT reagent is linear to 2,000 IU/L.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 26 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Crestat Diagnostics, Inc.  
C/O Colin Getty  
KAMIYA Biomedical Company  
910 Industry Drive  
Seattle, Washington, 98188

e: K980902  
N-ASSAY L AST/GOT  
Regulatory Class: II  
Product Code: CIT  
Dated: March 2, 1998  
Received: March 10, 1998

Dear Mr. Getty:

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 Gutman*

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

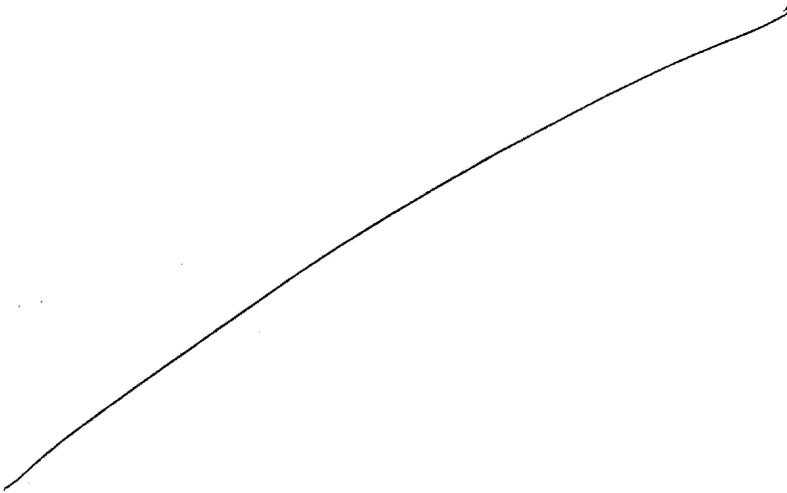
# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K980902

Device Name: N-ASSAY L AST/GOT (AST Assay Reagent)

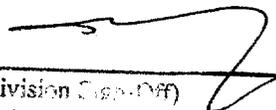
## Indications For Use:

The intended use for the N-ASSAY L AST/GOT Reagent is for the quantitative determination of serum aspartate aminotransferase (AST) activity in human serum in the diagnosis and treatment of certain types of liver, heart, and muscle diseases. For in vitro diagnostic use only.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of CDRH Laboratory Services  
510(k) Number K980902

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Optional Format 1-2-96)