

AUG 19 1997

### VIII. Safety and Effectiveness Summary

The ASSERACHROM® tPA test kit is intended for the quantitative determination of tissue-type plasminogen activator (tPA) antigen in citrated plasma by the sandwich technique of enzyme immunoassay (EIA) known as enzyme-linked immunosorbent assay (ELISA).

Mouse monoclonal anti-tPA antibody is coated on the inside wall of a plastic microwell. The plasma to be tested is allowed to incubate in the microwell for two hours at room temperature, during which any tPA present is captured by the monoclonal antibody. Next, a second (and different) mouse monoclonal anti-tPA antibody coupled with peroxidase is added to the microwell for another 2-hour incubation at room temperature; this antibody-enzyme conjugate binds to another antigenic determinant of the tPA molecule that is already bound to the microwell in the first incubation step. The bound enzyme is revealed by its action on ortho-phenylenediamine in the presence of hydrogen peroxide to produce a yellow color; after addition of a strong acid to stop the enzymatic action, the intensity of the color developed bears a direct relationship to the tPA level initially present in the test plasma.

The kit provides sufficient reagents to perform 96 tests in micro-ELISA plate format. Reagents in intact (unopened) kits remain stable for 18 months after their date of manufacture, when stored at 2°-8°C. Reconstituted reagent stabilities are as follows: Reagent ① (*antibody-coated microwell strips*) must be used immediately after opening of its package; Reagent ② (*anti-tPA-Peroxidase*), 24 hours at 2°-8°C; Reagent ③a (*ortho-Phenylenediamine*) dissolved together with Reagent ③b (*Urea Peroxide*), 1 hour at room temperature (18°-25°C); 1:10 diluted Reagent ④ (*Dilution Buffer*) and 1:20 diluted Reagent ⑤ (*Washing Solution*), 15 days at 2°-8°C, when free of any contamination; both the Reagent ⑥ (*tPA Calibrator*) and Reagent ⑦ (*tPA Control*), 4 hours at 20°C.

The ASSERACHROM® tPA reagent system has a detection limit of 1 ng/ml; a working range from 1 ng/ml up to the tPA level of Reagent ⑥ (*tPA Calibrator*, up to 50 ng/ml); *intra-assay* reproducibility of < 6.5%; *inter-assay* reproducibility of < 8%.

The ASSERACHROM® tPA test kit is claimed to be substantially equivalent to the predicate device TintElize® tPA test kit which is also an ELISA procedure for tPA available from Biopool (K934314).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
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Andrew Loc B. Le, Ph.D.  
Director, Regulatory Affairs  
and Quality Assurance  
American Bioproducts Company  
Five Century Drive  
Parsippany, New Jersey 07054

AUG 19 1997

Re: K971519/S2  
Trade Name: ASSERACHROM® tPA Test Kit  
Regulatory Class: II  
Product Code: GGP  
Dated: August 5, 1997  
Received: August 7, 1997

Dear Dr. Le:

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 requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 320) 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.

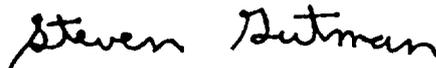
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (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 K971519)

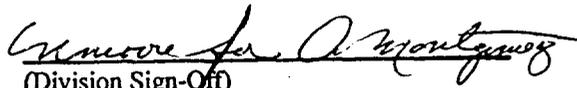
Device Name: ASSERACHROM® tPA Test Kit

Indications for Use:

The ASSERACHROM® tPA test kit is intended for the quantitative determination of tissue-type plasminogen activator (tPA) antigen in citrated plasma by the sandwich technique of enzyme immunoassay (EIA) known as enzyme-linked immunosorbent assay (ELISA).

The quantitative determination of tPA is generally performed during the assessment of the fibrinolytic system of a patient, for instance, following a thrombotic episode.

In addition, it has been reported that a high antigenic level of tPA is associated with a greater risk of myocardial infarction or vascular cerebral accident. Finally, quantitative tPA assays are useful in the detection of hypofibrinolytic and hyperfibrinolytic states.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 971519

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(Concurrence of CDRH, Office of Device Evaluation (ODE))

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K971519

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)