

MAY 19 1999

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## 510(k) Summary

**Submitter's Name/Address**

Abbott Laboratories  
1920 Hurd Drive  
Irving, Texas 75038

**Contact Person**

Linda Morris  
Senior Regulatory Specialist MS 1-8  
ADD Regulatory Affairs  
(972) 518-6711  
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**Date of Preparation of this Summary:**

March 25, 1999

**Device Trade or Proprietary Name:**

ACP

**Device Common/Usual Name or Classification Name:** Acid Phosphatase

**Classification Number/Class:**

Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K991010.

**Test Description:**

Acid Phosphatase is an *in vitro* diagnostic assay for the quantitative determination of total and prostatic acid phosphatase in human serum. The Acid Phosphatase assay is a clinical chemistry assay in which the acid phosphatase in the sample catalyzes the hydrolysis of alpha-naphthylphosphate liberating the alpha-naphthol and phosphate. The alpha-naphthol is then coupled with diazotized 2-amino-5-chlorotoluene (Fast Red TR) to form a diazo dye. The absorbances measured at 412 and 660 nm are directly proportional to the amount of acid phosphatase present in the sample. The addition of L-Tartrate inhibits prostatic acid phosphatase, but does not inhibit other isoenzymes. The difference between the two protocols (Total Acid Phosphatase and Non-Prostatic Acid Phosphatase) is the level of prostatic acid phosphatase in the sample.

**Substantial Equivalence:**

The Acid Phosphatase assay is substantially equivalent to the Trace® Acid Phosphatase Assay (K880798) on the Hitachi® 717 Analyzer.

These assays yield similar Performance Characteristics.

**Similarities:**

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of total and prostatic acid phosphatase.
- Both assays yield similar clinical results.

**Differences:**

- There is a minor difference in the assay range.

**Intended Use:**

The Acid Phosphatase assay is used for the quantitation of total and prostatic acid phosphatase in human serum.

**Performance Characteristics:**

Comparative performance studies for the Total Acid Phosphatase protocol were conducted using the AEROSET™ System. The Total Acid Phosphatase method comparison yielded acceptable correlation with the Trace Acid Phosphatase assay on the Hitachi 717 Analyzer. The correlation coefficient = 0.995, slope = 1.057, and the Y-intercept = 0.417 U/L. Precision studies were conducted using the Total Acid Phosphatase protocol. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 101 is 3.9% and Level 2/Panel 102 is 2.7%. Total Acid Phosphatase is linear up to 87.90 U/L. The limit of quantitation (sensitivity) of Total Acid Phosphatase is 0.513 U/L. These data demonstrate that the performance of Total Acid Phosphatase is substantially equivalent to the performance of the Trace Acid Phosphatase assay on the Hitachi 717 Analyzer.

Comparative performance studies for the Prostatic Acid Phosphatase protocol were conducted using the AEROSET™ System. The Prostatic Acid Phosphatase method comparison yielded acceptable correlation with the Trace Acid Phosphatase assay on the Hitachi 717 Analyzer. The correlation coefficient = 0.989, slope = 1.062, and the Y-intercept = 0.651 U/L. Precision studies were conducted using the Prostatic Acid Phosphatase protocol. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 101 is 5.2% and Level 2/Panel 102 is 4.0%. Prostatic Acid Phosphatase is linear up to 77.46 U/L. The limit of quantitation (sensitivity) of Prostatic Acid Phosphatase is 0.674 U/L. These data demonstrate that the performance of Prostatic Acid Phosphatase is substantially equivalent to the performance of the Trace Acid Phosphatase assay on the Hitachi 717 Analyzer.

**Conclusion:**

The Acid Phosphatase assay is substantially equivalent to the Trace Acid Phosphatase assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 19 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Linda Morris  
Senior Regulatory Specialist  
ADD Regulatory Affairs  
Abbott Laboratories  
1920 Hurd Drive  
Irving, Texas 75038

Re: K991010  
Trade Name: Acid Phosphatase (ACP)  
Regulatory Class: II  
Product Code: CKB  
Dated: March 25, 1999  
Received: March 26, 1999

Dear Ms. Morris:

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 (Pre-market 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.

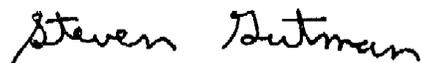
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

510(k) Number (if known): K991010

Device Name: Acid Phosphatase

Indications For Use:

An acid phosphatase (total or prostatic) test system is a device intended to measure the activity of the acid phosphatase enzyme in serum.

Jean Lopez  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K991010

(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)