

AUG - 4 1997

510(k) Summary  
BAS Plasma Catecholamine Kit  
Summary of Safety and Effectiveness

**Intended Use:**

Catecholamine test system is a device intended to determine whether a group of similar compounds epinephrine and norepinephrine are present in plasma. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine secreting tumors (pheochromocytoma, neuroblastoma, ganglioneuroma, and retinoblastoma).

**Description:** The BAS Plasma Catecholamine Kit employs liquid chromatography with electrochemical detection to separate and quantitate epinephrine (E) and norepinephrine (NE) in human plasma under isocratic conditions as defined in the package insert. BAS provides the mobile phase for the elution of these analytes from the liquid chromatography column, which is also provided, as well as critical reagents for sample preparation. There is one complete start-up kit as well as one accessory replacement kit which will be offered for sale. The accessory replacement kit contains replacement reagents and mobile phase for sample preparation and analysis. The kit is designed for in-vitro applications only. All reagents and kit supplies contain the appropriate warnings as to irritants, corrosiveness or toxicity, etc. The Plasma Catecholamine Kit is not used in any way to sustain human life or to prevent impairment of human health. Therefore, the kit poses no safety hazard to the patients. The Bioanalytical Systems Plasma Catecholamine Kit has been demonstrated to be substantially equivalent to the Bio-Rad Plasma Catecholamine by HPLC Kit.

When the Bioanalytical Systems procedure was compared to the predicate device (the Bio-Rad Plasma Catecholamine Kit by HPLC) the following correlation data were obtained:

| Mean Concentration for All Samples Assayed in pg/mL |      |             |      |                |      |
|---|------|-------------|------|----------------|------|
|   |      | Epinephrine |      | Norepinephrine |      |
|   |      | BAS         | CAD  | BAS            | CAD  |
| # of Samples  |      | 70          | 70   | 70             | 70   |
| Range   | High | 2434        | 2369 | 3488           | 3285 |
|   | Low  | 15.8        | 12.2 | 130            | 163  |
| Mean  |      | 441         | 393  | 827            | 760  |
| Std. Deviation                                      |      | 558         | 514  | 720            | 653  |
| Cor. Coef. (R value)                                |      | 0.994412    |      | 0.993926       |      |
| Y Intercept   |      | 13.35       |      | -9.17          |      |
| Slope   |      | 1.075183    |      | 1.091721       |      |

\*Correlation Coefficient is based on the sample for sample regression of the assayed concentration

BAS = BAS method; CAD = commercially available device method (Bio-Rad)

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**Date Submitted:** July 30, 1997



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  
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Enclosure

510(k) Number (if known): K972167

Device Name: Plasma Catecholamine Kit

Indications For Use:

Catecholamine test system is a device intended to determine whether a group of similar compounds epinephrine and norepinephrine are present in plasma. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine secreting tumors (pheochromocytoma, neuroblastoma, ganglioneuroma, and retinoblastoma.)

(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 Clinical Laboratory Devices

510(k) Number

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)