

17473274

510(k) NOTIFICATION

Sigma Diagnostics Inc.

OCT 31 1997

ACCUCOLOR™ High Calibrator

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## ATTACHMENT 1

### Summary of Safety and Effectiveness

## Summary of Safety and Effectiveness Accucolor High Calibrator. Product No. A3089

This product is designed for use with Accucolor Antithrombin III Assay Kit (CRS117A). The normal range of plasma Antithrombin III (AT-III) has been reported from 79-125% in Plasma <sup>1,2,3,4</sup>. A normal population range determined at Sigma Diagnostics (n=70) was 83-119% (mean 101.1±9.8). This product provides a reference material with an assigned value slightly above the normal range.

The safety and effectiveness of the Sigma Accucolor High Calibrator (A3089) has been demonstrated by its substantial equivalence to Sigma Product A7432. Both products are used for the calibration of ATIII assays. Both products have values assigned using a secondary standard, which was assigned from a traceable WHO International Reference Preparation for Antithrombin III.

The human source material from which this product was derived was found negative for HbsAg and for antibodies against HCV, HIV-1, and HIV-2 by approved test methods. The "Precautions" section of the data sheet instructs the user in handling and disposal of this product and directs the user to sources of additional information on the product.

1. Odegard O, Lie M, Ablidgaard U. Heparin Cofactor Activity Measured with an Amidolytic Method. 1975 *Thrombosis Research* 6:287-294.
2. Rosenberg R, Bauer K. The Heparin-Antithrombin System: A Natural Anticoagulant Mechanism. *In Hemostasis and Thrombosis; Basic Principles and Clinical Practice*, Colman R, Hirsh J, Marder V, and Salzman E. Eds. Third Edition, 1994 pp 837-860. Lippincott Co., Philadelphia, PA. USA.
3. Bick R. Clinical Relevance of Antithrombin III. 1982 *Seminars in Thrombosis and Hemostasis* 8:276-287.
4. Demers C, Henderson P, Blajchman M, Wells M, Mitchell L, Johnston M, Ofosu F, Fernandez-Rachubinski F, Andrew M, Hirsh J, Ginsberg J. An Antithrombin III Assay Based on Factor Xa Inhibition Provides a More Reliable Test to Identify Congenital Antithrombin III Deficiency Than an Assay Based on Thrombin Inhibition. 1993 *Thrombosis and Haemostasis* 69:231-235.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

OCT 31 1997

William Gilbert, Ph.D.  
Manager, Scientific Affairs  
Sigma Diagnostics Inc.  
545 South Ewing Avenue  
St. Louis, Missouri 63103

Re: K973274  
ACCUCOLOR™ High Calibrator  
Regulatory Class: II  
Product Code: GIZ, JBQ  
Dated: October 2, 1997  
Received: October 3, 1997

Dear Dr. Gilbert:

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.

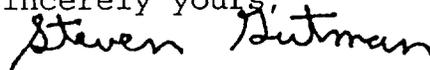
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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): \_\_\_\_\_

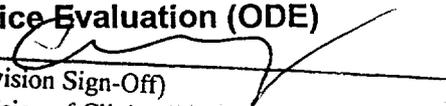
Device Name: Sigma Diagnostics ACCUCOLOR™ High Calibrator

**Indications For Use:**

Sigma Diagnostics ACCUCOLOR™ High Calibrator is for use with the Sigma Diagnostics ACCUCOLOR™ Antithrombin III (AT-III) to determine the plasma level of antithrombin III (a substance which acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).

(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 2973274

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use