

JUN 23 2000

Section 3
IL Test™ Liquid Antithrombin - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4464

Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4464

Summary Prepared:

December 15, 1999 (Revised April 11, 2000)

Name of the Device:

IL Test™ Liquid Antithrombin

Classification Name(s):

864.7060	Antithrombin III Assay	Class II
81JBQ	Antithrombin III Quantitation	

Identification of Predicate Device(s):

K980499 IL Test™ Antithrombin

Description of the Device/Intended use(s):

IL Test™ Liquid Antithrombin is an automated chromogenic assay for the quantitative determination of Antithrombin in human citrated plasma as an aid in the diagnosis of hereditary and acquired Antithrombin deficiency.

This *in vitro* diagnostic test is based on a synthetic chromogenic substrate and on Factor Xa inactivation. As a consequence, it is specific and not influenced by Heparin Cofactor II. Antithrombin levels in patient plasma are measured automatically on IL Coagulation Systems.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

IL Test™ Liquid Antithrombin uses the same test principle as the predicate device (IL Test™ Antithrombin) and is substantially equivalent in performance, intended use and safety and effectiveness.

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Summary of Performance Data:

Method Comparison

In method comparison studies evaluating 118 citrated plasma samples (40 normals and 78 abnormal) on an ACL 6000 and an ACL Futura, the slopes and correlation coefficients (r) for IL Test™ Liquid Antithrombin versus the predicate device are shown below:

<u>New Device vs. Predicate Device</u>		
IL System	Slope	r
ACL 6000	0.99	0.995
ACL Futura	1.01	0.994

Within Run Precision

Within run precision assessed over multiple runs using three levels of control plasma gave the following results:

ACL 6000	Normal Level	Abnormal Level I	Abnormal Level II
Mean (% Activity)	102.6	53.6	22.1
% CV	2.54	3.27	7.54
ACL Futura	Normal Level	Abnormal Level I	Abnormal Level II
Mean (% Activity)	104.6	54.2	25.2
% CV	2.10	2.47	12.10



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN 23 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
Manager, Regulatory Affairs
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K994238
Trade Name: IL Test™ Liquid Antithrombin
Regulatory Class: II
Product Code: JBQ
Dated: April 11, 2000
Received: April 12, 2000

Dear Ms. Marble:

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.

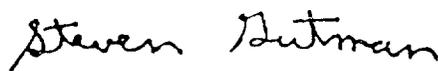
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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): 994238

Device Name: IL Test™ Liquid Antithrombin

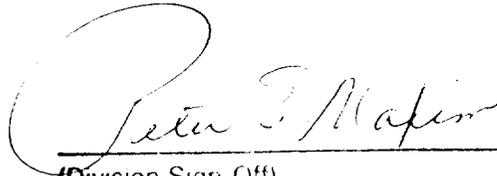
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This *in vitro* diagnostic test is based on a synthetic chromogenic substrate and on Factor Xa inactivation. As a consequence, it is specific and not influenced by Heparin Cofactor II. Antithrombin levels in patient plasma are measured automatically on IL Coagulation Systems.

(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 Critical Laboratory Devices

510(k) Number

994238

Prescription Use _____
(Per 21 CFR 801.019)

OR Over-The-Counter Use _____