

DEC 18 1998

BIO-RAD

**Bio-Rad
Laboratories**

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Diagnostics Group
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Irvine, California 92618-2017
Telephone: (949) 598-1200

510(k) Summary

Submitter

Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA
(949)598-1285
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Contact Person

Elizabeth Platt

Date of Summary Preparation

December 8, 1998

Device (Trade & Common Name)

Liquichek ANA Control, Centromere Pattern

Classification Name

Class II, 82DHN
CFR 866.5100: Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control.

Devices to Which Substantial Equivalence is Claimed

Kallestad Quantafluor Autoantibody Positive Control
Sanofi Diagnostics Pasteur
Chaska, Minnesota
K813592

Statement of Intended Use

Liquichek ANA Control, Centromere Pattern is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing of antinuclear antibodies (ANA).



Description of the Device

Liquichek ANA Control, Centromere Pattern is prepared from human serum with added preservatives and stabilizers. This product is provided in liquid form for convenience. This product contains 0.1% sodium azide as a preservative.

Statement of How Technological Characteristics Compare to Substantial Equivalent Device

A table is provided below comparing the similarities between the Bio-Rad Liquichek ANA Control, Centromere Pattern and the device to which substantial equivalence is claimed.

	Kallestad Quantafluor Autoantibody Positive Control	Bio-Rad Liquichek ANA Control, Centromere Pattern
Intended Use	Autoantibody positive control for Kallestad Quantafluor Fluorescent Autoantobody Test with mouse kidney, mouse stomach/kidney, Hep-2 cell line, or <i>Crithidia luciliae</i> substrates.	An unassayed quality control serum for monitoring indirect immunofluorescent testing of antinuclear antibodies (ANA).
Form	Lyophilized	Liquid
Matrix	Human Serum	Human Serum
Levels	Positive	Negative, Positive, High Positive
Storage	2-8°C	2-8°C
Analytes	ANA (Centromere, SSA, SSB, Scl-70, Sm, RNP, Spindle, Nucleolar) AMA ASMA APCA Anti-nDNA	ANA (Centromere Pattern)
Open Vial Claim	6 weeks at 2-8°C 4 months at -20°C	30 Days at 2-8°C



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 18 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Elizabeth Platt
Regulatory Affairs Supervisor
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA 92618

Re: K984397
Trade Name: Liquichek ANA Control, Centromere Pattern, Model 203
Regulatory Class: II
Product Code: DHN
Dated: December 8, 1998
Received: December 9, 1998

Dear Ms. Platt:

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.

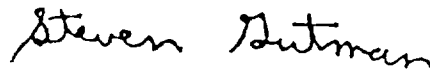
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

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: K984397

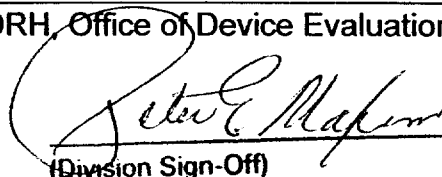
Device Name: Liquichek ANA Control, Centromere Pattern

Indications for Use:

Liquichek ANA Control, Centromere Pattern is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing of antinuclear antibodies (ANA).

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K984397

Prescription Use ✓

OR Over-The Counter Use _____