

DEC 18 1998



**Bio-Rad  
Laboratories**

*Diagnostics Group  
9500 Jeronimo Road  
Irvine, California 92618-2017  
Telephone: (949) 598-1200*

K984400

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## 510(k) Summary

### Submitter

Bio-Rad Laboratories  
9500 Jeronimo Road  
Irvine, CA  
(949)598-1285  
Fax (949)598-1555

### Contact Person

Elizabeth Platt

### Date of Summary Preparation

December 8, 1998

### Device (Trade & Common Name)

Liquichek ANA Control, Speckled 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, Speckled 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, Speckled 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, Speckled Pattern and the device to which substantial equivalence is claimed.

	Kallestad Quantafluor Autoantibody Positive Control	Bio-Rad Liquichek ANA Control, Speckled 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 (Speckled Pattern)
Open Vial Claim	6 weeks at 2-8°C 4 months at -20°C	30 Days at 2-8°C



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: K984400  
Trade Name: Liquichek ANA Control, Speckled Pattern, Model 202  
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.

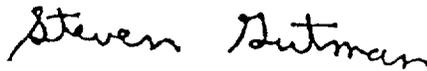
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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,



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:   K 984400  

Device Name:   Liquichek ANA Control, Speckled Pattern  

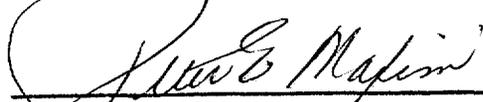
Indications for Use:

Liquichek ANA Control, Speckled 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)

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(Concurrence of CDRH, Office of Device Evaluation)



(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number \_\_\_\_\_

Prescription Use  \_\_\_\_\_

OR Over-The Counter Use \_\_\_\_\_