MAY 19 2004

Summary of Safety and Effectiveness
Liquichek ToRCH Plus IgM Control

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

March 26, 2004

2.0 Device Identification

Product Trade Name:	Liquichek ToRCH Plus IgM Control
Common Name:	Multi-analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

VIROCLEAR ToRCH & VIROCLEAR ToRCH -M
Blackhawk BioSystems, Inc.
San Ramon, California

510 (k) Number: K942295

4.0 Description of Device

Liquichek ToRCH Plus IgM Control, Positive is prepared from negative human serum based material with mouse IgM monoclonal antibodies conjugated to non-specific human IgM molecules for each analyte tested. The positive control reagent also contains constituents of animal origin and preservatives. The following are the specificities of each monoclonal antibody:

Analyte	IgM Monoclonal antibody specificity
Cytomegalovirus (CMV)	p52, pp65, and gB
Epstein-Barr Virus EBV (VCA)	gp125
Herpes Simplex Virus Type 1 (HSV-1)	gC1
Herpes Simplex Virus Type 2 (HSV-2)	gG2
Lyme (Borrelia burgdorferi)	OspA and OspB
Rubella Virus	E1
Toxoplasma gondii	p30

5.0 Intended Use

Liquichek ToRCH Plus IgM Control is intended for use as an unassayed quality control serum to monitor precision of IgM laboratory testing procedures for the analytes listed in this package insert. This product is not intended for use in blood donor screening assays.

6.0 Comparison of the new device with the Predicate Device

Liquichek ToRCH Plus IgM Controls claim substantial equivalency to the VIROCLEAR ToRCH and VIROCLEAR ToRCH-M Controls currently in commercial distribution (K942295).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Liquichek™ ToRCH Plus IgM Control (New Device)	Blackhawk BioSystems, Inc. VIROCLEAR ToRCH Control (Predicate Device K942295)
Similarities		
Intended Use	Liquichek ToRCH Plus IgM Control is intended for use as an unassayed quality control serum to monitor precision of IgM laboratory testing procedures for the analytes listed in this package insert. This product is not intended for use in blood donor screening assays.	VIROCLEAR ToRCH / VIROCLEAR ToRCH-M: is intended for use as an unassayed precision quality reagent with in vitro assay procedure for determination of IgG and IgM antibodies to TOXO, Rubella virus CMV and HSV (1 & 2)
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Preservatives	Contains preservatives	Contains preservatives
Open Vial Claim	60 days at 2 to 8°C	60 days at 2°C to 8°C
Number of Levels	Reactive (positive) and Non-reactive (negative)	Reactive and Non-reactive
Differences		
Storage (Unopened)	–20°C or colder Until expiration date	2°C – 8°C Until expiration date
Analytes	IgM antibodies to: Cytomegalovirus (CMV) Epstein-Barr Virus (EBV) Viral Capsid Antigen (VCA) Herpes Simplex Virus Type 1/2 (HSV-1/2) Lyme (Borrelia burgdorferi) Rubella Virus Toxoplasma gondii ▪ It does not test for antibodies to IgG.	IgM and IgG antibodies to: Cytomegalovirus (CMV) Herpes Simplex Virus Type 1/2 (HSV-1/2) Rubella Virus Toxoplasma gondii It does not test for antibodies to: ▪ Lyme (Borrelia burgdorferi) ▪ Epstein-Barr Virus (EBV) Viral Capsid Antigen (VCA)

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ ToRCH Plus IgM Control. Product claims are as follows:

7.1 Open vial: All analytes will be stable for 60 days when stored at 2 to 8°C.

7.2 Shelf Life: 3 Years at -20°C or colder

7.3 Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 9 2004

Ms. Elizabeth Platt
Regulatory Affairs Manager/Quality Assurance
Bio-Rad Laboratories
Diagnostics Group
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k040822
Trade/Device Name: Liquichek™ ToRCH Plus IgM Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: March 26, 2004
Received: March 30, 2004

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k040822

Device Name: **Liquichek ToRCH Plus IgM Control**

Indications For Use: Liquichek ToRCH Plus IgM Control is intended for use as an unassayed quality control serum to monitor precision of IgM laboratory testing procedures for the analytes listed in this package insert. This product is not intended for use in blood donor screening assays.

Analytes Listed in the package insert:

- Cytomegalovirus (CMV) IgM
- Epstein-Barr Virus (EBV) Viral Capsid Antigen (VCA) IgM
- Herpes Simplex Virus Type 1/2 (HSV-1/2) IgM
- Lyme *(Borrelia burgdorferi)* IgM
- Rubella Virus IgM
- *Toxoplasma gondii* IgM

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k040822