**Bio-Rad Laboratories**

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

01 35 '04 FEB -6 12:53

February 2, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Citizen Petition

Dear Sir or Madam:

For and on behalf of Bio-Rad Laboratories, we are hereby formally submitting the attached Citizen Petition to the Food and Drug Administration for response.

Please contact me if you require any additional information at (949)598-1280 or *donna_chapman@bio-rad.com.*

Respectfully,

Donna Chapman

Donna Chapman
RA/QA Manager
Bio-Rad Laboratories

2004P-0055

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BIO-RAD

Bio-Rad Laboratories

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

February 10, 2004

Lyle Jaffe
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Citizen Petition

Mr. Jaffe,

Bio-Rad Laboratories approves releasing the information identified as "confidential" in Attachment A of our Citizen Petition (Docket Number 2004P-0055).

The documents in this attachment indicate "confidential" since this is how they appeared original in the Liquichek ToRCH Plus Control (K013716) 510(k) documents we photocopied.

Please contact me if you require any additional information at (949)598-1280 or *donna_chapman@bio-rad.com*.

Respectfully,

Donna Chapman

Donna Chapman
RA/QA Manager
Bio-Rad Laboratories

# Table of Contents


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2 **Attachment A**

Liquichek ToRCH Plus Control
(K013716)
510(k) Documents

3 **Attachment B**

Example of Bio-Rad's Unified Labeling

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